No. 19-55739

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

TATIANA KOROLSHTEYN,
Plaintiff-Appellant,

v.

COSTCO WHOLESALE CORPORATION and NBTY, INC.,
Defendants-Appellees.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF CALIFORNIA
DISTRICT COURT NO. 3:15-CV-709-CAB-RBB

APPELLEES' ANSWERING BRIEF

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Defendants-Appellees Costco Wholesale Corporation and NBTY, Inc., state as follows:

1. NBTY, Inc., is now known as The Nature's Bounty Co.

2. Neither Costco Wholesale Corporation nor The Nature's Bounty Co. has any parent corporation.

3. No publicly held corporation owns 10% or more of either Costco Wholesale Corporation's or The Nature's Bounty Co.'s stock.

If changes to the foregoing become known during the course of this appeal, Costco Wholesale Corporation and The Nature's Bounty Co. will amend this Corporate Disclosure Statement to bring such additional names to the attention of the Court.

Dated: June 16, 2020

Sidley Austin LLP

/s/ Jean-Claude André
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Attorneys for Defendants-Appellees
Costco Wholesale Corporation and
NBTY, Inc.

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I

INTRODUCTION AND ISSUE PRESENTED

The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, as amended by the Nutritional Labeling and Education Act, 21 U.S.C. §§ 343 *et seq*., expressly preempts any state-law "requirement respecting [certain specified] claim[s] . . . made in the label or labeling of food that is not identical to the requirement of section 343(r)" of the FDCA. 21 U.S.C. § 343-1(a)(5).

Plaintiff Tatiana Korolshteyn's complaint brought state-law challenges to claims on the label of TruNature Ginkgo Biloba with Vinpocetine ("TruNature Ginkgo") that it "supports alertness & memory," "can help 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." Plaintiff challenges these claims on the basis that the product "does not provide the represented mental clarity, memory or alertness benefits."

Under section 343(r)(6), a dietary supplement manufacturer may make a so-called "structure/function" claim on its product—like those on TruNature Ginkgo—that "describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans" or "characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function," if certain conditions are satisfied. 21 U.S.C. § 343(r)(6).

The only "requirement of section 343(r)," 21 U.S.C. § 343-1(a)(5), that this case implicates is section 343(r)(6)(B)'s requirement that "the manufacturer of the dietary supplement *has substantiation* that such [structure/function claims are] truthful and not misleading." But before both the district court and this Court, Plaintiff has (1) advocated for a more-demanding standard bordering on scientific consensus that is "not identical to the [substantiation] requirement of section 343(r)" and (2) argued that, under that standard, the six studies that she presented to the district court purportedly showing that ginkgo is useless were sufficient to overcome the *dozens* of studies presented by Defendants showing that ginkgo has a wide range of cognitive benefits.

The question presented here is:

Whether the district court correctly decided, as a matter of law, that TruNature Ginkgo's label claims were substantiated and that Plaintiff's state-law challenges were therefore preempted under the FDCA.

II

STATEMENT OF THE CASE

A. Jurisdiction and Timeliness

The district court's jurisdiction rested on 28 U.S.C. § 1332(d)(2). This Court's jurisdiction rests on 28 U.S.C. § 1291.

The district court granted summary judgment for Defendants on June 25, 2019 (*see* ER 6-13)[1] and entered judgment on June 26, 2019 (*see* ER 5). Plaintiff filed an amended notice of appeal on July 2, 2019. (*See* ER 1-4.) The notice was timely. *See* Fed. R. App. P. 4(a)(1)(A).

B. Background

1. The FDCA, NLEA, and DSHEA

In passing the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, Congress charged the Food and Drug Administration ("FDA") with "protect[ing] the public health" by

[1] "ER" refers to the Excerpts of Record filed by Appellant, "AOB" to Appellant's Opening Brief, and "SER" to the Supplemental Excerpts of Record filed by Defendants contemporaneously with this brief. Each such reference is followed by the applicable page reference. "MJN Ex." refers to the exhibits attached to Appellant's Motion to Take Judicial Notice, followed by the applicable exhibit number and a reference to the page number generated by this Court's CM/ECF system (because some of the exhibits do not have internal page references).

ensuring that "foods are safe, wholesome, sanitary, and properly labeled." 21 U.S.C. § 393(b)(2)(A). In 1990, Congress amended the FDCA with the Nutrition Labeling and Education Act ("NLEA"), Pub. L. No. 101-535, 104 Stat. 2353 (1990), which established new requirements governing the labeling of food and dietary supplements. *See* 21 U.S.C. § 321(ff) ("a dietary supplement shall be deemed to be a food within the meaning of this chapter"). In 1994, Congress amended the FDCA yet again when it enacted the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), Pub. L. No. 103-417, 108 Stat. 4325 (1994), which provides the FDA with regulatory authority over dietary supplements.[2] Congress explicitly found in the text of DSHEA that, because "dietary supplements are safe within a broad range of intake" and "the benefits of [supplements] in health promotion and disease prevention have been documented increasingly in scientific

[2] Defendants agree with Plaintiff (AOB 12) that the FTC generally regulates the *advertising* of dietary supplements, while the FDA generally regulates the *labeling* of dietary supplements. *See, e.g.,* https://www.consumer.ftc.gov/blog/2017/07/dietary-supplement-concerns-tell-ftc-and-fda.

studies," consumers "should be empowered to make choices" about taking them. DSHEA § 2, 108 Stat. at 4325-26.

DSHEA implemented two fundamental shifts in dietary supplement regulation. First, DSHEA exempted "dietary supplements" from either FDA drug approval or FDA food additive approval, finding both processes overly burdensome. 21 U.S.C. § 321(g)(1). Second, DSHEA expressly permitted dietary supplement "structure/function claims," defined as statements "describ[ing] the role of a nutrient or dietary ingredient intended to affect the structure or function in humans [or] characteriz[ing] the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function."[3] 21 U.S.C. § 343(r)(6)(A).

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[3] "The FDA has published guidance in the Federal Register discussing, among other things, acceptable structure/function claims." *Dachauer v. NBTY, Inc.*, 913 F.3d 844, 847 (9th Cir. 2019) (citing Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 65 Fed. Reg. 1000 (Jan. 6, 2000)). This "guidance" document is referred to throughout this brief as the "Final Rule" because it includes the Final Rule issued by the FDA following public notice and comment. *See* 65 Fed. Reg. at 1000 (describing rulemaking history).

The FDA subsequently issued a guidance memorandum entitled *Guidance for Industry: Substantiation for Dietary Supplement Claims*

Rather than requiring the stringent standard of "significant scientific agreement" required for other types of food and supplement claims,[4] Congress chose to require a different, more-flexible, and less-stringent standard for structure/function claims. Congress provided that such a structure/function claim "may be made" if, among other things not implicated by Plaintiff's causes of action, "the dietary supplement manufacturer has *substantiation* that such statement is

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Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (Jan. 2009), http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm073200.htm, which is referred to throughout this brief as "FDA Guidance" and is attached as Exhibit 1 to Plaintiff's Motion for Judicial Notice.

[4] For both foods and dietary supplements, the NLEA first allowed "health claims," defined as any claim "made in the label or labeling of [a] food[, including a dietary supplement,] which expressly or by implication . . . characterizes the relationship of any nutrient . . . to a disease or a health-related condition." NLEA § 3(a), 104 Stat. at 2357; *see also* 21 C.F.R. § 101.14(a)(1). For such claims, Congress not only required FDA pre-approval, but also provided that the FDA must apply a substantiation standard of "significant scientific agreement." Under this standard, "the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles)" must show "that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence." NLEA § 3(a), 104 Stat. at 2359; 21 C.F.R. § 101.14(c).

truthful and not misleading,"[5] 21 U.S.C. § 343(r)(6)(B) (emphasis added), which the FDA has since defined as "competent and reliable scientific evidence" ("CARSE") consisting of "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.'" FDA Guidance, MJN Ex. 1, at 12.[6]

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[5] The two other preconditions to a dietary supplement making a structure/function claim are that the product "contains a prominent disclaimer that the Food and Drug Administration ("FDA") has not evaluated the statement and that the product 'is not intended to diagnose, treat, cure, or prevent any disease'; and . . . the statement itself does not 'claim to diagnose, mitigate, treat, cure, or prevent' disease." *Dachauer,* 913 F.3d at 846-47 (quoting 21 U.S.C. § 343(r)(6)).

