Appeal No. 19-55739

In The United States Court Of Appeals
For The Ninth Circuit

Tatiana Korolshteyn, individually, and on behalf of
all others similarly situated,
Plaintiff-Appellant,
v.
Costco Wholesale Corporation, *et al.*,
Defendants-Appellees.

Appeal From the United States District Court
for the Southern District of California
No. 3:15-cv-709-CAB-RBB, Hon. Cathy Ann Bencivengo

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CORPORATE DISCLOSURE STATEMENT

Plaintiff-Appellant certifies under Federal Rule of Appellate Procedure 26.1 that she has no parent corporation and there is no publicly held corporation that owns 10% or more of her stock.

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INTRODUCTION

This appeal is about whether California consumers have the right to protect themselves from false and misleading dietary supplement labels that violate not only California's consumer laws, but also federal requirements governing supplement labeling.

The specific question presented is whether a federal law designed to protect consumers from false and misleading dietary supplement label claims—the Food, Drug, and Cosmetic Act, or "FDCA"—preempts state law claims seeking to hold a supplement manufacturer liable for claiming that its "TruNature Ginkgo Biloba" supports memory function and brain health when the overwhelming weight and totality of the scientific evidence proves that Ginkgo Biloba does nothing—it is no better than a placebo.

Because the FDCA only preempts state laws that differ from federal labeling requirements, and Plaintiff's state law claims are functionally identical to, and reinforce, federal law requirements governing false labeling, the answer to this question is necessarily "no." The District Court found the answer to be "yes," even though its decision will, if left to stand, undermine the federal labeling scheme and strip consumers of their rights under California law to hold manufacturers liable for false and deceptive labeling.

This is no small matter in terms of public health. The agency with authority to enforce the FDCA's labeling requirements, the United States Food and Drug Administration ("FDA"), has found that falsely labeled dietary supplements pose an urgent threat to public safety.[1] There are more than 85,000 dietary supplements on the market, and more entering each year as barriers to entry are low with no pre-market FDA approval required. Yet, overburdened federal regulators can devote only a small percentage of their resources to enforcing federal labeling requirements on dietary supplement manufacturers.[2]

State law plays a crucial role in filling this enforcement gap. Congress understood that state consumer protection laws help ensure that manufacturers are held to account for failing to comply with the federal requirement that supplement labels not be false or misleading. That is why, in passing the FDCA, Congress only preempted state law requirements that are "not identical" to federal law. *See* 21 U.S.C. § 343(a).[3] The decision below thwarts this scheme by stripping away the

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[1] *See* Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 65 Fed. Reg. 1001-01, 1044–45 (Jan. 6, 2000), attached to the Motion for Judicial Notice ("RJN") filed concurrently herewith as Document 4.

[2] *See* Office of the Inspector General, Department of Health and Human Services, Dietary Supplements: Structure/Function Claims Fail to Meet Federal Requirements (2012), attached to the RJN as Document 3 (documenting widespread non-compliance with the FDA's substantiation requirements for structure/function claims).

[3] Courts have interpreted the requirement as meaning that the state law must be identical to or not conflict with the FDCA (*i.e.*, if state law imposes lesser regulatory

crucial layer of state law protection against false and misleading labeling. If left to stand, it not only leaves consumers uncompensated for their injuries, but effectively gives unscrupulous manufacturers a green light to lie with impunity.

In dismissing this lawsuit, the District Court failed to appreciate that Plaintiff's claims mirror federal labeling standards governing dietary supplements and thus, under the plain terms of the FDCA's express preemption clause, are not preempted. Both the FDCA and the California laws on which Plaintiff-Appellant Tatiana Korolshteyn relies—the Unfair Competition Law ("UCL") and the Consumers Legal Remedies Act ("CLRA")—prohibit product labels that are false or misleading. And both schemes determine falsity based on the same evidentiary standard—the totality of the evidence. The FDA has published guidelines informing manufacturers that supplement label claims will be substantiated as true or determined to be false by weighing the totality of the evidence.

Both Parties' experts agreed that the totality of the evidence was the applicable standard. ER 124 at 60:2-5; ER131-132, ¶¶ 11, 14; ER149 at 120:9-16; ER156-157, ¶ 16; ER204-205, ¶ 3; ER257 at 51:24-52:9; ER260-61 at 172:3-173:6. Yet, the District Court did not consider the FDA guidelines' totality of the evidence

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burdens upon a dietary supplement manufacturer than those under Federal Law, there is no conflict). *See Gallagher v. Bayer AG*, 2015 WL 1056480, at *5–6 & n.6 (N.D. Cal. Mar. 10, 2015).

standard at all. Instead, in direct contravention of those guidelines, the District Court concluded that the federal scheme requires only that the manufacturer point to *any* evidence in its favor—no matter how suspect or how heavily outweighed by contrary evidence—to show that its claims are true. By misstating the federal standard, the District Court inaccurately concluded that Plaintiff's claims were preempted.

The District Court's erroneous preemption holding is particularly egregious based on this evidentiary record. During an initial round of summary judgment briefing (which resulted in grant of summary judgment for Defendants, later reversed by this Court), Plaintiff produced expert testimony that the totality of the scientific evidence established that Ginkgo Biloba does nothing. Apparently because the vast weight of the evidence shows that Defendants' Products do not work as represented, Defendants' experts consciously eschewed performing a totality of the evidence analysis. Instead, Defendants' experts merely found some evidence that they thought supported Defendants' labeling claims – most of which were disease studies in contravention of the label's express disclaimer that the Product does not "diagnose, treat, cure, or prevent any disease" – which Plaintiff's expert has also exposed as highly flawed. ER123-125 at 59:25-61:6; ER259 at 67:12-18; ER262-263 at 186:19-187:17; ER264 at 189:20-22; ER265 at 192:7-23; ER203-220.

But even if Defendants' experts had submitted totality of the evidence opinions that differed from and opposed Plaintiff's expert, which they did not, the District Court's preemption holding would be wrong as a matter of law. Under this Court's decision in *Sonner v. Schwabe*, 911 F.3d 989, 992 (9th Cir. 2018) (where plaintiff did not challenge the competency and reliability of defendants' cited studies), and its prior holding in this matter (where Plaintiff's expert did challenge the competency and reliability of Defendants' studies, as well as providing affirmative evidence of inefficacy), reversing the District Court's prior grant of summary judgment, the question of what the totality of the evidence showed would still be a material question of fact, precluding summary judgment. In essence, the District Court has usurped what this Court found to be a fact issue for the jury and instead has improperly found that Defendants have complied with the Dietary Supplement Health and Education Act ("DSHEA"), a law passed by Congress to amend the FDCA. The District Court found compliance with DSHEA by doing what this Court previously held could not result in summary judgment. The District Court apparently believes that even though the question of whether Defendants' labeling claims are false and misleading is one for the jury under the CLRA and UCL, whether it is false and misleading for preemption purposes under DSHEA and the FDCA is to be adjudged under a different and lesser standard. This is just not

so as both statutory schemes apply the identical totality of the evidence analysis to determine falsity.

This ruling is both legally wrong and disastrous for consumers. It effectively strips consumers of the right to seek any remedy under state law for being tricked into buying supplements, no matter how outrageously false and misleading the labels. This Court should right this unfair, unlawful, and dangerous result.

