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.
Defendants 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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INTRODUCTION AND SUMMARY OF ARGUMENT

When Congress passed the Nutrition Labeling and Education Act ("NLEA"), it understood that state-law remedies can powerfully reinforce federal goals, in this case by allowing private plaintiffs to sue under state laws designed to protect consumers from mislabeled supplements.

To that end, Congress gave the Food and Drug Administration ("FDA") and the Federal Trade Commission ("FTC") certain enforcement responsibilities under the NLEA (*see* D.E. 17 ("Korolshteyn Br."), at 12), but it *also* gave injured consumers the right to sue for false labeling under state law so long as their claims are "identical" to requirements imposed by federal law. *See* 21 U.S.C. § 343-1(a)(5).

That's true here. Plaintiff Tatiana Korolshteyn is seeking to hold Defendants liable for marketing a supplement that falsely claims to support memory function and "brain health" when it is no better than a placebo. Her lawsuit is functionally identical to a federal misbranding action that could be brought by the FTC or the FDA against Defendants, both in terms of the substantive standard (false or misleading, *see* 21 U.S.C. § 343(r)(6)), and in terms of the evidentiary burden (Plaintiff must prove her case by a preponderance of evidence). This is exactly what the FTC or the FDA would have to prove in a federal suit under the NLEA. *See infra* at II.C.2.

This is also exactly the kind of lawsuit Congress intended to allow consumers to bring in order to reinforce the NLEA's public health goals. Dietary supplements bearing structure/function claims do not require federal preapproval before sale; instead, federal law creates a type of honor system for such claims, whereby sellers or advertisers have to possess "substantiation" that any such claim is neither false nor misleading. *See* 65 Fed. Reg. 1001, 1003 (Jan. 6, 2000); 21 U.S.C. § 343(r)(6). Although the existence (*vel non*) of such substantiation can be challenged by the FTC or FDA in a federal misbranding action, that rarely occurs, because these agencies lack sufficient resources to investigate whether adequate "substantiation" exists for every single structure/function claim on every single supplement label.

Yet, as the FDA has stated, falsely labeled supplements threaten public health, even when they are "merely" useless. *See* 65 Fed. Reg. at 1044–45 (useless 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…."); *accord Brady v. Bayer Corp.,* 237 Cal. Rptr. 3d 683, 685 (Cal. App. 2018) (discussing harms caused by "charlatan[s]…peddling unfounded remedies to unsuspecting citizens with little or no access to doctors").

Congress knew this to be true, and so—in lieu of including a private right of action in the NLEA—it gave private plaintiffs the authority to fill the enforcement gap by challenging false or misleading structure/function claims under state law.

See Consumer Justice Ctr. v. Olympian Labs, Inc., 121 Cal. Rptr. 2d 749, 753 (Cal. App. 2002) (noting that the NLEA "has no private enforcement provision comparable" to California's). That's what this lawsuit is all about: giving consumers a remedy that Congress omitted from the NLEA but expressly *preserved* under state law.

Contrary to this scheme, the District Court's ruling in this case imposes a nearly impenetrable barrier to private enforcement. Similar to the first summary judgment ruling in this case, which was overruled on appeal (*see Korolshteyn v. Costco*, 755 Fed. Appx. 725 (9th Cir. 2019) (unpublished)), the District Court reasoned that there is only *one* circumstance in which a structure/function claim lacks "substantiation" under federal law: where there is "*no* competent and reliable evidence" to support such a claim. *See* ER010. Based on this absolute standard, which conflicts with the totality of the evidence approach required by *both* the FDA and state law, the District Court found this lawsuit preempted because Defendants had, during the prior round of summary judgment briefing in this case, introduced some admissible evidence that Gingko biloba (TruNature's supposedly "active" ingredient) is not a mere placebo.

Under this view of the law, so long as a defendant can produce one "warm body" to vouch for a structure/function claim, it is immune from suit—both under state law and under federal law. In practice, this would mean the only

structure/function lawsuits that could escape preemption would involve supplements that might be affirmatively harmful, as opposed to "merely" useless. *See* ER012 (citing *Dachauer v. NBTY, Inc.*, 913 F.3d 844, 847-48 (9th Cir. 2019)). But "[n]othing in *Dachauer* suggests the FDCA preempts all state causes of action against structure/function claims that are false and misleading." *Mullins v. Premier Nutrition Corp.*, 13-CV-01271-RS, 2019 WL 8164376, at *2 (N.D. Cal. Aug. 29, 2019). *See also Capaci v. Sports Research Corp.*, 445 F. Supp. 3d 607, 621 (C.D. Cal. 2020) ("This court agrees…that the Ninth Circuit 'did not rule so narrowly' in *Dachauer*…") (citations omitted).