Neither of those requirements is implicated here because Plaintiff has not disputed that TruNature Ginkgo contains section 343(r)(6)'s required disclaimer, which appears prominently on the product's packaging. (*See* SER 849, 851, 853, 855, 857.) And Plaintiff expressly concedes in her opening brief that "this lawsuit does *not* challenge the structure/function brain health claim . . . on the ground that the Product fails to prevent a particular disease." (AOB 25; *accord id.* at 41-42.)

[6] In actuality, the FTC first coined the CARSE standard, *see* FTC, *Dietary Supplements: An Advertising Guide for Industry*, at 3 (issued April 2001), http://business.ftc.gov/documents/bus09-dietary-

2. Plaintiff, Her Purchase, and Her Class-Action Complaint

Defendant Costco Wholesale Corporation sells TruNature Ginkgo, which is manufactured by Defendant The Nature's Bounty Co.[7] The product label contains various structure/function claims, including that ginkgo "supports alertness & memory," "works as an antioxidant," "can help with mental clarity and memory," and "also helps maintain healthy blood flow to the brain to assist mental clarity and memory, especially occasional mild memory problems associated with aging." (SER 848-57.) The label also contains the above-referenced section 343(r) disclaimer that the product's claims "have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease." (*Id.*)

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supplements-advertising-guide-industry/ (MJN Ex. 2 ("FTC Guidance")), and the FDA subsequently adopted it, *see* FDA Guidance, MJN Ex. 1, at 12.

[7] When the lawsuit commenced, Defendant The Nature's Bounty Co. was known as NBTY, Inc.

Plaintiff Tatiana Korolshteyn purchased TruNature Ginkgo at her local Costco. (SER 871-72.) She took the supplement a few times and, then, based on advice from a lawyer-friend that ginkgo did not work (SER 878-79, 886-94), filed this lawsuit on behalf of herself and all other similarly situated consumers alleging that the label claims were false,[8] in violation of (1) California's unfair competition law ("UCL"),

[8] Although Plaintiff characterizes her claims as being that Defendants' label is "false *and misleading*" (e.g., AOB at 1, 16 (emphasis added)), at no point has Plaintiff ever alleged what is necessary to advance a "misleading" claim under California law: that TruNature Ginkgo's label, *while true,* nonetheless created an impression or communicated a message *beyond* what the label stated. *See, e.g., Kasky v. Nike, Inc.*, 27 Cal. 4th 939, 951 (2002) (noting that the UCL and CLRA prohibit both "advertising which is false, [and] also advertising which although true, is either actually misleading or which has the capacity, likelihood or tendency to deceive or confuse the public." (citation omitted)). Rather, Plaintiff has always pursued the theory that the words on TruNature Ginkgo's label were false on their face—promising memory support without science to support that claim. For this reason, the district court concluded that Plaintiff was not pursuing a misleading claim but instead simply alleging falsity. (*See* ER 74 ("Although the TAC alleges and Plaintiff argues on summary judgment that the Label Claims are 'false and misleading,' she is really alleging and arguing that the Label Claims are misleading *because they are false*."); *see also* ER 7 ("Plaintiff Tatiana Korolshteyn alleges she bought a bottle of TruNature Gingko based on the allegedly *false* representations on the product label.") (emphasis added)).). Defendants accordingly focus here, as the district court did, on Plaintiff's allegation of "falsity."

California Business & Professions Code § 17200 *et seq.*; and (2) California's Consumer Legal Remedies Act ("CLRA"), California Civil Code § 1750 *et seq*. (ER 324-340.)[9]

3. The Parties' Competing Experts

To support her allegations that TruNature Ginkgo "does not provide the represented mental clarity, memory or alertness benefits" (ER 325), Plaintiff offered the expert opinion of Dr. Richard Bazinet (ER 126-47 (report), 202-52 (rebuttal report)).[10] Although TruNature Ginkgo's label expressly disclaimed the treatment of diseases and never promised to improve memory, five of the six studies on which Bazinet based his opinion researched whether ginkgo can prevent dementia or Alzheimer's disease or improve memory:

- S. DeKosky et al., *Ginkgo biloba for Prevention of Dementia: A randomized Controlled Trial*, JAMA (2008) 300(19): 2253-62 (SER 901-11.)

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[9] ER 324-40 is Plaintiff's Third Amended Complaint—the complaint that was operative when the district court granted summary judgment.

[10] Plaintiff also offered the expert opinion of Dr. Martin Lee, a biostatistician. (ER 150-201 (report).) But his opinion was expressly limited to the statistical methods employed in the studies on which Dr. Bazinet relied, did not evaluate any studies substantively, and is thus irrelevant to the issue on appeal. (*See* SER 144.)

- M. van Dongen et al., *The Efficacy of Ginkgo for Elderly People with Dementia and Age-Associated MemoryImpairment: New Results of a Randomized Clinical Trial*, J. Am. Geriatrics Society (2000) 48: 1183-89 (SER 932-43.)

- B. Vellas et al., *Long-term use of standardised Ginkgo biloba extract for the prevention of Alzheimer's disease (GuidAge): a randomized placebo-controlled trial*, Lancet Neurol (2012) 11: 851-59 (SER 922-30.)

- P. Solomon et al., *Ginkgo for Memory Enhancement: A Randomized Controlled Trial*, JAMA (2002) 288(7): 835-40 (SER 953-58.)

- K. Laws et al. *Is Ginkgo biloba a cognitive enhancer in healthy individuals? A meta-analysis*, Human Psychopharmacology (2012) 27: 527-33 (SER 945-51.)

And as Defendants explained to the district court, the one study that could arguably be relevant to Defendants' claims regarding ginkgo's ability to "support" certain cognitive functions—B. Snitz et al. *Ginkgo biloba for Preventing Cognitive Decline in Older Adults: A Randomized Trial*, JAMA (2009) 302(24): 2663-70 (SER 913-20)—was "unreliable" because, among other things, it did not include a per-protocol analysis but instead only an Intent-To-Treat ("ITT") analysis in which nearly 40% of the subjects in the "ginkgo group" were *not* following their treatment regimen (i.e., *not* actually taking ginkgo as

told).[11] (*See* SER 151.)

For their part, Defendants submitted to the district court "over two dozen studies"—38, in fact—"concluding ginkgo has a wide range of benefits to both healthy and cognitively impaired individuals, including supporting mental performance and memory and treating cognitive impairment, dementia, headaches, tinnitus, and peripheral arterial disease." (ER 271.)

4. The District Court's Original Summary Judgment Ruling

Relying on a then-growing body of case law recognizing that studies both in support of, and casting doubt on, a product's efficacy will not suffice to prove falsity, defendants moved for summary judgment. (ER 272, 278-80, 282-84.) The district court agreed: "if the evidence as to an advertising claim is equivocal, as would be the case if reasonable experts offer contradictory opinions on the truth or falsity of statements, a plaintiff cannot prove the falsity of the statements." (ER

[11] The Snitz study suffered from numerous other methodological flaws discussed at note 25, *infra*.

71 n.2; *see also generally* ER 68-76, 87-89.) Defendants were therefore "entitled to summary judgment."[12] (ER 89.)