STATEMENT OF JURISDICTION

The District Court had original jurisdiction because this is a class action arising under the Class Action Fairness Act ("CAFA"), 28 U.S.C. § 1332(d)(2). On June 25, 2019, the District Court granted Defendants' motion for summary judgment on grounds that all claims were expressly preempted by the FDCA, and did not allow Plaintiff to amend her Third Amended Complaint. ER006-013. Final judgment was entered on June 25, 2019. ER005.

Plaintiff timely filed an amended notice of appeal on July 2, 2019. ER001-004. This Court has jurisdiction to review a final judgment. 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

Whether the District Court erred in ruling that Plaintiff's state law causes of action against a dietary supplement manufacturer are preempted by the FDCA, when both federal and California law prohibit the use of false or misleading labels on

dietary supplements and both use the same standard of proof in determining if a label claim is false.

STATEMENT OF THE CASE

I. Federal Law Governing Dietary Supplements.

Because the federal preemption issues in this case depend upon whether Plaintiff's state law claims are functionally identical to federal standards governing the labeling of dietary supplements, it is necessary to understand the relevant federal statutory and regulatory framework.

a. Statutory Framework.

The FDCA was enacted in 1938 to "protect the public health by ensuring that foods are safe, wholesome, sanitary, and properly labeled." 21 U.S.C. § 393(b)(2)(A). To this end, the FDCA explicitly prohibits the misbranding of food. 21 U.S.C. § 331(a)-(c). Food is "misbranded" if its labeling is "false or misleading in any particular." 21 U.S.C. § 343(a)(1). Supplements are classified as food and subject to the prohibition against false or misleading labeling. *Dachauer v. NBTY, Inc*., 913 F.3d. 844, 847–48 (9th Cir. 2019) ("*Dachauer*").

In 1990, Congress amended the FDCA through passage of the Nutrition Labeling and Education Act ("NLEA"). The purpose of the NLEA was to create uniform national standards regarding the labeling of food and to prevent states from adopting inconsistent requirements regarding the labeling of nutrients. *Farm*

Raised Salmon Cases, 42 Cal. 4th 1077, 1086 (2008). To that end, the NLEA includes an express preemption provision that provides, in relevant part:

> no state . . . may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce . . . (5) any requirement respecting any claim of the type described in section 343(r)(1) of this title made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title . . . .

21 U.S.C. § 343-1(a)(5).

Under this provision, state law claims are preempted *only* to the extent they impose supplement labeling requirements that differ from the FDCA's supplement labeling requirements. *Dachauer*, 913 F.3d at 847. *See also Gallagher*, 2015 WL 1056480, at *4 (Under FDCA, state law claims are preempted only "where application of state laws would impose more or inconsistent burdens on manufacturers than the burdens imposed by the FDCA"). "[I]f state law seeks to impose liability consistent with the FDCA, the law is not preempted." *Salazar v. Honest Tea, Inc*., 74 F. Supp. 3d 1304, 1311 (E.D. Cal. 2014).

In 1994, Congress further amended the FDCA through DSHEA, which gives FDA regulatory authority over dietary supplements. Because DSHEA is part of the FDCA, applicable FDCA provisions—including the express preemption provision and the prohibition against false or misleading labeling—apply to supplements. *Dachauer*, 913 F.3d at 847–48; 65 Fed. Reg. at 1002 ("[T]he labeling of dietary supplements must comply with all applicable requirements of the act and

regulations. For example, an otherwise acceptable structure/function claim might nevertheless be false or misleading for other reasons, causing the product to be misbranded under section 403(a)(1) of the act.").[4]

FDCA labeling requirements for supplements depend on whether the label statements are found to constitute "structure/function" claims or "disease" claims. A "structure/function" claim—the type of claim at issue in this case—relates to the ability of a supplement to maintain a healthy "structure or function" in the human body. *See* 21 U.S.C. § 343(r)(6)(A); 21 C.F.R. §§ 101.93(f), (g)(2). In contrast, labeling that "suggest[s] disease prevention or treatment" constitutes a "disease" claim. *Dachauer*, 913 F.3d at 847 (citing 65 FR 1000 at 1028). Disease claims, unlike structure/function claims, must be pre-approved by the FDA prior to sale of the product.

To comply with the FDCA, structure/function claims must meet three specific requirements: (1) the manufacturer must have substantiation that the statement is truthful and not misleading;[5] (2) the statement must contain a prominent disclaimer

[4] For simplicity, this brief refers to the NLEA and DSHEA provisions as part of the FDCA.

[5] This substantiation requirement should not be confused with the "lack of substantiation" doctrine, a judicial doctrine prohibiting California consumer protection claims where the plaintiff alleges only that there is *no* scientific evidence for the structure/function claim at issue. *See Sonner*, 911 F.3d at 993. As will be explained more fully below, the lack of substantiation doctrine is inapplicable to cases, such as this, where the plaintiff has provided affirmative scientific evidence that the claim is misleading. *See id.*

that the FDA has not evaluated the statement and that the product "is not intended to diagnose, treat, cure, or prevent any disease"; and (3) the statement must not "claim to diagnose, mitigate, treat, cure, or prevent" disease. 21 U.S.C. § 343(r)(6). Further, as noted above, the structure/function claim must comply with the FDCA's general prohibition on "false or misleading" labeling. *Id.* at § 343(a)(1).

b. FDA's Regulations Governing Structure/Function Claims.

In January 2000, the FDA published its final regulations governing "statements made for dietary supplements concerning the effect of the product on the structure or function of the body." 65 Fed. Reg. 1001-01. In the accompanying preamble, the FDA emphasized that, unlike dietary supplements that make "disease claims," which cannot be sold without prior FDA approval, "[t]here is no comparable testing and approval process for dietary supplements marketed with structure/function claims . . . ." *Id*. at 1003.

As a result, although some supplements making structure/function claims "have been shown to be safe and have benefits, . . . many marketed supplements have not been the subject of adequate studies to establish whether or not they are safe and effective, or the nature of the benefits they may provide." *Id*. Indeed, the agency stated, "few dietary supplements have been the subjects of adequately designed clinical trials," even though "there may be important health-related

consequences associated with taking a dietary supplement, even if the product does not bear disease claims." *Id*. at 1005.

The FDA then explained that there are some protections for consumers built into the FDCA regarding dietary supplements marketed with structure/function claims. In particular, "the manufacturer must possess substantiation that the statement is truthful *and* not misleading." *Id*. at 1001 (emphasis added). In other words, the statement must not be false.

To pass this test, the statement "must include all information that is material in light of the claims made for the product and the consequences that may result from its use (see section 201(m)) of the [FDCA]." *Id*. at 1005. The FDA explained that "dietary supplements that do not do what they claim to do are misbranded." *Id.* at 1007.

The FDA ultimately decided not to address the substantiation requirement for dietary supplement labels in a formal regulation. *See id.* at 1032 ("[T]he agency does not believe that this final rule is the appropriate venue to address the substantiation requirement."). Rather, the FDA stated, the agency planned to "issue a guidance document to provide additional information regarding structure/function

and disease claims." *Id*. at 1007. More on the FDA's guidance is discussed below.[6]

c. Federal Enforcement of Dietary Supplement Standards.