Defendants seem to recognize that the District Court's ruling is indefensible, so they try to back away from it by arguing that federal substantiation is actually a "flexible" approach that requires some unspecified modicum of "competent and reliable scientific evidence," not just a "warm body." D.E. 34 ("Defendants' Br."), at 8. Defendants then argue that, because the District Court found some of their studies admissible during the *first* summary judgment proceeding in this case, their structure/function claim is "substantiated" under federal law—and thus this lawsuit is necessarily preempted. *Id.* at 50-52.

Defendants' and the District Court's approaches both fail for the same reason: they misunderstand that, under federal law, a structure/function claim is not "substantiated" just because a manufacturer claims to have one or more studies to

support it. Rather, in the event the FTC or FDA decides to test such a claim, federal law measures substantiation by weighing the *total body* of scientific evidence and—crucially—allows both the FTC and the FDA to challenge a manufacturer's purported "substantiation" in a federal misbranding action. *See* Korolshteyn Br. at 13 (citing 15 U.S.C. §§ 45(b), (m)(1)(A), 53(b)).

When challenged, the burden is on the agency to prove that a structure/function claim is false and/or misleading. *See Nat'l Council Against Health Fraud, Inc. v. King Bio Pharm., Inc.*, 107 Cal. App. 4th 1336, 1348–50 (Cal App. 2003) ("*King Bio*"). That is no different from this lawsuit: Korolshteyn is challenging Defendants' purported "substantiation" as contrary to the weight of evidence. And if allowed to proceed on the merits, *she* will have the burden of proof, just like the FTC or FDA in a federal misbranding action. Because this lawsuit is functionally identical to federal law, it is not preempted under Section 343-1(a)(5).

Both the Defendants' and the District Court's approaches fail for a second reason: they both seek to transform the question of federal preemption into a fact-intensive, merits-oriented determination that requires the court to determine the admissibility of Defendants' studies, arbitrarily determine how many studies are enough to "substantiate" a structure/function claim, and engage in a prohibited merits determination of their "competence and reliability." That's not how the law

works. Under the NLEA, preemption is a question of law that requires a court to decide whether the state and federal *standards* for evaluating a structure/function claim are functionally identical—and here, they are. The lower court's conclusion to the contrary should be reversed.

ARGUMENT

I. KOROLSHTEYN'S CLAIMS ARE SUBJECT TO A STRONG PRESUMPTION AGAINST PREEMPTION.

Defendants' argument (at 27-31) that the presumption against preemption does not apply when Congress has enacted an express preemption clause fails for three reasons.

First, it doesn't matter. With or without the presumption, the District Court made an error of law and should be reversed.

Second, contrary to Defendants' contention, *Puerto Rico v. Franklin Cal. Tax-Free Tr.*, ___ U.S. ___, 136 S. Ct. 1938 (2016), did not abolish a presumption against express preemption as later cases recognize. *See Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 771 n.9 (3d Cir. 2018) (rejecting notion that "[a]ny presumption against express preemption no longer exists" especially where preemption concerns matters states have historically regulated).[1]

Third, this Court, considering preemption under the statute at issue here—the

[1] All citations and internal quotations are omitted herein unless otherwise stated.

NLEA—reaffirmed the presumption against preemption and held the NLEA did not preempt California false advertising claims under the UCL and CLRA. *Durnford v. MusclePharm Corp*., 907 F.3d 595, 601 (9th Cir. 2018). So the presumption applies.

II. KOROLSHTEYN'S CLAIMS ARE FUNCTIONALLY IDENTICAL TO FEDERAL LAW AND THUS NOT PREEMPTED.

Defendants also argue (at 31-49) that Korolshteyn's lawsuit is preempted because it seeks to impose a requirement not identical to federal law. Defendants are wrong because both state and federal law require that a structure/function claim be neither false nor misleading as determined by the same totality of the evidence standard.

A. Statutory Background.

The relevant preemption provision is set forth in the NLEA, which forbids states from imposing any "requirement" respecting food labeling "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, any state-law claim "not identical" to NLEA Section 343(r) is preempted. Effective—not exact—identity is required. *See, e.g.*, *Farm Raised Salmon Cases*, 175 P.3d 1170, 1086, n.8 (Cal. 2008) ("FDA regulations make clear that the phrase 'not identical to' in section 343–1(a)(3) 'does not refer to the specific words in the requirement'"). Even if the words used in the state

requirement are not exactly the same, the state requirement is effectively the same so long as it does "the same thing that the Federal law does." *Id.*; *see also Simpson v. The Kroger Corp.*, 162 Cal. Rptr. 3d 652, 657 (Cal. App. 2013).

Section 343(r)(6) governs dietary supplements that purport to help maintain a healthy "structure or function" in the human body. This provision states, among other things, that a structure/function claim on a supplement label complies with federal law if the manufacturer "ha[s] substantiation that the statement is truthful and not misleading." 21 U.S.C. § 343(r)(6)(B).