Plaintiff appealed to this Court, and while that appeal was pending, this Court decided *Sonner v. Schwabe North America, Inc.*, 911 F.3d 989 (9th Cir. 2018) (per curiam)—another dietary supplement false advertising case brought under the UCL and CLRA. There, this Court rejected the notion that a plaintiff opposing a typical summary judgment motion "must not only produce affirmative evidence, but also fatally undermine the defendant's evidence." *See id.* at 993. Rather, to defeat such a summary judgment motion, the plaintiff "need only

[12] The district court also denied the parties' motions to exclude the other side's experts. (ER 77-86). Specifically, the district court denied Plaintiff's motion to exclude defense experts Susan Mitmesser and Edward Rosick after engaging in a thorough evaluation of the studies on which their opinions relied (ER 80-86) and concluding that their "reasoning is valid," "sufficiently reliable[,] and relevant to the issue of whether Plaintiff can prove that the Label Claims are false" (ER 83, 86). The district court denied Plaintiff's motion to exclude defense expert Stephen Ogenstad and Defendants' motion to exclude Richard Bazinet and Martin Lee "as moot" because the court found that Defendants were "entitled to summary judgment regardless of the admissibility" of their opinions. (ER 86.)

produce evidence of a genuine dispute of material fact that could satisfy the preponderance of the evidence standard at trial." *Id.* at 992.

Shortly thereafter, "[b]ased on the recently released opinion" in *Sonner*, this Court reversed the district court's original grant of summary judgment for Defendants and remanded. *Korolshteyn v. Costco Wholesale Corp.*, 755 F. App'x. 725, 726 (9th Cir. 2019).[13]

5. FDCA Preemption and the Summary Judgment Ruling Now Before This Court

On remand, Defendants again moved for summary judgment, but this time based on, among other things, the express preemption provision of the NLEA, 21 U.S.C. §§ 343-1(a)(5), as interpreted by this Court's intervening decision in *Dachauer v. NBTY, Inc.*, 913 F.3d 844 (9th Cir. 2019). (ER 61-63.)

a. The FDCA's Express Preemption Provision

In addition to the new requirements governing the labeling of food and dietary supplements discussed above (*see* pp. 4-8, *supra*), the NLEA amended the FDCA to "expressly preempt[] any state law that

[13] This Court affirmed the district court's denial of Plaintiff's *Daubert* motions and admission of the testimony of Defendants' expert witnesses. *Korolshteyn*, 755 F. App'x. at 726; *see* note 12, *supra*.

establishes '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.'" *Dachauer*, 913 F.3d at 847 (quoting 21 U.S.C. § 343-1(a)(5)); *accord* 21 U.S.C. § 343-1(a)(4). The phrase "not identical" 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 . . . , or [d]iffer from those specifically imposed by or contained in the applicable provision (including any implementing regulation) . . . of the act." 21 C.F.R. § 100.1(c)(4).

Although section 343(r) contains numerous requirements for the labeling of different kinds of food (many of which apply to dietary supplements), the only requirement implicated by Plaintiff's causes of action (as discussed above) is section 343(r)(6)(B)'s requirement that Defendants have "substantiation" that TruNature Ginkgo's structure/function claims are "truthful and not misleading." *Dachauer,* 913 F.3d at 846-47 (quoting 21 U.S.C. § 343(r)(6)). If Defendants satisfy that requirement, then Plaintiff's causes of action are preempted.

b. The District Court's Finding that Plaintiff's Causes of Action Were Preempted

The district court found Plaintiff's causes of action preempted. The court noted that "Defendants' Label Claims are permissible structure/function claims pursuant to the FDA's guidance . . . [,] meet all the federal labeling requirements," and Plaintiff "agrees that such statements are permissible structure/function claims." (ER 10-11.) This was so because "Defendants' Label Claims do not suggest disease prevention or treatment and use acceptable general terms to represent that the product 'supports alertness & memory,' that 'Gingko biloba can help with mental clarity and memory,' and that '[i]t also helps maintain healthy blood flow to the brain to assist mental clarity and memory, especially occasional mild memory problems associated with aging.'" (*Id.* (quoting ER 325).)

The court acknowledged that "both parties offered scientific evidence supporting and contradicting" the accuracy of those claims. (ER 11.) The court also recognized that, outside of the preemption context, such conflicting scientific evidence ordinarily would "create[] a genuine dispute of material fact for the fact-finder." (ER 11 (citing *Sonner*, 911 F.3d at 992).) But, the court reasoned, "this does not

foreclose a finding that Plaintiff's claims are preempted under the NLEA and the Court must first address the issue of preemption." (*Id.*)

With respect to section 343(r)'s various requirements, the court acknowledged that the only one that required discussion was "the first requirement" of section 343(r)(6)—namely, "that the manufacturer has substantiation that the statement is truthful and not misleading." (*Id.*) The court explained that, according to "FDA guidance," what will constitute sufficient substantiation is "competent and reliable scientific evidence" that supports the claim and prevents a manufacturer from "making improbable representations" about its product's efficacy. (ER 10-11.)

The court found that Defendants had such substantiation because, as the court acknowledged, it had previously denied Plaintiff's motion to exclude Defendants' experts, and "the Ninth Circuit . . . affirmed" *that* ruling. (ER 11; *see also* note 13, *supra*.) In that prior ruling, the court engaged in a thorough evaluation of the studies on which defense experts Susan Mitmesser and Edward Rosick had relied (ER 80-86) and concluded that their "reasoning is valid," "sufficiently reliable[,] and relevant to the issue of whether Plaintiff can prove that the Label

Claims are false" (ER 83, 86). The court credited 10 studies in particular "where the authors conclude that Ginkgo biloba had positive effects in ways that support the Label Claims." (ER 80-82, 85-86 (citing and discussing studies).)

To the extent that Plaintiff continued to maintain that her causes of action were nonetheless not preempted because "it is still incumbent upon the manufacturer to ensure that [its label] statements are not false and misleading" under a supposed general prohibition on "false or misleading" labeling, the court was "not persuaded by Plaintiff's mischaracterization of the federal requirements." (ER 11.)

The court acknowledged that certain causes of action for "false or misleading" labeling may not be preempted, such as the example that this Court gave in *Dachauer*. (ER 11-12 (discussing *Dachauer*, 913 F.3d at 844, 849).) That example involved a plaintiff's challenge to a structure/function claim that certain supplements "promote immune health." *Dachauer*, 913 F.3d at 848. This Court held that the plaintiff's challenge was not preempted because, even if substantiated as to some classes of consumers, the claim did not warn of the potential for increased risk of all-cause mortality in others, which could violate the

federal requirement that food labels disclose "'[m]aterial with respect to consequences which may result from use of the article' under normal conditions of use or the conditions of use that the label prescribes." *Id.* at 848-49 (quoting 21 C.F.R. § 1.21(a)(2)).

Here, Plaintiff made no such claim. Instead, Plaintiff sought to "upend" section 343(r)(6)'s substantiation requirement with a "requirement[] under California law that either alters or adds to the requirement that the manufacturer has substantiation that [its] structure/function claims are truthful and not misleading." (ER 12-13.) "Such requirements would directly or indirectly impose obligations or contain provisions not identical to the federal requirements," the court concluded, and are therefore preempted. (*Id.*)

This appeal followed.

III

SUMMARY OF ARGUMENT

The FDCA expressly preempts any state-law "requirement respecting [certain specified] claim[s] . . . made in the label or labeling of [dietary supplements] that is not identical to the requirement of section 343(r)" of the FDCA. 21 U.S.C. § 343-1(a)(5). The district court,

which was required to resolve the preemption question as a matter of law notwithstanding the parties' competing studies about ginkgo biloba's efficacy, properly found Plaintiff's state-law causes of action preempted by section 343-1(a)(5).

As a threshold matter, Plaintiff's repeated suggestion that the preemption question was one for a jury is wrong. The Supreme Court's recent decision in *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1676, 1680 (2019), makes clear that "a judge, not the jury, must decide the pre-emption question" and do so even if the issue presents "contested brute facts."