Both the FDA and the United States Federal Trade Commission ("FTC") have enforcement authority regarding dietary supplements. FTC, Dietary Supplements: An Advertising Guide for Industry at 1 (April 2001), attached to the RJN as Document 2.[7]

The FTC enforces the structure/function standard with regard to the *advertising* of supplements. *See Nat'l Council Against Health Fraud, Inc. v. King Bio Pharm., Inc.*, 107 Cal. App. 4th 1336, 1348–50 (2003) ("*King Bio*") (explaining FTC enforcement role regarding dietary supplement advertising); FTC Advertising Guide at 1 ("As applied to dietary supplements, . . . [t]he FTC has primary responsibility for claims in *advertising* . . . .") (emphasis in original).

Under the FDCA, the FTC has explained, "before disseminating an ad, advertisers must have adequate substantiation for all objective product claims." FTC Advertising Guide at 3. To determine whether the substantiation requirement

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[6] The FDA published its guidance in 2009. *See* FDA, Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (2009) ("FDA Guidance"), attached to the RJN as Document 1. *See also* 74 Fed. Reg. 304 (January 5, 2009) (notice announcing availability of FDA Guidance), attached to the RJN as Document 5.

[7] The FTC Advertising Guide can be found at http://bit.ly/36UUGWi.

has been met, the FTC stressed that "[s]tudies cannot be evaluated in isolation. The surrounding context of the scientific evidence is just as important as the internal validity of individual studies." *Id*. at 14.

The FTC further cautioned that advertisers must "consider *all relevant research* relating to the claimed benefit of a supplement and should not focus only on research that supports the effect, while discounting research that does not." *Id.* (emphasis added). "Ideally," the FTC added, "the studies relied on by an advertiser would be largely consistent with the surrounding body of evidence. *Wide variation in outcomes of studies and inconsistent or conflicting results will raise serious questions about the adequacy of an advertiser's substantiation*." *Id.* (emphasis added). And, importantly, "[i]f a stronger body of surrounding evidence runs contrary to a claimed effect, even a qualified claim is likely to be deceptive." *Id*.

If, after an investigation, the agency finds that there is "reason to believe" that a violation of the FDCA has occurred, it may issue either an administrative complaint or file suit in federal court alleging that the advertising is false or misleading. *See* 15 U.S.C. § 45(b), (m)(1)(A); 15 U.S.C. § 53(b). *See also King Bio,* 107 Cal. App. 4th at 1349. In either case, "the FTC bears the burden of proving that an advertising claim is false or misleading." *Id.* at 1348 (citations omitted). "In other words, the FTC may administratively impose on an advertiser the burden of producing evidence to substantiate its advertising claims, *but the FTC, in an*

action for false advertising, bears the burden of proving the advertising claim is, in fact, false or misleading." *Id*. (emphasis added).

The FDA, in turn, is responsible for enforcing the structure/function standards regarding dietary supplement *labels*. *See* FDA Guidance at Part I.B ("FDA has exclusive jurisdiction over the safety, and primary jurisdiction over the labeling, of dietary supplements."). Like the FTC, the FDA will first conduct an internal investigation if it believes that a dietary supplement is being sold in violation of the substantiation requirement. *See* Office of the Inspector General, Dietary Supplements at 3 (FDA, *inter alia*, "monitor[s] adverse event reports and consumer complaints [and] search[es] the Internet for supplements that do not comply with regulations"). If the agency determines that a manufacturer does not possess adequate substantiation (according to the standards set forth below), it then can bring an enforcement action against the advertiser. *See* 21 U.S.C. § 331(a)–(c); 21 U.S.C. § 332. In that event, the FDA—like the FTC—bears the burden of proving that a labeling claim is, in fact, false or misleading. *U.S. v. Universal Mgmt. Servs., Corp.*, 191 F.3d 750, 754 (6th Cir. 1999) ("To show a violation of [21 U.S.C. § 331(a), (k)], the *Government must prove* . . . the [products] are adulterated or misbranded . . . .") (emphasis added); Office of the Inspector General, Dietary

Supplements at 5 ("In any legal proceeding concerning structure/function claims, FDA must prove that the claim is false or misleading").

Like the FTC, the FDA "recommend[s] that dietary supplement manufacturers carefully draft their labeling claims and carefully review the support for each claim to make sure that the support relates to the specific product and claim, is scientifically sound, and *is adequate in the context of the surrounding body of evidence*." FDA Guidance at Part I.B (emphasis added). In determining whether the substantiation standard has been met, the FDA recommends that manufacturers consider a number of issues in their assessment, including "the totality of the evidence." *Id*. at Section II.E.

With regard to the "totality of the evidence," the FDA Guidance states that a manufacturer must "consider the strength of the *entire body of evidence*, including criteria such as quality, quantity (number of various types of studies and sample sizes), relevance of exposure, and consistency and replication of the findings." *Id*. (emphasis added). The FDA adds:

> To determine whether the available scientific evidence is adequate to substantiate a claim, *it is important to consider all relevant research, both favorable and unfavorable.* Ideally, the evidence used to substantiate a claim agrees with the surrounding body of evidence. *Conflicting or inconsistent results raise serious questions as to whether a particular claim is substantiated*.

Id. (emphasis added).

II. This Lawsuit.

This case arises out of false statements on the labels of "TruNature Ginkgo Biloba with Vinpocetine" (the "Product"), which is manufactured by defendant NBTY, Inc. and sold at the stores of defendant Costco Wholesale Corporation. *See* ER006-007.

Plaintiff-appellant Tatiana Korolshteyn ("Plaintiff") alleged that Defendants engaged in false and misleading conduct in violation of the UCL and CLRA by representing that the Product "supports alertness & memory," helps with "mental clarity and memory," and "helps maintain healthy blood flow to the brain to assist mental clarity and memory, especially occasional mild memory problems associated with aging" (collectively, the "brain health benefits"). ER325, ¶¶ 1, 2.

The Complaint alleged that such claims were false or misleading because "[t]he clear weight of the credible scientific evidence and the consensus in the scientific community among experts in the field, based upon numerous well-controlled randomized clinical trials ('RCTs'), is that ginkgo biloba and vinpocetine supplementation does not provide any such brain health benefits." *Id*. at ¶ 2.

The Complaint further alleged that three comprehensive meta-analyses conducted in 2002, 2007, and 2012 concluded that "ginkgo biloba supplements have no positive effect on cognitive function in healthy individuals." ER330, ¶¶ 16–17. The 2002 analysis concluded that Ginkgo Biloba "cannot be recommended," (*id.* at

¶ 18); the 2007 analysis concluded that there is "no convincing evidence that G. Biloba has a positive effect on any aspect of cognitive performance in healthy people . . ." and further stated that "there is little to be gained from further research designed to establish whether or not there is a nootropic effect of G. Biloba in healthy subjects," (ER330-331, ¶ 19); and the 2012 review reached the same conclusions. ER331, ¶ 20. Plaintiff's expert conducted a totality of the evidence analysis and submitted affirmative proof, including several studies in healthy individuals confirming these allegations that Ginkgo Biloba supplements have no positive effect on cognitive function. ER127-145; ER203-220.

III. The First Summary Judgment Motion.

On May 9, 2017, shortly after the District Court certified the Class, Defendants moved for summary judgment, arguing that Plaintiff was effectively bringing a "lack of substantiation case," which is prohibited under California law by allegedly seeking to place the burden on Defendants to show *lack* of falsity.

Plaintiff responded that "this is not a lack of substantiation case," (ER110)—rather, she has put forward overwhelming affirmative evidence that Defendants' dietary supplement label claims are false and misleading (ER106 (the "totality of the evidence shows Defendants' product does not provide the promised brain health evidence")). *See also* ER100 ("Plaintiff is not claiming that Defendants lack substantiation for the brain health benefits. Plaintiff's evidence establishes that the

overwhelming weight of competent scientific evidence shows that Defendants' [Product] is no better than a placebo.").