Section 343(r)(6)(B)'s "truthful and not misleading" standard is similar to the language in Section 343(a)(1), which is the general misbranding provision for the entire NLEA. That provision, which pertains to *all* food labeling (not just structure/function claims on dietary supplements), states that food labels cannot be "false or misleading." *See* 21 U.S.C. § 343(a)(1). But unlike 21 U.S.C. § 343(r)(6)(B), which pertains specifically to structure/function claims on dietary supplements, Section 343(a)(1) does not say anything about "substantiation."

Section 343(r)(6)(B)'s substantiation requirement is not defined in the NLEA. Instead, it is defined in labeling guidelines issued by the FDA, based on advertising guidelines written by the FTC. *See* Korolshteyn Br. at 12-15. These guidelines provide that before marketing a dietary supplement bearing a structure/function claim, a manufacturer must possess "substantiation" that the claim is supported by

scientific studies "largely consistent with the surrounding body of evidence." *Id*. at 12.

But the fact that a manufacturer claims to have sufficient "substantiation" under Section 343(r)(6)(B) doesn't necessarily mean it has complied with federal law. If, after an investigation, the FDA or FTC has "reason to believe" a manufacturer lacks such substantiation, the agency can file suit, in which case the agency "bears the burden of proving the structure/function claim is, in fact, false or misleading." *Id*. (quoting *King Bio*, 107 Cal. App. 4th at 1349).

Consistent with this federal scheme, Korolshteyn is arguing that her lawsuit is not preempted because both Section 343(r)(6)(B) of the NLEA and California's consumer laws require Defendants' structure/function claim to be neither false nor misleading. *See id.* at 29-31.

She further argues that the *standard of proof* for determining whether that's true is the same under state and federal law: she must show, based on the preponderance of the scientific evidence, that Defendants' structure/function claim is false or misleading. *See id.* at 31-36. Because Korolshteyn's state-law claims mirror the federal substantive and evidentiary standards for dietary-supplement labeling under Section 343(r)(6)(B), this suit is not preempted by the NLEA.

B. Korolshteyn Agrees that this Case Is Subject to Section 343(r)(6)(B)'s Substantiation Requirement.

In order to avoid this straightforward conclusion, Defendants argue that

Korolshteyn is relying on the wrong federal standard for measuring compliance with the NLEA. *See* Defendants' Br. at 31-33. Specifically, Defendants say Plaintiff is trying to substitute the bare-bones "false and misleading" standard of 21 U.S.C. § 343(a)(1) (which applies to all food labeling) for Section 343(r)(6)(B)'s specific requirement that a manufacturer of a dietary supplement bearing a structure/function claim must "*have substantiation* that the statement is truthful and not misleading." 21 U.S.C. § 343(r)(6)(B) (emphasis added).

In so arguing, Defendants appear to be suggesting that Section 343(a)(1)'s general "false and misleading" standard is more stringent than the "truthful and not misleading" standard of Section 343(r)(6)(B) because, even though both provisions require that labeling be "truthful and not misleading," Section 343(a)(1) says nothing about substantiation—and "substantiation," in Defendants' view, is a "flexible" standard that does not require a manufacturer to prove its label is actually true. *See* Defendants' Br. at 32 ("Plaintiff's briefing…ignores the requirement that manufacturers *have substantiation* that their structure claims are truthful and not misleading and instead advocates for a standard bordering on scientific certainty") (emphasis in original); *id*. at 36 ("substantiation is not an inquiry into the absolute—i.e., whether something is 'true' or 'false'").

This argument is based on a false premise: that Korolshteyn "ignores" the substantiation requirement of Section 343(r)(6)(B). Defendants' Br. at 32.

Actually, Korolshteyn *agrees* that this case is governed, on the federal side, by Section 343(r)(6)(B). In fact, a sizable portion of her Opening Brief is devoted to explaining why the substantiation requirement of Section 343(r)(6)(B) is functionally identical to the standard of proof for determining the falsity (*vel non*) of a dietary-supplement label under state law. *See* Korolshteyn Br. at 31-36.

Defendants ignore Korolshteyn's discussion entirely. Instead, they seize on the fact that Korolshteyn *also* makes fleeting reference to Section 343(a)(1), which sets forth the *general* misbranding standard for food labeling. But Defendants misunderstand Korolshteyn's argument. Korolshteyn mentioned Section 343(a)(1) (which applies to all food labeling) to show that, as a general matter, the FDCA and California law both impose the same "false and misleading" standard with regard to all food-labeling claims, including those involving dietary supplements. *See id.* at 29. But Korolshteyn *agrees* with Defendants that the specific governs the general (*see* Defendants' Br. at 40-41), and that structure/function claims are specifically governed, on the federal side, by Section 343(r)(6)(B). Far from abandoning the federal "substantiation" standard—Korolshteyn says her lawsuit *mirrors* it, and thus

is not preempted under Section 343-1(a)(5). *See* Korolshteyn Br. at 31-40.[2]

C. Korolshteyn's Claims Are Based on the FDA's Totality of the Evidence Standard, Not a Standard "Bordering On Scientific Certainty."