With respect to the merits, the district court first properly rejected Plaintiff's attempt to disregard the specific requirement of section 343(r) that a dietary supplement manufacturer "*has substantiation* that such [a structure/function] statement is truthful and not misleading" and create a different standard. The plain text of the NLEA's preemption provision requires compliance with section 343(r)(6)(B)'s substantiation requirement—not the general "false and misleading" prohibition found in section 343(a)(1). Additionally, section 343(r)(6)(B)'s substantiation requirement cannot be construed to mean

the same thing as section 343(a)(1)'s general requirement because doing so would render "has substantiation" superfluous. Similarly, under a long-standing rule of interpretation favoring the specific over the general, any conflict between the two provisions must be resolved in favor of section 343(r)(6)(B)'s specific requirement for structure/function claims over section 343(a)(1)'s general requirement for any food. Nor can the FDA's Final Rule supply the extra-textual requirement that Plaintiff seeks because the agency had no occasion to promulgate such a rule during its rulemaking and, in light of Congress's clear text, would not have had the authority to do so in any event.

Contrary to Plaintiff's assertion on appeal, the district court did not misapply the applicable standard for substantiation. Although Plaintiff insists that the district court failed to consider the "totality of the evidence" in evaluating the parties' competing studies, the court in fact discussed the "competent and reliable evidence" standard—of which the "totality of the evidence" is but one factor—three times in its eight-page order. Additionally, the district court was well-familiar with the parties' competing scientific studies from Defendants' initial summary judgment motion and the parties' competing *Daubert* motions, had

specifically credited 10 of the 38 studies that Defendants had submitted, and specifically cross-referenced its prior ruling in the summary judgment order now under this Court's review. Accordingly, the record directly refutes Plaintiff's assertion that the district court erroneously applied a "warm body" and/or "one-study-is-enough" standard when it determined that Defendants had sufficient substantiation for TruNature Ginkgo's claims.

Finally, the scientific record fully supports the district court's substantiation finding. Not only did Defendants submit 38 studies supportive of TruNature Ginkgo's claims, many of those studies are beyond reproach—including at least four of the ten that the district court credited. In contrast, Plaintiff supported her challenge to TruNature Ginkgo's claims with only six studies. Moreover, this Court's decision in *Dachauer v. NBTY, Inc.*, 913 F.3d 844 (9th Cir. 2019), prohibits Plaintiff from relying on five of them as a matter of law because they studied disease prevention and/or evaluated claims that TruNature Ginkgo's label does not make, and the sixth, remaining study was significantly methodologically flawed.

The district court's order granting Defendants summary judgment should be affirmed.

IV

ARGUMENT

A. Standard of Review

The grant of summary judgment is reviewed *de novo*, *see Branch Banking & Tr. Co. v. D.M.S.I., LLC*, 871 F.3d 751, 759 (9th Cir. 2017), "as are questions of preemption," *Silvas v. E*Trade Mortg. Corp.*, 514 F.3d 1001, 1004 (9th Cir. 2008).

B. The District Court Properly Found Plaintiff's Causes of Action Preempted

1. Defendants' Preemption Defense Was Properly One for the Court

As a threshold matter, Plaintiff repeatedly asserts that, in deciding the preemption issue, the district court "erred in concluding as a matter of law that Defendants have 'competent and reliable' evidence to support their brain health claims because . . . . whether the testimony is competent and reliable is for the jury, not the District Court, to decide" (AOB 36) and the court thus did "what this Court previously held could not result in summary judgment" (AOB 5 (citing *Sonner*, 911 F.3d at 992); *see also id.* at 33-34, 37.) Plaintiff is incorrect.

Preemption "is a threshold legal question." *Dachauer*, 913 F.3d at 847 (deciding issue, even though district court did not reach it, because it was raised below and a threshold legal issue). As such, as the Supreme Court recently clarified, "a judge, not the jury, must decide the pre-emption question." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1676 (2019) (addressing FDCA preemption); *see also id.* at 1680 ("In this context, . . . the 'better positioned' decisionmaker is the judge."). This was so, the Court explained, notwithstanding that the court may have to resolve certain "contested brute facts."[14] *Id.* at 1680. In the preemption context, "we consider these factual questions to be subsumed within an already tightly circumscribed legal analysis. And we do not believe that they warrant submission alone or together with the larger pre-emption question to a jury."[15] *Id.*

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[14] The Court cited so-called "*Markman* hearings" over the proper construction of a patent claim as an example of another context in which it has "determined that the question is 'for the judge and not the jury,'" *Albrecht*, 139 S. Ct. at 1680 (quoting *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 378 (1996)), even though claim construction has "evidentiary underpinnings" and may involve "credibility judgments" about witnesses, *Markman*, 517 U.S. at 389-90.

[15] That the Court would so hold makes sense because preemption is like other threshold "issues of 'judicial traffic control'"—such as

Contrary to Plaintiff's assertion, neither *Sonner* nor this Court's prior decision in this case compels a contrary conclusion. (AOB 5, 36-37.) Neither case held (either as law of the Circuit in the published *Sonner* decision or as law of the case in the unpublished earlier decision in this case) that disputed factual questions underlying a preemption determination must go to a jury.[16] Neither case so held because in neither case had the defendants moved for summary judgment based on FDCA preemption. *Albrecht*, however, did address that issue in the setting of FDCA preemption and held that "'subsidiary factual disputes' that are part and parcel of the broader [preemption] question" must be

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subject-matter jurisdiction, personal jurisdiction, venue, forum non-conveniens, abstention, and exhaustion—where a "a judge rather than a jury decides disputed factual questions." *Albino v. Baca*, 747 F.3d 1162, 1170 (9th Cir. 2014) (discussing various contexts in which the judge decides disputed factual questions) (citation omitted).

[16] Lest there be any doubt, *Sonner* repeatedly cited *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986), and *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986)—two of the trilogy of cases decided by the Supreme Court in 1986 to clarify the standards for ordinary summary judgment motions.

decided by the judge.[17] *Albrecht*, 139 S. Ct. at 1680. Accordingly, the district court was correct to "first address the issue of preemption" and resolve it as a matter of law. (ER 11.)

2. There Is No "Presumption Against Preemption"

Perhaps recognizing the weakness of her attack on the district court, Plaintiff begins by arguing for the first time here on appeal that "there is a strong presumption against preemption" that "applies with

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[17] Since *Albrecht*, the lower courts have consistently heeded its instruction to resolve preemption issues as a matter of law. *See, e.g.*, *Yamagata v. Reckitt Benckiser LLC*, No. 17-CV-03529-VC, --- F.Supp.3d ---, 2020 WL 1505724, at *2 (N.D. Cal. Mar. 30, 2020) (following *Albrecht* to find that whether challenges to structure/function claims on a glucosamine supplement were preempted "is a question of law, and so it's for the Court to decide fully on summary judgment, even if the resolution of a factual dispute is involved"); *Ridings v. Maurice*, No. 15-00020-CV-W-JTM, --- F.Supp.3d ---, 2020 WL 1264178, at *3 (W.D. Mo. Mar. 16, 2020) (the court—"and not a jury—would need to be the factfinder on the potentially dispositive question of whether [the defendant]'s affirmative defense of preemption could be established so as to bar [the plaintiffs'] state law failure-to-warn claims"); *In re Zofran (Ondansetron) Prod. Liab. Litig.*, No. 1:15-MD-2657-FDS, 2020 WL 1816351, at *1 (D. Mass. Jan. 7, 2020) (discussing grant of permission to file renewed motion for summary judgment post-*Albrecht* despite earlier finding that "that there were disputed issues of material fact precluding" preemption finding); *Risperdal & Invega Cases*, No. B284002, --- Cal. Rtpr. 3d ---, 2020 WL 2896715, at *6 (Cal. Ct. App. May 8, 2020) ("the trial court was correct to decide" the issue whether failure-to-warn claims were preempted by FDA regulations "without submitting any purported underlying factual questions to a jury").

. . . particular force . . . because consumer protection laws, such as the UCL and CLRA, are within California's historic police powers." (AOB 26-27, *see also id.* at 22.) Contrary to what Plaintiff would have this Court believe, there is no presumption against preemption—let alone, a "strong" one—in express preemption cases like this.