Plaintiff pointed out that Defendants' argument was effectively that "even a single study purportedly showing efficacy, no matter how unreliable, proves efficacy . . . ." ER095. Defendants' approach, Plaintiff argued, seeks "to alter the applicable scientific standard" for determining falsity as enunciated by both the FTC (in its 2004 Policy Statement) and the FDA (in its 2009 Guidance). *Id.*

IV. The District Court's First Summary Judgment Ruling.

On August 23, 2017, the District Court granted Defendants' motion for summary judgment finding a plaintiff cannot survive summary judgment when a defendant presents *any* admissible expert testimony "that there is scientific support for the alleged misrepresentations," regardless of the extent and persuasiveness of the plaintiff's evidence of falsity. ER075-076.

V. This Court's Reversal of the First Summary Judgment Ruling.

Plaintiff appealed that decision to this Court. *See* 9th Cir. Appeal No. 56435 (the "First Appeal"). This Court reversed the District Court's initial grant of summary judgment, holding that the District Court "fail[ed] to apply the appropriate substantive evidentiary standard of a preponderance to claims brought under California's consumer protection laws." *Korolshteyn v. Costco*, 755 F. App'x 725 (Nov. 9, 2018) (Mem.).

In the Court's view, the District Court stumbled by "appl[ying] a tougher, conclusive standard" when it held "that the existence of scientific studies supporting the alleged benefits of the product precluded the appellants from conclusively proving falsity in the appellees' product labeling." *Id*. This Court remanded "so that the district court may apply the newly clarified standard." *Id*. (citing *Sonner*, 911 F.3d at 992).

VI. The Second Summary Judgment Motion.

Following remand to the District Court, Defendants moved to decertify the Class and again for summary judgment. *See* ER037-064. Defendants devoted the first 19 pages of their motion to arguing for the first time that the Class should be decertified based on an alleged lack of commonality and the supposed presence of some uninjured Class members. *See* ER043-061. Only in the last three pages of their brief did Defendants argue—again for the first time—that Plaintiff's claims *must* be preempted because Defendants' labels "are typical structure-function claims of the sort the FDA has determined to be appropriate." ER061-063.

Defendants did not acknowledge that: (1) supplements with structure/function claims are marketed without any prior FDA approval of their labels; (2) the FDA has the authority to investigate and, if necessary, bring a misbranding action against a manufacturer for false or misleading structure/function claims; and/or (3) the same "totality of the evidence" standard applies both with regard to private lawsuits like

this one and to enforcement actions brought by the FDA. Thus, that these are "typical structure/function claims" does not establish that they are in compliance with the FDCA. In fact, the FDA made clear that it was not approving such brain health claims as to any particular supplement as they still must be truthful and non-misleading. 65 Fed. Reg. at 1002, 1007, 1032.

VII. The District Court's Second Summary Judgment Ruling.

The District Court granted Defendants' motion on preemption grounds, stating that "Defendants' Label Claims are permissible structure/function claims pursuant to the FDA's guidance and meet all the federal labeling requirements." ER010. Yet, without acknowledging the FDA Guidance to the contrary, the Court found that Defendants need only possess adequate substantiation and that federal law does not define "substantiation." *See* ER010. The District Court stated a "common sense interpretation of 'substantiation'" involves "competent and reliable scientific evidence" and the federal requirements merely "prevent a manufacturer from circumventing the substantiation requirements [by] making improbable representations where *no competent and reliable evidence would exist.*" ER010-011 (emphasis added).

The court reasoned that Defendants had introduced some admissible evidence that their labels are not misleading—pointing out this Court had "affirmed the denial of motions to exclude expert reliance on such evidence," (ER011) —and that this

was sufficient to preempt Plaintiff's claims, even though this Court had just reversed the District Court's prior finding that Defendants' evidentiary showing was sufficient to entitle them to summary judgment on the merits under the applicable FDCA standards. *Korolshteyn*, 755 F. App'x at 725 (reversing and remanding).

Relying on *Dachauer*, the District Court also held that the *only* claims that survive preemption under the FDCA where there is some admissible evidence of efficacy is where the Plaintiff "claim[s] that the Defendants' products are *harmful as opposed to useless* . . . ." ER012 (emphasis added). On this point, the Court cited an FDA regulation providing that a label "shall be deemed to be misleading if it fails to reveal facts" that are "*[m]aterial with respect to consequences which may result*" from normal use. *Id*. (citing 21 C.F.R. § 1.21(a)(2)) (emphasis added). The Court reasoned that the only facts that could possibly be "material" with "respect to consequences which may result" from normal use of a dietary supplement are facts showing that the supplement is affirmatively harmful, as opposed to facts showing that the Product will not have any of the advertised effects. *See id*.

Based on the above, the District Court concluded that Plaintiff's claims are preempted because they "seek to impose requirements under California law that

either alter[] or add[] to the requirement that the manufacturer has substantiation that the structure/function claims are truthful and not misleading." *Id*.

Plaintiff timely filed her amended notice of appeal on July 2, 2019. ER001-004. She now asks this Court to reverse the District Court's decision below and remand for further proceedings.

STANDARD OF REVIEW

Because the District Court ruled that Plaintiff's claims are preempted as a matter of law, its decision is reviewed *de novo*. *Galvez v. Kuhn*, 933 F.2d 773, 776 (9th Cir. 1991). The party asserting preemption bears the burden of persuasion. *Stengel v. Medtronic Inc*., 704 F.3d 1224, 1227 (9th Cir. 2013).

SUMMARY OF THE ARGUMENT

Plaintiff's claims are subject to a "strong presumption against preemption" because the FDCA only preempts claims that "seek to establish any requirement" that is "not identical to" federal labeling requirements. 21 U.S.C. § 343(a). In keeping with this language, state law claims that do not seek to "'impose more or inconsistent burdens on manufacturers than the burdens imposed by the FDCA'" are not preempted. *Bradach v. Pharmavite, LLC*, 735 F. App'x 251, 253 (9th Cir. 2018) (citation omitted). This presumption against preemption applies with particular force here because consumer protection laws, such as the UCL and CLRA, are within California's historic police powers.

Accordingly, Plaintiff's lawsuit is only preempted if this Court finds, despite the "strong presumption" against preemption, that this lawsuit seeks to impose more or inconsistent burdens on Defendants than are imposed by the FDCA. It unquestionably does not, because Plaintiff's claims *directly mirror* federal labeling standards governing dietary supplements.

The relevant federal statute—the FDCA, as amended by the NLEA and DSHEA—prohibits "false and misleading" labels on dietary supplements. Under this federal scheme, a supplement is misbranded if, based on a review of the "totality" of the "competent and reliable scientific evidence," any statement on that supplement's label is in fact false or misleading.

The consumer protection laws underlying this case—the UCL and the CLRA—likewise allow a plaintiff to hold a manufacturer liable for "false or misleading" labeling. And the evidentiary standard for proving such a claim under state law is the same as the federal standard: the burden is on the plaintiff to prove that the label is in fact false or misleading under a totality of the evidence analysis. Thus, federal law and state law are in lockstep when it comes to the standards for determining whether a dietary supplement's label is false or misleading.