The only real disagreement here is as to the meaning of Section 343(r)(6)(B)'s substantiation requirement—and how that standard compares to requirements imposed by California's consumer protection laws. If this Court agrees with Korolshteyn that her state-law claims mirror *that* requirement, then it must reject Defendants' preemption argument.

Returning to Section 343(r)(6)(B): that provision states that a structure/function claim on a supplement label complies with federal law if the manufacturer "*ha[s] substantiation* that the statement is *truthful and not misleading*." 21 U.S.C. § 343(r)(6)(B) (emphases added).

The second italicized phrase—"truthful and not misleading"—is not at issue here. As Korolshteyn has explained, California's consumer protection laws allow a plaintiff to hold a manufacturer liable for "untrue or misleading" labeling.

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[2] Defendants' mistaken claim that Korolshteyn has "ignored" the federal substantiation requirement strips their remaining statutory arguments of any relevance. *See* Defendants' Br. at 31-42. Thus, for example, Defendants argue that the NLEA's "plain language requires only 'substantiation.'" *Id*. at 34. But Korolshteyn has no quarrel with that proposition; she agrees that NLEA Section 343(r)(6)(B)'s substantiation requirement governs the federal side of the preemption analysis.

Korolshteyn Br. at 29-30 (citing Cal. Bus. & Prof. Code § 17200). This is functionally equivalent to the "truthful and not misleading" language of Section 343(r)(6) of the NLEA—and Defendants do not contend otherwise.

The only issue here relates to the *first* italicized phrase in Section 343(r)(6)(B): that a manufacturer must "have substantiation" that its structure/function claim is neither false nor misleading before it can sell its product. Korolshteyn says her lawsuit is functionally the same as that standard (and therefore not preempted) because, in a suit like this one and in a federal misbranding action, the plaintiff must show, based on totality of the evidence, that the structure/function claim is false or misleading. *See id.* at 32 n.9, 32-34; *see also Korolshteyn*,755 Fed. Appx. at 726 (holding that "the district court erred in granting summary judgment by failing to apply the appropriate substantive evidentiary standard of a preponderance to claims brought under California's consumer protection laws) (citing *Sonner v. Schwabe N. Am., Inc*., 911 F.3d 989, 992 (9th Cir. 2018)).

Defendants argue (at 38) that Korolshteyn's claims are based on a "scientific consensus" substantiation standard, whereas the *federal* substantiation requirement is a "flexible" standard that is "not an inquiry into the absolute—i.e., whether something is 'true' or 'false.'" Defendants' Br. at 36. Thus, say Defendants, "the standard for which Plaintiff advocates would seemingly require such consensus and render Congress's selection of the flexible substantiation standard in section

343(r)(6)(B) a nullity." *Id.* at 38.

Nothing about this argument is correct.

As a threshold matter, it bears repeating that the FDCA does not require *any* federal pre-approval of a structure/function claim on a supplement label. *See* Korolshteyn Br. at 10 (citing 65 Fed. Reg. at 1003 (FDA labeling rule stating that, unlike dietary supplement labels that make "disease claims," "[t]here is no comparable testing and approval process for dietary supplements marketed with structure/function claims…")). Although both the FDA and FTC have the authority to investigate whether substantiation actually exists, and to bring a federal misbranding action if they conclude it doesn't, that's entirely optional on the agencies' part. So the fact a manufacturer *says* it possesses adequate "substantiation" doesn't mean it actually *does*—and it certainly doesn't immunize it from a federal investigation or misbranding action.

That being said, Defendants' interpretations of state consumer protection law *and* the federal substantiation requirement are incorrect, as explained below.

1. Korolshteyn's Claims Do Not Require Defendants to Prove a "Scientific Consensus" Supporting Their Label.

First, as to the state-law side of the equation, Korolshteyn has *never* contended that, to avoid liability under state law, Defendants must show that their labeling claims are supported by "scientific consensus." Defendants' Br. at 38. To the contrary, Korolshteyn has *always* argued, both in this appeal and in her prior appeal

to this Court (of the first summary judgment ruling, *see Korolshteyn*, 755 Fed. Appx. at 725), that *she* has the burden of proving falsity by a preponderance of the evidence. *See* Korolshteyn Br. at 33.