In 2016, the Supreme Court clarified that no presumption against preemption applies where, as here, the federal statute in question contains an express preemption clause. *See Puerto Rico v. Franklin California Tax-Free Tr.*, 136 S. Ct. 1938, 1946 (2016) ("[B]ecause the statute 'contains an express pre-emption clause,' we do not invoke any presumption against pre-emption but instead 'focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent.'").

In post-*Puerto Rico* decisions, this Court properly recognized *Puerto Rico*'s controlling rule and has appropriately rejected the application of such a presumption in express preemption cases. *See Lusnak v. Bank of Am., N.A.*, 883 F.3d 1185, 1191 (9th Cir.), *cert. denied*, 139 S. Ct. 567 (2018) (holding "there is no presumption against preemption" in context of Dodd-Frank Wall Street Reform and

Consumer Protection Act because it expressly provides that "state laws are preempted if they 'prevent[ ] or significantly interfere[ ] with the exercise by the national bank of its powers'"); *Atay v. County of Maui*, 842 F.3d 688, 699 (9th Cir. 2016) (no presumption against preemption in express preemption cases); *cf. Berezovsky v. Moniz*, 869 F.3d 923, 930 (9th Cir. 2017) (recognizing that "[t]he presumption against preemption is rebutted. . . . through an express preemption clause" and observing that Federal Foreclosure Bar provision of the Housing and Economic Recovery Act did not have one). So too have the majority of other circuits interpreting *Puerto Rico*. *See Dialysis Newco, Inc. v. Cmty. Health Sys. Grp. Health Plan*, 938 F.3d 246, 258-59 (5th Cir. 2019) (no presumption against preemption in express preemption cases); *Air Evac EMS, Inc. v. Cheatham*, 910 F.3d 751, 762 n.1 (4th Cir. 2018) (same); *Watson v. Air Methods Corp.*, 870 F.3d 812, 817 (8th Cir. 2017) (same); *EagleMed LLC v. Cox*, 868 F.3d 893, 903-04 (10th Cir. 2017) (same). The only outlier is the Third Circuit, which declined to apply *Puerto*

Rico in a few lines in a footnote. *See Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 771 n.9 (3d Cir. 2018).[18]

Plaintiff relies on a single post-*Puerto Rico* decision, *Durnford v. MusclePharm Corp.*, 907 F.3d 595 (9th Cir. 2018), to argue in favor of an anti-preemption presumption. But *Durnford* relied on only pre-*Puerto Rico* precedent, *see* 907 F.3d at 601 (citing *Wyeth v. Levine*, 555 U.S. 555, 565 & n.3 (2009); *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 334-35 (3d Cir. 2009)), had no authority to contravene *Puerto Rico*, and likely overlooked it because the defendant in that case did not cite it—let alone address the plaintiff's presumption argument at all, *see* Appellee's Br. at 14-28, *Durnford v. MusclePharm Corp.* (No. 16-15374) (9th Cir. filed Dec. 2, 2016), *available at* 2016 WL 7046879.

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[18] In *Shuker*, the Third Circuit sought to limit *Puerto Rico*'s holding to cases not invoking the traditional police powers of the states. *See id.* But *Puerto Rico* contains no such limitation, and other circuits have rejected similar attempts to read *Puerto Rico* so narrowly. *See, e.g.*, *Dialysis Newco*, 938 F.3d at 258 (rejecting argument that courts should "not read [*Puerto Rico*] broadly" because it applies only in bankruptcy cases). Moreover, *Shuker* misses the thrust of *Puerto Rico*'s anti-presumption holding. The Supreme Court eschewed the presumption "*because* the statute 'contains an express pre-emption clause,'" which is "the best evidence of Congress's pre-emptive intent." *Puerto Rico*, 136 S. Ct. at 1946. That reasoning has nothing to do with whether the statute in question involves traditional police powers.

Even if a presumption against preemption did apply, it would not change the outcome here, where the preemption provision at issue in this case is as clear as they come. *See* 21 U.S.C. § 343-1(a)(5) ("[N]o State . . . may directly or indirectly establish under any authority or continue in effect . . . 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"); NLEA § 6(c)(1), 104 Stat. at 2364 (codified at 21 U.S.C. § 343-1 note) ("The [NLEA] shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [section 343-1]."). That clarity would assuredly rebut any presumption even if one were applicable.

3. The District Court Properly Rejected Plaintiff's Attempt to Impose a Requirement Not Found in Section 343(r)

The crux of Plaintiff's challenge to the district court's grant of summary judgment is that her causes of action are not preempted because "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." (AOB 6-7

(Plaintiff's "Statement of the Issues").) Plaintiff's briefing, however, 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.

In her "Statutory Framework" section, Plaintiff asserts that, in addition to section 343(r)(6)'s substantiation requirement, a structure/function claim must "[f]urther" "comply with the FDCA's general prohibition on 'false or misleading' labeling" and cites section 343(a)(1). (AOB 10; *see also id.* at 29.) And in the section discussing the "FDA's Regulations Governing Structure/Function Claims," she quotes the Final Rule's recitation of section 343(r)(6)(B)'s substantiation requirement and then characterizes it "[i]n other words" as requiring that "the statement must not be false." (AOB 11 (quoting 65 Fed. Reg. at 1001).)

But regardless of from where Plaintiff derives it, Congress has rejected her desired standard. Congress in DSHEA expressly eschewed the "significant scientific agreement" standard required for drugs (which, even then, is not as demanding as the standard that Plaintiff seeks to impose) and noticeably did not condition a manufacturer's

ability to make a structure/function claim on section 343(a)(1)'s "general prohibition" on "'false or misleading'" labeling. (AOB 10.) Rather, Congress conditioned a manufacturer's ability to make a structure/function claim on the requirement that "the manufacturer of the dietary supplement *has substantiation* that such statement is truthful and not misleading." 21 U.S.C. § 343(r)(6) (emphases added). And it is compliance with *that* section 343(r) requirement—not compliance with a higher standard divined from section 343(a)(1) or the Final Rule—that triggers NLEA preemption. The district court was therefore correct to "not [be] persuaded by Plaintiff's mischaracterization of the federal requirements." (ER 11.)

a. Settled Principles of Statutory Construction Preclude Plaintiff's Attempt to Impose a Statutory Requirement Not Found in Section 343(r)

Section 343(a)(1) of the FDCA, which pertains to food labeling generally, states that food labels cannot be "false or misleading." As set forth above, the NLEA's express preemption provision is triggered by compliance with "the requirement[s] of section 343(r)." 21 U.S.C. § 343-1(a)(5). Although subsection (r) contains various provisions specifying when a food will be deemed misbranded and what is required to be on a

food's labeling, the only subsection (r) requirement implicated by Plaintiff's causes of action is the specification in paragraph (r)(6)(B) that a structure/function claim "*may be made* if . . . the manufacturer of the dietary supplement *has substantiation* that such statement is truthful and not misleading." 21 U.S.C. § 343(r)(6) (emphases added).

i. The FDCA's Plain Language Requires Only "Substantiation"

"It is well established that 'when the statute's language is plain, the sole function of the courts—at least where the disposition required by the text is not absurd—is to enforce it according to its terms.'" *United States v. Lillard*, 935 F.3d 827, 836 (9th Cir. 2019) (quoting *Lamie v. U.S. Tr.*, 540 U.S. 526, 534 (2004)). Here, the text of the NLEA's preemption provision is clear that preemption will be triggered if a dietary supplement satisfies subsection (r)'s requirements. *See Yamagata v. Reckitt Benckiser LLC*, No. 17-CV-03529-VC, 2020 WL 1505724, at *2 n.2 (N.D. Cal. Mar. 30, 2020) ("The absolute prohibition on false or misleading statements that plaintiffs point to appears in section 343(a), not section 343(r). . . . Accordingly, the plaintiffs may not rely on the more demanding requirements of section 343(a) to sustain claims attacking the truthfulness of structure/function

statements."). Noticeably absent from § 343-1(a)(5)'s preemption provision is any reference to section 343(a)(1)'s general prohibition or any other requirement that a structure/function claim satisfy any standard beyond "substantiation." This Court's task is thus to enforce the preemption provision as Congress wrote it. *See, e.g., Durnford*, 907 F.3d at 599, 602 ("That section 343(a) prohibits false or misleading statements *in general* does not alter our analysis" that "the possibility of liability under state law for nitrogen spiking" is preempted by the FDCA because "binding" "FDA regulations approve of the use of nitrogen as a proxy" "even if the label might be considered misleading" under section 343(a)).