The District Court's conclusion to the contrary was based on its misunderstanding of federal labeling requirements. According to the lower court, federal law merely "prevent[s] a manufacturer from circumventing the

substantiation requirements [by] making improbable representations *where no competent and reliable scientific evidence exists*." ER011 (emphasis added). In other words, in the District Court's view, so long as a manufacturer presents *any* "competent and reliable scientific evidence" to substantiate its labeling claims—no matter how insignificant or heavily outweighed by contrary evidence—it complies with federal labeling law and any attempt by a private plaintiff to prove its claims false or misleading is preempted.

This ruling conflicts with the FDA's own guidance regarding dietary supplement labeling, which provides that the determination of whether a supplement label containing a structure/function claim is adequately substantiated is to be evaluated by examining the *totality* of the evidence. Because that very same totality of the evidence standard underlies Plaintiff's claims in *this* case, this lawsuit is perfectly in sync with federal law—and is not preempted.

In fact, Plaintiff's expert is the only expert in this case that has employed a totality of the evidence approach. Defendants' experts testified that, while they agreed that this was the correct scientific approach, they did no more than find some support for Defendants' claims. ER123-125 at 59:25-61:6; ER131-132, ¶¶ 11, 14; ER149 at 120:9-16; ER156-157, ¶ 16; ER204-205, ¶ 3; ER257 at 51:24-52:24; ER260-61 at 172:3-173:6; ER265 at 192:12-23.

The District Court further erred by holding that preemption is required by this Court's ruling in *Dachauer*. But, *Dachauer* did not hold, nor even suggest, that dietary supplement manufacturers are released from state law liability when the supplements they market do not do what their labels claim they do. *Dachauer* merely held that a state law challenge to a structure/function claim is preempted where the basis for the challenge is that the dietary supplement does not prevent a particular disease or other adverse health outcome. *Dachauer* held that, because *that* type of state law challenge conflates the federal distinction between structure/function claims and disease claims (which are subject to different labeling requirements under federal law), the state lawsuit is different from federal law and, thus, is preempted.

Dachauer's holding has no bearing here because this lawsuit does *not* challenge the structure/function brain health claim on Defendants' Product on the ground that the Product fails to prevent a particular disease. Rather, Plaintiff challenges the claim on the ground that the Product *does not actually support brain health*. Unlike in *Dachauer*, this suit is in lockstep with federal labeling standards and, as a result, is not preempted. In fact, the "some" evidence upon which Defendants' experts rely and which the District Court also relied upon, are disease studies involving, for example, Alzheimer's disease. ER079.

ARGUMENT

THE DISTRICT COURT ERRED IN FINDING PLAINTIFF'S CLAIMS EXPRESSLY PREEMPTED BY THE FDCA.

I. Overarching Preemption Principles Weigh Heavily Against Federal Preemption of Plaintiff's Claims.

Federal preemption of state law claims by the FDCA is subject to three well-established limiting principles, all of which weigh heavily against any finding of preemption in this case.

First, "federal preemption arising from the provisions at issue in this case is, by statutory prescription, *express preemption only*." *Durnford v. MusclePharm Corp.*, 907 F.3d 595, 601 (9th Cir. 2018) (emphasis added). *See also id.* (citing NLEA § 6(c)(1) (codified at 21 U.S.C. § 343-1)) ("The [NLEA] shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [section 343-1]."). If a court determines that express preemption does not exist under the plain language of the statute, that is the end of the inquiry; other forms of preemption—*i.e.*, field and conflict—simply do not apply. *Id.*

Second, there is a strong presumption against preemption that applies with particular force to consumer claims. As the Supreme Court has explained, "because the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state law causes of action. In all pre-emption cases, and particularly in those in which Congress has 'legislated . . . in a

field which the States have traditionally occupied,' we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). *See also Durnford*, 907 F.3d at 601.

The presumption against preemption applies with even more particular force here because consumer protection laws, such as the UCL and CLRA, are within California's historic police powers. *Id.*; *Farm Raised Salmon Cases*, 42 Cal. 4th at 1088. Likewise, laws regulating the proper marketing of food, including the prevention of deceptive sales practices, are also within California's historic police powers. *Id.*

Third, with regard to the preemption clause at issue, which provides that no state may "directly or indirectly establish . . . any requirement [of] . . . the labeling of food that is not identical to" federal requirements (21 U.S.C. § 343-1(a)(5)), it is firmly established that state law claims that do not seek to "impose more or inconsistent burdens on manufacturers than the burdens imposed by the FDCA" are not preempted. *Bradach*, 735 F. App'x. at 253. *See also Dachauer*, 913 F.3d at 846–47 (FDCA only preempts state law requirements "that differ from the FDCA's requirements"). Rather, the "FDCA as amended by the NLEA contemplates state

regulation and enforcement along with federal regulation." *Lockwood v. Conagra Foods, Inc.*, 597 F. Supp. 2d 1028, 1032 (N.D. Cal. 2009).[8]

Federal regulations provide the same. The phrase "not identical to" means "that the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food [that] . . . [a]re not imposed by or contained in the applicable [federal regulation] . . . or [d]iffer from those specifically imposed by or contained in the applicable [federal regulation]." 21 C.F.R. § 100.1(c)(4).

Accordingly, Plaintiff's lawsuit seeking to hold Defendants accountable for false or misleading advertising is not preempted *unless* state law imposes more or inconsistent burdens on Defendants than are imposed by the FDCA. There is no such inconsistency at issue. As explained below, this lawsuit is a perfect match with federal labeling laws governing dietary supplement labeling and, thus, is not preempted.

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[8] *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 759 (9th Cir. 2015) ("FDCA does not expressly preempt state causes of action" alleging labels are false or misleading); *Salazar v. Honest Tea, Inc.*, 74 F. Supp. 3d 1304, 1311 (E.D. Cal. 2014) ("[I]f state law seeks to impose liability consistent with the FDCA, the law is not preempted."); *Farm Raised Salmon*, 42 Cal. 4th at 1094 ("Congress did not intend to preempt state rules that merely duplicate some or all of the federal requirements.") (brackets and internal quotation marks omitted); *Consumer Justice Ctr. v. Olympian Labs, Inc.*, 99 Cal. App. 4th 1056, 1064 (2002) (FDCA and state unfair competition laws are "complementary schemes: One which allows dietary supplements to reach the market, the other which allows claims made on behalf of those supplements to be tested in court for veracity").

II. This Lawsuit is Not Preempted Because it is Predicated on State Law Standards That Are Functionally Identical to Federal Requirements.

The District Court's first error lay in its failure to understand that this lawsuit is predicted on state law standards that are functionally identical to federal requirements governing dietary supplement labeling. Both the statutory standards *and* the burden of proof governing false labeling claims are the same under state and federal law. And this lawsuit is being litigated in perfect keeping with federal statutory and regulatory standards governing dietary supplements. The District Court's contrary ruling was wrong.

a. The Statutory Standards Are The Same.

We begin with the relevant statutes establishing the substantive standards for food labeling and advertising.

On the **federal side**, the FDCA explicitly prohibits the misbranding of food. 21 U.S.C. § 331(a)-(c). Food is "misbranded" if its labeling is "false or misleading in any particular." 21 U.S.C. § 343(a)(1). Supplements are classified as food and subject to the prohibition against false or misleading labeling. *Dachauer*, 913 F.3d at 847–48.