Defendants' contrary contention appears to be based on the same erroneous argument that was already rejected by this Court in its decision reversing the District Court's initial grant of summary judgment for Defendants. *See Korolshteyn*, 755 Fed. Appx. at 725. Defendants first sought summary judgment on the ground that Korolshteyn is improperly seeking to place the burden on Defendants to show lack of falsity. *See* Korolshteyn Br. at 16-19. Korolshteyn responded that, in truth, she has put forward overwhelming affirmative evidence that Defendants' dietary supplement label claims are false and misleading. *See id.* at 18. Yet the District Court ruled for Defendants, based on its erroneous view that Korolshteyn was impermissibly trying to shift the burden of proof onto Defendants—something a private plaintiff is not allowed to do under California law. *See* ER075-76; *see also King Bio*, 107 Cal. App. 4th at 1348–50. This Court reversed, 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*, 755 Fed. Appx. at 725.

Despite this ruling, Defendants are back before this Court arguing that Korolshteyn's state-law claims place the burden on *Defendants* to show that its label

is supported by a "scientific consensus." This time, Defendants make that argument in an attempt to show that Korolshteyn's claims are preempted by federal law, rather than in a bid for summary judgment on the merits.

But Defendants are just as wrong now as they were the first time around. As this Court has already ruled, Korolshteyn has always contended that *she* bears the burden of proving that Defendants' label is false and misleading. *See id.* Her argument is that, on balance, the *weight* of scientific evidence shows that Defendants' label is false and misleading. And, as explained below, that is no different from the proof that must be shown by the FDA or FTC in a federal misbranding action under the FDCA—ergo no preemption. *See Capaci*, 445 F. Supp. 3d at 607, 621 (finding no preemption where "plaintiffs cite multiple studies that indicate that the Product has no effect on the structure and function of the body in that the Product is incapable of "'providing] weight-loss or appetite control benefits in humans.'"); *Gallagher v. Bayer AG*, 14-CV-04601-WHO, 2015 WL 1056480, at *7 (N.D. Cal. Mar. 10, 2015) ("Not preempted would be a claim that 'supports heart health' as a structure/function claim is a false and misleading statement contrary to scientific studies").

2. Under the FDCA, Substantiation Is Measured by the Totality of the Evidence and Can Be Challenged in a Misbranding Action.

On the federal side of the equation, Defendants suggest that federal law immunizes a supplement manufacturer from liability so long as the manufacturer has

an iota of "substantiation" that its label is neither false nor misleading. That, too, is incorrect.

As a threshold matter, Defendants never actually say what federal substantiation requires. Instead, Defendants vaguely describe federal substantiation as a "flexible" requirement that differs in some undefined way from state law, and is not about truth or falsity at all. *See* Defendants' Br. at 36 ("substantiation is not an inquiry into the absolute—i.e., whether something is 'true' or 'false'").

Defendants then simply assert, without any support or analysis, that Korolshteyn's claims would somehow render that nebulous standard "a nullity" because, under Defendants' version of California law, Defendants will be liable for false labeling unless they can show that their structure/function claims are supported by a "scientific consensus." *Id*. at 37.

There are two distinct problems with this argument.

First, it mischaracterizes Korolshteyn's claims. As just explained, this lawsuit will not force Defendants to prove *anything*; rather, to prevail in this case, just as in any other labeling case, Korolshteyn must prove, by a preponderance of the evidence, that Defendants' label is false or misleading. This Court's prior ruling in this case already confirmed this very thing. *See Korolshteyn,* 755 Fed. Appx. at 725.

Second, Defendants' argument mischaracterizes what federal substantiation

requires. The District Court incorrectly assumed that the FDCA's substantiation requirement merely "prevent[s] a manufacturer from…making improbable representations *where no competent and reliable scientific evidence exists*." ER011 (emphasis added). It's understandable why Defendants would like such a requirement: a toothless standard like that would give supplement manufacturers free rein to foist all manner of overpriced snake oil on an unsuspecting public, so long as they can persuade one scientist to put his or her name on an industry-financed study.

Fortunately, that's not how the federal substantiation requirement actually works. As Korolshteyn has explained, both the FTC and the FDA Guidances make clear that substantiation under Section 343(r)(6)(B) is evaluated by looking at the *totality* of competent and reliable scientific evidence. Korolshteyn Br. at 31 (citing FDA Guidance at Section II.E.) (emphasis added).[3]

The FDA's Guidance states: "the strength of the *total body of scientific evidence* is the critical factor in assessing whether a claim is substantiated." Korolshteyn RJN Doc. 1 at 15 (emphasis added). Each piece of evidence "should

[3] The FDA Guidance is attached to Korolshteyn's RJN (D.E. 19) as Doc. 1. The FTC's Guidance (on which the FDA Guidance is based, *see* Korolshteyn Br. at 12 & n.6) is attached to Korolshteyn's RJN (D.E. 19) as Doc. 2. The former governs false labeling actions under the FDCA. The latter governs false advertising actions under the Federal Trade Commission Act. *See id.*

be considered in the context of *all available information*[.]" *Id.* And—crucially—"[c]onflicting or inconsistent results raise *serious questions* as to whether a particular claim is substantiated." *Id.* at Section II.E. (emphasis added) (cited in Korolshteyn Br. at 31).