ii. Plaintiff's Apparent Reading Would Violate the Rule Against Superfluities

To the extent Plaintiff reads section 343(r)(6)(B)'s substantiation requirement as being equivalent to section 343(a)(1)'s general prohibition—as opposed to section 343(r)(6)(B) representing Congress's expression of how a dietary supplement manufacturer demonstrates compliance with section 343(a)(1)'s general prohibition—such a construction would be untenable because it would render the modifier "has substantiation" in section 343(r)(6)(B) a nullity. "Under accepted

canons of statutory interpretation, [this Court] must interpret statutes as a whole, giving effect to each word and making every effort not to interpret a provision in a manner that renders other provisions of the same statute inconsistent, meaningless or superfluous." *Boise Cascade Corp. v. U.S. E.P.A.*, 942 F.2d 1427, 1432 (9th Cir. 1991); *see also Lindsey v. Tacoma-Pierce Cty. Health Dept.*, 195 F.3d 1065, 1074 (9th Cir. 1999) (applying *Boise Cascade Corp.*, *supra*, and anti-superfluity canon to find county resolution preempted).

The distinction between substantiation and Plaintiff's desired standard is significant because substantiation is not an inquiry into the absolute—i.e., whether something is "true" or "false." Rather, as the FDA has explained, the "competent and reliable scientific evidence" standard that it applies to determine whether a labeling claim is substantiated is "flexib[le]." FDA Guidance, MJN Ex. 1, at 12; *see also United States v. Bayer Corp.*, No. 07-01(JLL), 2015 WL 5822595, at *3, *14 (D.N.J. Sept. 24, 2015) ("There is no set protocol for how to conduct research that will be acceptable under the FTC substantiation doctrine. The FTC's standard for evaluating substantiation is sufficiently flexible to ensure that consumers have access to information about emerging

areas of science.");[19] *Nat'l Council Against Health Fraud, Inc. v. King Bio Pharm., Inc.*, 133 Cal. Rptr. 2d 207, 217 (Ct. App. 2003) ("The level of substantiation necessary . . . varies depending on the claim made. Sometimes, clinical testing is required . . . , but this is not always the case. . . . [W]hat constitutes a reasonable basis depends on a number of factors." (citing FTC Policy Statement Regarding Advertising Substantiation, 49 Fed. Reg. 30999 (Aug. 2, 1984)).)

The FDA applies this flexibility for good reason. A product's efficacy may vary from consumer to consumer, and experts may disagree about the extent of a product's efficacy. In short, "there are no certainties in science." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 590 (1993); *see also Messick v. Novartis Pharm. Corp.*, 747 F.3d 1193, 1198 (9th Cir. 2014) ("[W]e have consistently recognized the difficulties in establishing certainty in the medical sciences." (citation omitted)). As courts have recognized, "'[u]nanimity of opinion in the scientific community, on virtually any scientific question, . . . is extremely rare. Only slightly less rare is a strong majority.'" *Basic*

[19] As noted earlier, the FDA modeled its substantiation standard on the FTC's. (*See* note 6, *supra*.)

Research, LLC v. Fed. Trade Comm'n, No. 2:09-CV-0779 CW, 2014 WL 12596497, at *10 (D. Utah Nov. 25, 2014) (quoting *United States v. Williams*, 583 F.2d 1194, 1198 (2d Cir. 1978)); *Bayer Corp.*, 2015 WL 5822595, at *9 (finding defendant's claim was adequately substantiated despite study finding it did not deliver benefits promised: "The study does not undercut Bayer's substantiation of PCH because many successful products, including FDA-approved drugs, have neutral studies."). Yet 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.

In contrast, Defendants' and the district court's reading of sections 343(a)(1) and 343(r)(6) allow both provisions to survive in harmony. Under that reading, section 343(a)(1)'s general prohibition on false and misleading labeling would still prohibit, and not preempt, a state law cause of action challenging any number of a host of labeling inaccuracies. *See, e.g.,* 21 U.S.C. § 343(b), (c), (e), (k), (m) & (q) (specifying when the inclusion or omission of information on a label relating to product name; manufacturer, packager, or distributor;

product weight; artificial additives; nutrient content; and other things may render a food misbranded).

And as this Court recognized in *Dachauer* and the district court discussed below (ER 12), certain "otherwise acceptable structure/function claim[s] might nevertheless be false or misleading for other reasons, causing the product to be misbranded under section 403(a)(1) of the act." 65 Fed. Reg. at 1002. There, this Court held that the FDCA did not preempt the plaintiff's challenge to the defendants' otherwise appropriate structure/function claim about "immune health" because, even if substantiated as to some classes of consumers, the claim did not warn of the potential that "their supplements *increase* the risk of all-cause mortality" in others, and binding regulations provide 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' under normal conditions of use or the conditions of use that the label prescribes."[20] 913 F.3d at 849 (quoting 21 C.F.R.

[20] Although *Dachauer* cited a regulation, the prohibition on "fail[ing] to reveal facts . . . with respect to consequences which may result from the use of the article . . . under . . . conditions of use as are customary or usual" also appears in 21 U.S.C. § 321(n), which section

§ 1.21(a)(2)); *accord Kaufman v. CVS Caremark Corp.*, 836 F.3d 88, 96 (1st Cir. 2016) (stating that a section 343(r)(6) disclaimer would "immunize" a structure/function claim if the manufacturer had "the required substantiation" *and* did not "misleadingly fail[] to disclose the harmful aspects of the nutrient's structure/function"). But "descri[ptions of] the role of a nutrient or dietary ingredient intended to affect the structure or function in humans" or "characterize[ations of] the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function," 21 U.S.C. § 343(r)(6)—even if disputed—are not within the ambit of section 343(a)(1)'s general prohibition.

iii. Section 343(r)(6)(B)'s Structure/Function-Specific Requirement Controls Over Section 343(a)(1)'s General Labeling Requirement

To the extent that, despite the foregoing, this Court is inclined to agree with Plaintiff that section 343(a)(1) should apply to

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343(r) incorporates. *See* 21 U.S.C. § 343(r)(2)(G)(iii) & (r)(3)(C)(iii). Thus, the requirement to disclaim side effects is "a requirement of section 343(r)" within the meaning of the NLEA's preemption provision.

structure/function claims, section 343(r)(6)'s substantiation standard would still have to control. This is because

> It is an old and familiar rule that, where there is, in the same statute, a particular enactment, and also a general one, which, in its most comprehensive sense, would include what is embraced in the former, the particular enactment must be operative, and the general enactment must be taken to affect only such cases within its general language as are not within the provisions of the particular enactment. This rule applies wherever an act contains general provisions and also special ones upon a subject, which, standing alone, the general provisions would include.

RadLAX Gateway Hotel, LLC v. Amalgamated Bank, 566 U.S. 639, 646 (2012) (citations and internal quotation marks omitted); *accord Andrews v. Sirius XM Radio Inc.*, 932 F.3d 1253, 1263 (9th Cir. 2019).