On the **state law side**, this "false or misleading" standard mirrors the statutory requirements Plaintiff seeks to enforce under California law. California's UCL prohibits any "unlawful, unfair or fraudulent business act or practice and unfair,

deceptive, untrue or misleading advertising." Cal. Bus. & Prof. Code § 17200. To plead a claim under the "fraudulent" prong of the UCL, a plaintiff must plausibly allege that the defendant's product claims are false or misleading. *Williams v. Gerber Prods., Co*., 552 F.3d 934, 938 (9th Cir. 2008). California's CLRA, in turn, prohibits "unfair methods of competition and unfair or deceptive acts or practices." Cal. Civ. Code § 1770.

The California Supreme Court has recognized that the UCL and CLRA "prohibit 'not only advertising which is false, but also advertising which[,] although true, is either actually misleading or which has a capacity, likelihood or tendency to deceive or confuse the public.'" *Kasky v. Nike, Inc.*, 27 Cal. 4th 939, 951 (Cal. 2016) (quoting *Leoni v. State Bar*, 39 Cal. 3d 609, 626 (1985)). The same is true with regard to the FDCA—in fact the FDA and the FTC provide examples in their guidances of claims which are "literally true" but false or misleading when taken in context. FTC Advertising Guide at 5, example 5; FDA Guidance, at Section II.C, Example 8 (structure/function claim that "studies show that the mineral supplement promotes 'Z'" is not supported where "[t]he general U.S. population does not have such a mineral deficiency").

Thus, both the FDCA and California law impose the same "false or misleading" standard regarding dietary supplements. Because the state law standard is "identical" to the federal requirement under the FDCA, there is no

preemption. 21 U.S.C. § 343-1(a)(5).

b. The Standard of Proof is the Same.

The standard of proof for establishing that a label is false or misleading is also the same under federal and California law.

Regarding **federal law**: as explained above, whether a structure/function claim on a supplement label is false or misleading under the FDCA is based on the totality of competent and reliable scientific evidence. Under the FDA's 2009 guidelines governing structure/function claims, "the strength of the *total body of scientific evidence* is the critical factor in assessing whether a claim is substantiated." FDA Guidance at Section II.E (emphasis added). Each piece of information "should be considered in the context of all available information[.]" *Id.*

The FDA could not be clearer on this point. Under the heading, "How Well Does the Totality of Evidence Support the Claims?" the FDA stated:

> In determining whether there is adequate evidence to substantiate a claim, one should consider the strength of *the entire body of evidence*, including criteria such as quality, quantity (number of various types of studies and sample sizes), relevance of exposure, and consistency and replication of findings.

Id. (emphasis added).

The agency continued: "it is important to consider all relevant research, both favorable and unfavorable. . . . *Conflicting or inconsistent results raise serious questions as to whether a particular claim is substantiated*." *Id.* (emphasis added).

If a supplement maker fails to make a satisfactory showing on this point at the internal investigation stage, its label can be challenged in court by the FDA, which then bears the burden of proof of showing that the label is false or misleading under federal law.[9]

The same is true under **California law** regarding a claim that a product's label is false or misleading. California courts determine the truth or falsity of a disputed fact by similarly weighing the totality of the evidence. *See Paduano v. Am. Honda Motor Co., Inc*., 169 Cal. App. 4th 1453, 1469 (2009) (whether claim is false under the UCL and CLRA is question of fact requiring "consideration and weighing of evidence from both sides") (citations omitted); *Linear Tech. Corp. v. Applied Materials, Inc*., 152 Cal. App. 4th 115, 134 (2007) (whether claim is false under UCL requires consideration and weighing of evidence from both sides); *see also Brady v. Bayer Corp*., 26 Cal. App. 5th 1156, 1164 (2018) (same).

As to dietary supplements, courts consider "whether a jury could reasonably

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[9] *See also FTC v. Pantron I Corp*., 33 F.3d 1088, 1097 (9th Cir. 1994) (although the manufacturer had some evidence the product was effective, the advertised claims were proven false based on the "overwhelming weight of the proof at trial"); *Carter Prods., Inc. v. FTC*, 268 F.2d 461, 496 (9th Cir. 1959) ("[T]he truth or lack of truth" of defendant's advertising "presented questions of fact to be determined by the Commission under all of the evidence."). *Accord* Federal Judicial Center, National Research Council, Reference Manual on Scientific Evidence 772–75 (3d ed. 2011), attached to the RJN as Document 6 (advocating, in cases involving "evidence-based medicine," a methodical analysis of the totality of the evidence, which includes weighing the evidence).

conclude that '*the totality of the evidence*' supports the conclusion" that the product does not do what the label says it does. *Mullins v. Premier Nutrition Corp*., 178 F. Supp. 3d 867, 895 (N.D. Cal. 2016) (emphasis added). A plaintiff bears the burden of showing that the defendant's claims "are false or misleading 'by testing, scientific literature, or anecdotal evidence.'" *Id*. at 892 (citing *King Bio*, 107 Cal. App. 4th at 1348). Summary judgment may not be granted where there is a genuine issue of fact about whether, based on the totality of the scientific evidence, a jury could find that a label is false or misleading. *Mullins*, 178 F. Supp. 2d at 895; *Zakaria v. Gerber Prods. Co.*, 2015 WL 4379743, at *3 (S.D. Cal. July 14, 2015) (summary judgment improper under California false advertising law "where the scientific evidence is inconclusive" as to actual falsity).

In *Sonner*, and in its prior ruling in this case, this Court reversed lower court rulings and held that the preponderance of the evidence standard applies to consumer fraud claims concerning dietary supplements and that the District Court here erred when it granted summary judgment on the ground that a defendant in such a case need only have some evidence in support of its claims (and the "some" evidence was challenged by Plaintiff's expert as highly flawed, and included Alzheimer's and other disease studies even though both parties' experts agreed that Ginkgo Biloba is not effective to treat Alzheimer's – presumably the same evidence the District Court relied upon for its ruling here). *Korolshteyn*, 755 F. App'x at 726; *Sonner*, 911 F.3d

at 993. Both of those holdings confirm that the standard for evaluating a falsity claim under California law is exactly the same as the applicable standard in a misbranding action under the FDCA – that false labeling claims are to be evaluated under a preponderance of the evidence standard.

In ruling to the contrary, the District Court stated that "FDA['s] guidance advances a common sense interpretation of 'substantiation,' as meaning 'competent and reliable scientific evidence.'" ER010. Based on this statement—which was taken from a First Circuit decision that actually *reversed* a finding of federal preemption regarding a dietary supplement containing a structure/function claim, *see Kaufman v. CVS Caremark Corp*., 836 F.3d 88, 93 (1st Cir. 2016)—the District Court seemed to conclude that so long as a defendant presents *any* "competent and reliable scientific evidence" to support the truth of its labeling claim, it has met the federal substantiation test.

The problem with the lower court's argument is that it ignores what the FDA Guidance actually says. Not only does the agency say that substantiation requires consideration of "all relevant research, both favorable and unfavorable," but it also emphasizes that "[c]onflicting or inconsistent results raise serious questions as to whether a particular claim is substantiated." FDA Guidance at Section II.E. It is also flatly contrary to the FTC's approach to proving that dietary supplement advertising is false or misleading under federal law. *See* FTC Advertising Guide at

14–15. It is impossible to reconcile the District Court's interpretation with these agency guidances.