Thus, the District Court erred in finding that a manufacturer satisfies the federal substantiation requirement so long as it has *any* scientific support for its structure/function claim. Defendants' argument that some unidentified amount of substantiation is enough, without reference to the totality of the evidence, is no more convincing than the District Court's approach, because it ignores what the FDA and FTC have actually said substantiation requires.

Equally erroneous is Defendants' suggestion that as long as a manufacturer *claims* to possess adequate "substantiation" for its structure/function claim, it has complied with the FDCA—and thus can't be sued under state law. As explained above, the mere fact that a manufacturer *says* it can substantiate its claim under 21 U.S.C. § 343(r)(6)(B) doesn't mean it actually *can* substantiate its claim: it's just the manufacturer's say-so, because there's no federal preapproval requirement for structure/function claims. Moreover, under the FDCA and FTC Act, both the FDA and the FTC have the authority to investigate whether a manufacturer possesses adequate substantiation that its structure/function claim is neither false nor misleading. *See* 15 U.S.C. §§ 45(b), (m)(1)(A), 53(b); *see also King Bio*, 107 Cal.

App. 4th at 1349. If either agency concludes that adequate substantiation is *lacking*, it can bring a misbranding action against the manufacturer, in which case the burden shifts to the agency to prove that the label is false or misleading. *King Bio*, 107 Cal. App. 4th at 1348; *see also 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…").

Consistent with the federal scheme, Korolshteyn may bring state-law claims against Defendants in which she will bear the burden of proving, by a preponderance of the evidence, that Defendants' label claims are false or misleading based on the totality of the evidence substantiation standard established by the FDA. *See Korolshteyn*, 755 Fed. Appx. 725; *see also Capaci*, 445 F. Supp. 3d at 621 (finding no preemption where "plaintiffs cite multiple studies that indicate that the Product has no effect on the structure and function of the body in that the Product is incapable of 'provid[ing] weight-loss or appetite control benefits in humans'"); *Gallagher*, 2015 WL 1056480, at *7 ("Not preempted would be a claim that 'supports heart health' as a structure/function claim is a false and misleading statement contrary to scientific studies").

Because the liability standards are the same and the evidentiary burden is the same, there is no preemption under 21 U.S.C. § 343-1(a)(5).

D. Korolshteyn's Claims Are Not "No-Substantiation" Claims.

Defendants' argument seems to confuse this case with what have been labeled "lack of substantiation" cases in the wake of *King Bio*. Clarification of what that term means, and why it does not apply here, may be helpful.

In *King Bio*, the California Court of Appeals held that private plaintiffs in a false advertising action under California law may not merely allege that the defendant lacks evidence for its advertising claims. 107 Cal. App. 4th at 1341-42. The court reasoned that, if such a claim were allowed to proceed, plaintiffs would impermissibly shift the burden of proof to defendants to establish that their claims are truthful. *Id*. Instead, the *King Bio* court concluded, plaintiffs bear the burden of proof in a false advertising lawsuit and must come forward with affirmative evidence that the product does not do what it claims to do. *See id.* at 1348 (nothing about the holding prevents future plaintiffs from proving the "falsity of the advertising claims…by testing, scientific literature, or anecdotal evidence").

Cases subject to dismissal under *King Bio* have been called "lack of substantiation" cases. *See Kwan v. SanMedica Int'l*, 854 F.3d 1088, 1094 n.2 (9th Cir. 2017) (citing cases). However, this phraseology may be confusing. There is a distinct difference between an allegation that a defendant has no evidence supporting a claim (impermissible under *King Bio*) and a lawsuit putting forward affirmative evidence that the claim is false or misleading (permissible under *King*

Bio). But "[i]n common usage, we might say that both [types of cases allege that the manufacturer's claims are] 'unsubstantiated….'" *See Eckler v. Wal-Mart Stores, Inc.*, No. 12-CV-727-LAB-MDD, 2012 WL 5382218, at *2-3 (S.D. Cal. Oct. 31, 2012).

For clarity, the *King Bio* lack of substantiation type case is perhaps better categorized as an "absence-of-evidence" case, where the defendant has the burden of proving that its label is neither false nor misleading. This is in contrast to what might be called an "affirmative-evidence" case where—as here—the plaintiff argues that a defendant lacks substantiation based on the *plaintiff's* own showing, based on the totality of the evidence, that a label is false or misleading.