Here, section 343(a)(1) is a non-specific provision generally providing that the labeling on any food may not be "false or misleading." Section 343(r)(6), however, pertains specifically to structure/function claims on dietary supplements and provides that such claims "may be made if . . . the manufacturer has substantiation that the statement is truthful and not misleading." Because the latter is the specific, it would ultimately trump section 343(a)(1) under the "old and familiar rule" even if section 343(a)(1) otherwise appeared applicable. *RadLAX Gateway Hotel*, 566 U.S. at 646.

iv. Congress's Selection of a Less-Demanding Substantiation Requirement is Far From Absurd

That Congress would require a less-demanding substantiation standard instead of an absolute "truth" or "falsity" standard for structure/function claims makes sense because, as already noted, a product's efficacy may vary from consumer to consumer and experts may disagree about the extent of a product's efficacy. Congress explicitly found in the text of DSHEA that "dietary supplements are safe within a broad range of intake," that "the benefits of [supplements] in health promotion and disease prevention have been documented increasingly in scientific studies," and that consumers "should be empowered to make choices" about taking them. DSHEA § 2, 108 Stat. at 4325-26. It is for these reasons that Congress "expand[ed] the scope of information in dietary supplement labeling by providing for claims to affect the structure or function of the body and the other types of claims authorized by section 403(r)(6) of the act." 65 Fed. Reg. at 1036-37; *accord id.* at 1010, 1022. It is also for these reasons that, so long as a manufacturer has substantiation to support its structure/function

claims (and complies with section 343(r)'s other requirements), Congress chose to preempt state-law challenges to such claims.

b. The FDA's Final Rule Cannot Supply a Requirement Not Found in Section 343(r)

To the extent that Plaintiff cites the FDA's Final Rule as supposedly supplying a requirement different from section 343(r)(6)(B)'s substantiation requirement, the agency neither had the occasion nor the authority to supply one. (AOB 8-9, 11, 42-43.)

The FDA's rulemaking was not undertaken to address prohibitions on falsity or the substantiation requirement. 65 Fed. Reg. at 1032 ("[T]he agency does not believe that this final rule is the appropriate venue.").[21] Indeed, Plaintiff acknowledges as much. (*See*

[21] The rulemaking proceedings make this abundantly clear. The Notice of Proposed Rulemaking announced that the FDA was "proposing regulations *defining the types of statements* that can be made concerning the effect of a dietary supplement on the structure or function of the body" and to "establish criteria for determining when a statement about a dietary supplement is a [disease] claim." *Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body*, 63 Fed. Reg. 23624, 23624 (April 29, 1998) (emphasis added). The FDA then held a public meeting "to solicit additional comments" on three issues, all of which related to the distinction between structure/function claims and disease claims—an issue that this case does not implicate. *Regulations on Statements Made for Dietary Supplements Concerning the Effect of*

AOB 11 (the Final Rule was not intended by the FDA "to address the substantiation requirement").)

Although there are statements in the Final Rule document that, read out of context, would appear to suggest that a manufacturer need not just have substantiation for its label claims, each of those statements was in response to public comments on the proposed rule published earlier in the Federal Register—not in the *promulgated rule* itself. For example, Plaintiff cites the statement that "'dietary supplements that do not do what they claim to do are misbranded.'" (AOB 11, 42-43 (quoting 65 Fed. Reg. at 1007).) But far from elevating a manufacturer's burden (or reflecting an already-elevated one), the FDA was simply responding to a comment advocating for a label disclaimer that some products' "effectiveness has not been proven." 65 Fed. Reg. at 1007. The FDA explained that it was declining to require such a disclaimer because "dietary supplements that do not do what they claim to do are misbranded" and permitting one could appear to

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the Product on the Structure or Function of the Body; Public Meeting, 64 Fed. Reg. 36824, 36824-26 (July 8, 1999). And the Final Rule itself accordingly focuses on the same distinction and the proper phrasing of structure/function claims. 65 Fed. Reg. at 1000-01, 1050.

"vitiate" the FDCA's various labeling requirements. *Id.* (citing, *inter alia*, section "(r)(6)(B)) of the act"). Defendants do not dispute that, if a manufacturer lacks substantiation to support its product's claims—unlike with respect to TruNature Ginkgo—then it is misbranded.

In any event, any suggestion that manufacturers can comply with all of the enumerated conditions that Congress set forth in Section 343(r) for permissible structure/function claims and yet *still* violate the statute would run afoul of Supreme Court precedent.

> When a court reviews an agency's construction of the statute which it administers, it is confronted with two questions. First, always, is the question whether Congress has directly spoken to the precise question at issue. *If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress*.

Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 842-43 (1984) (emphases added).

Here, as set forth above, the intent of Congress regarding when a structure/function claim "may be made" is clearly set forth in the statute: "if … the manufacturer of the dietary supplement *has*

substantiation that such statement is truthful and not misleading." 21 U.S.C. § 343(r)(6) (emphasis added). Therefore, "that is the end of the matter." *Chevron,* 467 U.S. at 842.

4. The District Court Properly Found that TruNature Ginkgo Satisfies the Only "Requirement of Section 343(r)" in Dispute

As the arbiter of preemption, the district court properly found that Plaintiff's challenges to Defendants' label claims were preempted because TruNature Ginkgo satisfies the only "requirement of section 343(r)" in dispute in this case—whether Defendants "ha[ve] substantiation" that TruNature Ginkgo's structure/function claims "are truthful and not misleading."[22]

Defendants submitted to the district court dozens of studies—38, in fact—concluding that ginkgo has a wide range of benefits to both healthy and cognitively impaired individuals, including supporting mental performance and memory and treating cognitive impairment,

[22] As noted earlier, Plaintiff has not disputed that Defendants satisfy the other two section 343(r)(6) requirements. (*See* note 5, *supra*.)

dementia, headaches, tinnitus, and peripheral arterial disease. (*See* ER 271.) The district court was familiar with and specifically credited many of those studies.

Specifically, in connection with Defendants' original summary judgment motion and the denial of Plaintiff's motion to exclude defense experts Susan Mitmesser and Edward Rosick, the court engaged in a thorough evaluation of the studies on which their opinions relied (ER 80-86) and concluded that their "reasoning is valid," "sufficiently reliable[,] and relevant to the issue of whether Plaintiff can prove that the Label Claims are false" (ER 83, 86). In doing so, the court singled out 10 studies in particular "where the authors conclude that Ginkgo biloba had positive effects in ways that support the Label Claims." (ER 80-82, 85-86; *see also* SER 4 (court discussing particulars of studies with Plaintiff's counsel).) And, as the district court noted in connection with finding TruNature Ginkgo's label claims substantiated in the summary

judgment order underlying this appeal, "the Ninth Circuit . . . affirmed" that ruling on Defendants' experts. (ER 11.)

a. The District Court Considered the "Totality of the Evidence"

In resisting the district court's conclusion that Defendants possessed sufficient substantiation, Plaintiff insists that the district court applied the wrong substantiation standard. Specifically, Plaintiff argues the district court ignored the "totality of the evidence" and, instead, adopted a "warm body" and/or "one-study-is-enough" standard. (AOB 3-4, 34-36, 44-45.) This argument finds no basis in the record.

As set forth above, the FDA and FTC require "competent and reliable scientific evidence" to substantiate structure/function claims for dietary supplements. FDA Guidance, MJN Ex. 1, at 12; *see also* note 6, *supra*. Here, the district court's order evidences the court expressly applied the CARSE standard. The court mentioned it three times over the course of its eight-page order, including when it defined "substantiation": "The FDCA does not define the term 'substantiation,' but FDA guidance advances a common sense interpretation of 'substantiation,' as meaning 'competent and reliable scientific evidence.'" (ER 10-11 (quoting *Kaufman*, 836 F.3d at 93).)

Furthermore, FDA Guidance lists various factors that are considered part of the CARSE analysis. One of those factors is the "totality of the evidence." FDA Guidance, MJN Ex. 1, at 13. As a result when a factfinder—like the district court here—applies the CARSE standard, the "totality of the evidence" is one of the things that the factfinder examines.

The record also refutes Plaintiff's argument that the court failed to consider evidence from both sides. In connection with the court's resolution of Defendants' initial motion for summary judgment and the parties' competing *Daubert* motions, the court expressly stated that it had "reviewed all the materials." (SER 2.) And the court's order underlying this appeal explicitly references its earlier thorough examination of the evidence—i.e., an examination of the totality of the evidence:

> As was discussed in this Court's previous order on summary judgment both parties offered scientific evidence supporting and contradicting Defendants' Label Claims. Although the Ninth Circuit reversed this Court's finding of summary judgment, it affirmed the denial of motions to exclude expert reliance on such evidence.