But if there were any doubt on that score, it would be dispelled by the specific examples provided by the FDA of cases where, in the agency's view, "the totality of the evidence does not support a proposed [structure/function] claim." FDA Guidance at Section II.E, Example 19. In one example, the FDA describes a firm that has "one study" demonstrating its product "to be effective in ameliorating nocturnal leg cramps," but the firm "is also aware of several other randomized controlled trials that do not show a benefit." *Id*.

A second example also describes a scenario where there was one "randomized, placebo controlled study in volunteers who had trouble falling asleep" supporting efficacy but "[t]here are several other high-quality studies . . . [finding] that the [supplement] did not consistently help people get to sleep." *Id*. at Section II.E, Example 20.

In both examples, even though the firm had some "competent and reliable" scientific evidence showing its product to be effective, substantiation was deemed lacking in light of the "totality of evidence." *Id*. One study, according to these examples, is clearly not enough.

The District Court's one-study-is-enough approach is also refuted by FTC's discussion of how it determines whether an advertiser has substantiated a

structure/function claim. *See* FTC Advertising Guide at 14–15. In one particularly telling example, the FTC hypothesizes that "[a]n advertiser wishes to make a claim that a supplement product will substantially reduce body fat." *Id*. at 14. "The advertiser," states the FTC, "has two controlled, double-blind studies showing a modest but statistically significant loss of fat at the end of a six-week period. However, there is an equally well-controlled, blinded 12-week study showing no statistically significant difference between test and control groups . . . . *Given the totality of the evidence on the subject, the claim is likely to be unsubstantiated*." *Id.* at 14–15 (emphasis added).

Because the lower court erred in finding one-study-is-enough to satisfy federal standards for proving falsity or deception, it was also wrong about preemption.

In addition to the District Court's error on the correct standard to use, the District Court also erred in concluding as a matter of law that Defendants have "competent and reliable" evidence to support their brain health claims because they introduced some admissible expert testimony. The District Court apparently equated admissible expert testimony with competent and reliable testimony. ER011. This is inappropriate because whether the testimony is competent and reliable is for the jury, not the District Court, to decide.

In evaluating expert testimony, judges play a gatekeeper role, "screen[ing] the jury from unreliable nonsense opinions" *City of Pomona v. SQM N. Am. Corp.*, 750 F.3d 1036, 1044 (9th Cir. 2014), but it is the "jury [that] decides how much weight to give that testimony," *Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010).

While the District Court may have been satisfied that Defendants' studies are not "unreliable nonsense," even under the District Court's incorrect application of federal law, the question of whether those studies are "competent and reliable" evidence is a disputed question of material fact that the jury must decide. *See Korolshteyn*, 755 F. App'x at 726 (the District Court erred in applying "a tougher, conclusive standard, holding that the existence of scientific studies supporting the alleged benefits of the product precluded the appellants from conclusively proving falsity in the appellees' product labeling"). *See also* ER 138, ¶ 33 (Plaintiff's expert testimony that opines, among other things, the studies Defendants rely upon "are of low quality, contain methodological errors, are of small sample size, or are simply not related to the claims on the products"); ER202-220.

c. This Lawsuit is Functionally Identical to Federal Law Standards Governing Structure/Function Claims.

The District Court also failed to understand that that this lawsuit is being litigated consistent with federal standards for proving falsity or deception under the FDCA. Both Plaintiff's complaint and her oppositions to summary judgment make

clear that she seeks to prove, based on the totality of the evidence, that Defendants' label claims are affirmatively false or misleading.

Plaintiff alleges, among other things, that "[t]he scientific evidence, from [randomized controlled trials], demonstrates that ginkgo biloba supplementation does not contribute to improved mental clarity, memory or alertness for anyone . . .. To the contrary, *the weight of scientific evidence* demonstrates that ginkgo biloba supplements do not provide any mental clarity, memory or alertness benefits." ER330, ¶ 16 (emphasis added). *See also* ER330-332, ¶¶ 17–23 (summarizing scientific evidence that Ginkgo Biloba has no beneficial effects on learning or memory).

In keeping with these allegations, in opposing Defendants' first motion for summary judgment (ER266-295), Plaintiff demonstrated, via voluminous evidentiary submissions from qualified experts, that "the overwhelming weight of competent scientific evidence shows that Defendants' [Ginkgo Biloba] is no better than a placebo and that Defendants' brain health benefit claims are false," (ER100). She also demonstrated the myriad flaws of the studies relied on by Defendants (*see* ER103-105); that "Defendants' experts admit that they did not do a totality of the evidence analysis in reaching their opinions about [Ginkgo Biloba]," (ER103); and

that "Defendants also completely ignore the three largest high-quality RCTs on" Ginkgo Biloba. ER105.

Plaintiff concluded that there are many "genuine issues of material fact which preclude summary judgment for Defendants, *as an analysis of the totality of the evidence shows [Ginkgo Biloba] did not provide the promised brain health benefits.*" ER101 (emphasis added).

In short, as this Court recognized in the First Appeal, this is *not* a "lack of substantiation" case seeking to place the burden on Defendants to prove affirmative truthfulness of their label. *Korolshteyn*, 755 F. App'x at 726. Rather, Plaintiff seeks to recover based on her affirmative showing of falsity based on the totality of the evidence. This approach is not merely consistent with the federal approach to dietary supplement labeling; it is *identical* to that approach and, thus, not preempted. *See Bradach*, 735 F. App'x at 253 ("Federal law does not preempt state requirements that statements on dietary supplement labels that are structure/function claims . . . be accurate and not misleading."); *Kanfer v. Pharmacare US, Inc.*, 142 F. Supp. 3d 1091, 1101–02 (S.D. Cal. 2015) (Plaintiffs false and misleading structure/function claim "theory is not preempted because state false-advertising laws are consistent with the FDCA's prohibition on false and misleading labeling . . . ."); *Sandoval v. PharmaCare US, Inc.*, 145 F. Supp. 3d 986, 994 (S.D. Cal. 2015) (lawsuit challenging product label with structure/function claim as false and misleading

under California law not preempted by FDCA); *Smith v. Allmax Nutrition, Inc.*, 2015 WL 9434768, at *8–9 (E.D. Cal. Dec. 24, 2015) (same); *Gallagher*, 2015 WL 1056480, at *7 (same).

Based on this Court's ruling in the First Appeal in this case rejecting Defendants' argument that this is an inappropriate lack-of-substantiation case (and thus cannot be brought under *King Bio*), the District Court's citation to *King Bio* is perplexing. *Compare* ER010 (citing *King Bio*, 107 Cal. App. 4th at 1344), *with Korolshteyn*, 755 F. App'x at 726 (recognizing that plaintiff here is seeking to "conclusively prov[e the] falsity in the appellees' product labeling"). The citation suggests that the District Court may have persisted in its belief that this *is* a "lack of substantiation" case—which, in turn, may have contributed to its conclusion that Plaintiff's claims are preempted (on a theory that the burden of proof in a state law lack-of-substantiation case, were such a case permitted, would differ from the burden in a federal misbranding action based on falsity).

If that belief did underlie the District Court's ruling, it was error as Plaintiff seeks to prove affirmative falsity based on the totality of the evidence. That being so, this lawsuit is functionally identical to the federal requirements for proving falsity in a misbranding action under the FDCA and is not preempted.

III. The District Court's Reliance on *Dachauer* was Misplaced.

The District Court compounded its error by appearing to hold that the *only* state law structure/function challenges that escape FDCA preemption where the defendant has some admissible evidence supporting the claims is where the label omits material information about a supplement's harmfulness. *See* ER011-012. The District Court seemed to think this conclusion is mandated by *Dachauer*. But, *Dachauer* holds no such thing.