Here, Defendants seem to suggest this is an "absence-of-evidence" case of the type described in *King Bio*, where a plaintiff is improperly seeking to shift the burden onto a defendant to *disprove* the falsity of its label. From that, Defendants seem to argue this suit is preempted because it requires them to show more "substantiation" for their structure/function claim then federal law requires.[4]

[4] This exact argument was recently made and rejected in *Capaci*, for all the reasons set forth in this Reply. *See* 445 F. Supp. 3d at 622; *see also Alvarez v. NBTY, Inc.*, 17-CV-00567-BAS-BGS, 2019 WL 2238632, at *6 (S.D. Cal. May 22, 2019) (holding that plaintiff was not advancing an impermissible lack of substantiation claim where she "produced at least 'debatable evidence demonstrating that the scientific consensus is on [her] side'"); *Brannon v. Barlean's Organic Oils, LLC*, 3:18-CV-01619-BTM-MDD, 2019 WL 4393653, at *3 (S.D. Cal. Sept. 12, 2019) (same).

This argument ignores that this Court has *already* held that that Korolshteyn is *not* seeking to shift the burden to Defendants to substantiate its claim. *See Korolshteyn*, 755 Fed. Appx. at 725. Indeed, as noted *infra* at III., Korolshteyn has produced myriad studies establishing that Ginkgo biloba has no effect. So this is an "affirmative-evidence" case of the type private plaintiffs are allowed to bring under *King Bio*, and there's no substantive difference between *that* kind of suit and a federal misbranding action under the FDCA. *See Capaci*, 445 F. Supp. 2d at 622.

King Bio confirms that fact. There, a private plaintiff tried to convince the court to allow it to bring an "absence-of-evidence" case against an advertiser, which would have shifted the burden of proof to the defendant to prove the truth of its label. In making this argument, the plaintiff "relie[d] on cases arising under the Federal Trade Commission Act (FTC Act)…to argue that federal law shifts the burden of proof to defendants in false advertising actions." *King Bio*, 107 Cal. App. 4th at 1348.[5]

Twice citing the *same* FTC Guidance at issue here (which the FDA Guidance discussed above is based on, *see* Korolshteyn Br. at 12 & n.6), the court *rejected* the plaintiff's argument on the ground that the FTC Act does *not* "shift[ ] the burden of proof to defendants in false advertising actions." 107 Cal. App. 4th at 1348. The

[5] The FTC Act gives the FTC the authority to bring false-advertising claims against dietary supplement manufacturers. 15 U.S.C. §§ 45(a), 52, 53(b).

King Bio court wrote: "Regardless of the level of substantiation required…, *the FTC still bears the burden of proving advertising claims are false or misleading*." *Id*. at 1349 (emphasis added).

"In other words," the court continued, "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*. at 1350 (emphasis added); *see also Dachauer,* 913 F.3d at 847 (discussing *King Bio*).

This is what Korolshteyn has been saying all along—that her claim is no different than a misbranding action alleging false advertising or false labeling under the FDCA. *Id*. *King Bio* confirms this beyond any shadow of a doubt. Because that's so, and because the evidentiary standard of proof is *also* the same in both federal and state cases under the FDCA, Korolshteyn's claims are functionally identical to federal law, and thus not preempted under 21 U.S.C. § 343-1(a)(5).

III. THE WEIGHT TO BE ACCORDED THE PARTIES' RESPECTIVE SCIENTIFIC STUDIES IS A MERITS-BASED DETERMINATION OF NO RELEVANCE TO PREEMPTION.

Korolshteyn agrees with Defendants that preemption "is a threshold legal question," not a factual issue. Defendants' Br. at 24 (citing *Dachauer*, 913 F.3d at 847). It is therefore surprising that Defendants engage in a lengthy discussion of the *factual* evidence presented to the District Court in connection with the first round

of summary judgment briefing in this case. *See id.* at 11-12, 50-55. As Defendants' own argument shows, this evidence is irrelevant to the issues in this appeal. The question here is whether federal law preempts Korolshteyn's claims. This has nothing to do with the quality of the parties' competing studies. Nevertheless, Korolshteyn briefly addresses it here because Defendants grossly mischaracterize the facts.

For example, Defendants contend they have 38 studies supporting TruNature's brain-health claims. *See id.* at 50; ER 203–20. As Korolshteyn explained in her opposition to Defendants' first summary judgment motion, however, Defendants' studies are all irrelevant, critically flawed, and/or support *Korolshteyn's* position, not Defendants'. *See* ER 98-101; ECF 189 at 9-12.[6]

In comparison, Korolshteyn has cited several large, high-quality randomized control trials that "individually and collectively demonstrate that there is *no effect of Ginkgo biloba on the brain health parameters at issue*." ER 213 (emphasis added). For example, Snitz 2009 was a blind, placebo-controlled clinical trial published in

[6] Defendants highlight four "studies" in particular, but—like the other 34—they suffer from serious flaws. For example, Kaschel 2009 (Defendants' Br. at 50) is a review article, not a study. SER 579-604. The FDA has stated that review articles are not "evidence that may substantiate a claim." FDA Guidance at Pt. D. Another example is Mix & Crew (2002) (Defendants' Br. at 50), where, of the 17 outcomes assessed, Ginkgo biloba had no effect in 13. SER 606-16. Mix & Crew is thus a negative study that, but for its poor design, could have been cited by *Korolshteyn's* expert. *See* ER 158-59, 209-10, 216.

the highly regarded *Journal of the American Medical Association*. SER 913-20. It was conducted over a six-year period, included 3,069 subjects (more than all of Defendants' studies combined), and analyzed whether Ginkgo biloba has brain health benefits for healthy persons (*the exact question at issue*). *Id.*; ER 133, 153-–55, 214-20. It concluded that Ginkgo biloba is completely ineffective. SER 914.