In *Dachauer*, this Court reasoned that, because the plaintiff was challenging a structure/function claim on the ground that the supplement did not prevent a particular disease (cardiovascular disease), the lawsuit sought to impose a requirement not identical to federal law and, thus, was expressly preempted by the FDCA. *See* 913 F.3d at 848 (finding claim preempted on ground that "Plaintiff's argument would vitiate the FDCA's distinction between disease claims and structure/function claims . . . ."). *See also Mullins v. Premier Nutrition Corp*., 2019 U.S. Dist. LEXIS 153698, at *10–11 (N.D. Cal. Aug. 29, 2019) (holding that the *Dachauer* "plaintiff's claims were preempted only to the extent he sought to prove the dietary supplement's label was false using evidence that did not disprove the claim").

This holding has no application here because Plaintiff is *not* challenging Defendants' structure/function claim on the ground that TruNature Ginkgo Biloba

does not prevent a particular disease. It is Defendants' experts who primarily rely on disease studies, which the District Court nevertheless found to be dispositive. In keeping with *Dachauer*, Plaintiff challenges Defendants' label as false on the ground that the supplements do not do what the label claims they do—*i.e.*, support brain health. And Plaintiff's expert relies on studies in healthy persons and whether Gingko Biloba provides the represented brain health benefits. ER132, ¶ 16. Thus, not only is Plaintiff's evidence squarely in compliance with *Dachauer*, it also mirrors the federal labeling scheme for dietary supplements: as the FDA has explained, "dietary supplements that do not do what they claim to do are misbranded." 65 Fed. Reg. at 1007. As this lawsuit, unlike in *Dachauer*, does not seek to impose any requirement that differs from federal law—it is not preempted.

Dachauer's second holding concerned defendants' failure to disclose that its supplement did not reduce all-cause mortality. 913 F.3d at 848–49. *Dachauer* found the FDCA preempts plaintiff's immune health claim because the FDCA "does not require that manufacturers substantiate structure/function claims about immune health with proof that their supplements reduce the risk of all-cause mortality." *Id.* at 849. "[A]ny such requirement under California law would differ from the FDCA's labeling requirements." *Id*.

This holding has no bearing here as this lawsuit is *not* challenging Defendants' label on the ground that the supplement fails to prevent any particular negative health

outcome.

Dachauer's final holding—that plaintiff's claim that defendants failed to disclose that their supplements "actually *increase* overall risk of death" was *not* preempted, despite its resemblance to a disease claim—was based on an FDA regulation stating that a food label "shall be deemed to be misleading if it fails to reveal facts" that are "[m]aterial with respect to consequences which may result from use of the article . . . ." *Id.* at 849 (citing 21 C.F.R. § 1.21(a)(2)). This Court reasoned that, because the FDA would "deem it misleading" for a supplement label not to reveal that a supplement might actually increase the risk of death, this claim was not preempted. *Id.*

The District Court erroneously construed this final holding to mean that the *only* false labeling lawsuits that escape preemption where some admissible evidence of efficacy exists are those predicated on material nondisclosure of *harmfulness*. That holding is inconsistent with the actual terms of Section 1.21(a)(2), which do not distinguish between nondisclosures of harmfulness and nondisclosures of uselessness, both of which are "material" to any reasonable consumer. It also assumes, wrongly, that section 1.21(a)(2) sets forth the exclusive basis for finding a structure/function claim to be misbranded under federal law—a conclusion at odds with the FDA's unequivocal statement that "dietary supplements that do not do what they claim to do are misbranded." 65 Fed. Reg. at 1007. *See also Kaufman*, 836

F.3d at 96 (holding that FDCA "does not immunize a structure/function claim for which the manufacturer lacks the required substantiation *or* that misleadingly fails to disclose the harmful aspects of the nutrient's structure/function.") (emphasis added).

And nothing in *Dachauer* itself holds, implies, or even hints that *only* structure/function claims based on material omissions of harmfulness survive preemption.

IV. The District Court's Ruling is Contrary to Public Policy.

The District Court's preemption ruling is not just legally wrong; it also poses a serious threat to consumer safety. In arguing against federal preemption, Plaintiff observed that "under Defendants' logic, they could sell anything … falsely claim [based on a scintilla of evidence] that it helps memory function, and any falsity claim would be preempted." ER033. The lower court rejected this argument as based on a "mischaracterization of federal requirements," because—in the court's view—the federal labeling requirements merely "prevent a manufacturer from . . . making improbable representations where no competent and reliable scientific evidence would exist." ER011.

If that *were* the federal labeling standard, then a supplement manufacturer could avoid liability under both federal *and* state law by merely offering up a warm body to vouch for the reliability of a single non-peer-reviewed, non-randomized,

corporate-funded study showing that its label *might* be truthful. That would be enough, in the lower court's view, even if the FDA (in a misbranding action) or a private plaintiff (in a case like this one) countered with a mountain of highly credible evidence to the contrary.

Under this understanding of the law, a dietary supplement manufacturer would have a bullet-proof defense against any claim that its product is mislabeled, giving it free rein to lie with impunity. This is not a trivial concern: individuals have been known to forego effective treatments or actions on the basis of false promises made about supplements. *See* 65 Fed. Reg. at 1044–45 (noting that falsely labeled dietary supplements may cause consumers to "self-treat for a serious disease by substituting a dietary product of uncertain value for a medical therapy that has been shown to be safe and effective . . . ."). *See also id*. at 1005 (noting that "there may be important health-related consequences associated with taking a dietary supplement, even if the product does not bear disease claims").

Indeed, the FDA has stated that mislabeled supplements pose "acute" risks to consumers—risks that can only be addressed by ensuring that supplement labels are neither false nor misleading. *Id*. at 1045. Yet, the District Court's ruling turns the FDCA and the FDA's regulations into a shield for manufacturers, rather than a sword to protect consumers. The District Court's embrace of this result—and the serious

health implications of its ruling—is deeply troubling and underscores why reversal is not just warranted, but urgently required.

CONCLUSION

For the foregoing reasons, the District Court's holding that Plaintiff's claims are preempted by the FDCA should be reversed.

Date: December 3, 2019

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH RULE 32-1

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32-1(a) because this brief contains 10,336 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. 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 proportionally spaced typeface using Microsoft Word 2013 in 14-point Time New Roman type.

Dated: December 3, 2019

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STATEMENT OF RELATED CASES

I am aware of one related case currently pending in this Court: Appeal No. 19-55671. The case, which is on appeal from *Kroessler v. CVS Health Corp.*, 387 F. Supp. 3d 1064 (S.D. Cal. 2019), raises a related legal issue, *see* Circuit Rule 28-2.6(c). In *Kroessler*, the Honorable Cathy Ann Bencivengo similarly held that plaintiff's false dietary supplement advertising claims pursuant to, *inter alia*, California consumer protection law were preempted by the FDCA.

Date: December 3, 2019

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CERTIFICATE OF SERVICE

I hereby certify that on December 3, 2019, I electronically filed Appellant's Opening Brief with the Clerk of Court for the United States Court of Appeals for the Ninth Circuit using the Appellate Electronic Filing System, which will send notification of such filing to the email addresses denoted on the Electronic Mail List.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Date: December 3, 2019

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