In short, Korolshteyn possesses ample evidence that Ginkgo biloba does not support memory function or brain health. As a result, the weight of the evidence will show that the label at issue is both false *and* misleading—and therefore violates both California and federal law.[7]

IV. FINDING PREEMPTION HERE WOULD THREATEN PUBLIC HEALTH AND CONTRAVENE CONGRESSIONAL INTENT.

Defendants also err in arguing that the District Court's decision would not harm public health and is consistent with congressional intent. Defendants' Br. at

[7] Defendants' contention (at 53) that Korolshteyn is impermissibly "relying on studies related to the prevention or treatment of a disease" rests on a mischaracterization of this Court's ruling in *Dachauer*, 913 F.3d 844. *Dachauer* stands for the proposition that a plaintiff cannot establish that a structure/function claim is misleading based *exclusively* on an expert's conclusion that the supplement does not prevent a disease. *Id.* at 848. *Dachauer* did *not* hold that a plaintiff's expert cannot rely *in part* on studies on the prevention or treatment of a disease to reach a conclusion that a supplement does not do what it claims to do (*e.g.*, support brain health). In any event, Korolshteyn's expert does rely on studies looking at healthy persons or those with only mild cognitive decline to determine whether Ginkgo biloba provides the represented brain health benefits. *See* ER132-133, ¶¶ 16, 18, 20, 21.

56-59. Under the District Court's approach (*see* ER011-012), the only claims that escape preemption are those alleging a supplement is affirmatively harmful, as opposed to merely useless. If adopted, that approach would allow deceptive labeling practices and leave consumers uncompensated for their injuries.

Even worse, that approach threatens public health. As the FDA has explained, ineffective dietary supplements may cause consumers to "forgo…early medical attention" or "substitut[e] a dietary product of uncertain value for a medical therapy that has been shown to be safe and effective." 65 Fed. Reg. at 1044-45; RJN Doc. 4. Thus, even useless supplements pose significant risks to consumers. Yet Defendants want to foreclose all state-law remedies.

Congress did not intend such a result. The quoted excerpts from the "findings" section of the Dietary Supplement Health and Education Act ("DSHEA") that Defendants rely upon (*see* Defendants' Br. at 58) were made *before* the substantiation standard at issue, as well as several other provisions intended to protect consumers from false and misleading labeling, were added as an amendment to DSHEA. *Compare* S. 784, 103d Cong. § 6 (as passed by Senate, Aug. 13, 1994), https://bit.ly/32c0JEg, *with* S. 784, 103d Cong. § 6 (as passed House, Oct. 7, 1994), https://bit.ly/3l9RJsh (adding substantiation requirement, disclaimer requirement, and 30-day notice requirement); *see also* Request for Judicial Notice filed herewith.

As Representative Henry Waxman stated in offering that amendment, it

represented a "compromise" that "allow[ed] manufacturers to…make certain statements about supplements if those…*statements are not false and misleading*." 140 Cong. Rec. H28488, 28668 (daily ed. Oct. 6, 1994) (emphasis added), https://bit.ly/2D9Yzwy.[8]

Defendants would no doubt prefer the earlier version of the statute. But the statute Congress actually passed requires supplement manufacturers to tell the truth on their labels. Defendants' contention that Korolshteyn's argument is "more appropriately addressed to the legislative branch than the judicial one" (Br. at 59) has it backwards. It is Defendants' approach to preemption that contravenes congressional intent. It should be rejected.

CONCLUSION

For the foregoing reasons and those stated in Korolshteyn's Opening Brief, the District Court's holding that Korolshteyn's claims are preempted by the FDCA should be reversed.

[8] *See also Regulation of Dietary Supplements*: *Hearing Before the H. Subcommittee on Health and the Environment,* 103rd Cong. 1-2 (July 29, 1993), https://bit.ly/3hXFNaL (statement of Rep. Waxman) ("It is my hope…we can develop an approach…[that] would guarantee the availability of safe dietary supplements *as long as they make no unproven claims*," and noting that "serious charges have been made that the FDA *doesn't adequately police false claims*") (emphases added); Request for Judicial Notice filed herewith.

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Respectfully submitted,

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1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7) because this brief contains 6,494, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

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CERTIFICATE OF SERVICE

I hereby certify that on September 21, 2020, I electronically filed **APPELLANT'S REPLY 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.

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