(ER 11 (citing ER 65-89).)

b. The District Court Properly Found on this Record that Defendants' Claims Were Substantiated

Although Plaintiff gives the misimpression that she had the weight of the evidence on her side, the record shows otherwise. (AOB 1, 17, 38.) As set forth above, in considering the "totality of the evidence," the district court considered all the studies submitted by the parties—including all 38 that Defendants presented.

Among the 10 that the district court specifically credited were:

- R. Kaschel, *Ginkgo biloba: specificity of neuropsychological improvement—a selective review in search of differential effects*, Human Psychopharmacology (2009) 24: 345-370 (SER 579-604.)

- J. Mix & W. Crews, Jr. *A double-blind, placebo-controlled, randomized trial of Ginkgo biloba extract EGb 761® in a sample of cognitively intact older adults: neuropsychological findings*, Human Psychopharmacology (2002) 17: 267-277 (SER 606-16.)

- R. Kaschel, *Specific memory effects of Ginkgo biloba extract EGb 761 in middle-aged healthy volunteers*, Phytomedicine 18 (2011) 1202-1207 (SER 618-23.)

- S. Zhang & Z. Xue, *Effect of Western medicine therapy assisted by Ginkgo biloba tablet on vascular cognitive impairment of none dementia*, Asian Pacific Journal of Tropical Medicine (2012) 661-664 (SER 758-61.)

Kaschel's 2009 review article of 29 double-blind, randomized, controlled trials found "consistent evidence" that "chronic administration" of ginkgo has positive effects on certain aspects of

cognitive function and specific memory tasks. (SER 579.) His subsequent (2011) double-blind, randomized, controlled trial evaluated the effect of ginkgo on 45- to 56-year-old healthy patients with respect to two specific memory tasks—one of which Kaschel hypothesized, based on prior reviews, would be sensitive to ginkgo, while the other was chosen because it would likely not. (SER 620-22 (setting out issues with respect to testing in healthy individuals).) Kaschel's results conformed to his hypothesis, finding that one aspect of memory was sensitive to ginkgo. (SER 621-22.) Mix & Crews' double-blind, randomized, controlled trial found "complementary evidence of the potential efficacy of relatively short-term (i.e., six-week) utilization of [ginkgo biloba extract] in enhancing certain neurocognitive/memory functions of cognitively intact older adults, 60 years of age and over," which "bolster[ed]" results from "previously published, small-scaled studies that have found improvements in cognitive functioning among older cognitively intact adults . . . and young, healthy volunteers." (SER 613-14.) And Zhang & Xue found, following a randomized controlled trial, that a 40 mg ginkgo biloba tablet three times a day for three months can "improve cognitive ability and cerebral blood flow supply of

patients with VCIND" (i.e., cognitively impairment without having yet reached the dementia stage). (SER 759.)

In any event, 38 studies—or even just the 10 credited by the district court or the four listed above in light of their quality—are more than enough to meet the federal standard for substantiation. *See Removatron Int'l Corp. v. F.T.C.*, 884 F.2d 1489, 1492 (1st Cir. 1989) ("usually two well-controlled scientific studies" will suffice); *see also POM Wonderful, LLC v. F.T.C.*, 777 F.3d 478, 489 (D.C. Cir. 2015) (referencing FTC's order requiring "at least two randomized and controlled human clinical trials (RCTs)").

This is particularly so in light of the irrelevance and/or lack of quality of Plaintiff's competing studies. *See* FDA Guidance, MJN Ex. 1, at 34) (recommending that manufacturers determine whether a "plausible explanation . . . explain[s] . . . disparate results"). Although Plaintiff asserts that her expert's opinion was based on "several studies in healthy individuals" (AOB 17), she omits that five of the six studies on which her expert relied were studies with endpoints related to disease prevention and/or studies that evaluated claims Defendants do not make. *See* Part II(B)(3), *supra* (listing Plaintiff's studies, which

evaluated whether ginkgo *treated* and/or *prevented* dementia and Alzheimer's or *improved* memory).

As this Court made clear in *Dachauer*, a plaintiff challenging a structure/function claim is prohibited from relying on studies related to the prevention or treatment of a disease because a structure/function claim, by definition, "may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases."[23] 21 U.S.C. § 343(r)(6)(C); *see Dachauer*, 913 F.3d at 848 (finding the plaintiff's challenge preempted because he "seeks to impose a requirement under California law that structure/function claims . . . made on a

[23] Plaintiff repeatedly criticizes Defendants' experts—and at one point, the district court—for relying on "disease studies." (AOB 4, 25 ("[T]he 'some' evidence upon which Defendants' experts rely and which the District Court also relied upon, are disease studies involving, for example, Alzheimer's disease.").) Like it or not, however, the ability to consider studies on the treatment and/or prevention of disease is a one-way street that only manufacturers may travel. As Dr. Mitmesser (whose opinion the district court admitted in the *Daubert* ruling upheld by this Court) explained, "when combined with studies in healthy persons, diseased population studies can be relied upon to determine efficacy." (SER 55.) This, of course, makes sense. If a methodologically sound study finds that a dietary supplement slows the rate of decline in a diseased population, that finding helps substantiate that the supplement is supporting the diseased structure or function of the body.

supplement's label require proof that the supplement treats or prevents . . . disease."); *Greenberg v. Target Corp.*, 402 F. Supp. 3d 836, 840 (N.D. Cal. 2019) ("[Dachauer's] evidence regarding the dietary supplements' inability to treat or prevent disease did not address its claim to affect human structure or function which was the subject of plaintiff's challenge."). Similarly, there is no basis to permit Plaintiff to challenge Defendants' label with a study indicating ginkgo does not improve memory when the label does not promise *improved* memory.[24]

The one remaining study that could arguably be relevant to Plaintiff's challenge to ginkgo's ability to "support" certain cognitive functions is insufficient to outweigh Defendants' substantiation. Most significantly, that study—B. Snitz et al. *Ginkgo biloba for Preventing Cognitive Decline in Older Adults: A Randomized Trial*, JAMA (2009)

[24] For example, if a study finds ginkgo improves memory, such a study would be evidence of the label claim that ginkgo supports memory. But a study indicating ginkgo does *not* improve memory says nothing about whether ginkgo "supported" memory because it does not analyze whether ginkgo helped in keeping a person's memory level at the same baseline over a time period during which one would expect to see decline. Improving memory is not the only hallmark of "supporting" memory.

302(24): 2663-70 (SER 913-20)—did not include a per-protocol analysis but instead only an Intent-To-Treat ("ITT") analysis.

By the end of the study, only 60% of the respondents in the ginkgo group were adherent. (SER 174-77.) Put differently, the study's authors concluded that, based on the data collected from the ginkgo test group, ginkgo was inefficacious—even though fully 40% of those respondents *were not actually taking* ginkgo as required by the protocol. Not surprisingly, even Plaintiff's biostatistician had to concede that such ITT studies are "conservative" insofar as they show greater susceptibility to a "Type II error" (i.e., a false negative where the researcher fails to find a treatment effective even though it is).[25] (SER 254-56; *see also* SER 253.)

[25] The Snitz study suffered from a handful of other statistical flaws that could have affected its reliability. For example, the study authors addressed the high rate of dropouts by imputing data for those patients using a statistical model. In other words, when faced with missing information, they had a computer "estimate" the value based on a set of existing assumptions, which Plaintiff's own expert agreed, "you don't know if that's right or not." (SER 154.) As such, as Plaintiff's expert also admitted, the FDA would *not* accept imputed data when evaluating applications for drug approvals. (*Id.*)

C. Plaintiff's Theoretical Parade of Horribles Is Unrealistic Because Unsubstantiated Claims Would Not Be Preempted

Unable to overcome the clarity of the FDCA's text and the strength of Defendants' substantiation, Plaintiff asserts that "the district court's ruling is contrary to public policy." (AOB 44.) She presents a parade of horribles, arguing that honoring the statutory framework will lead to a world where deceptive snake oil salesmen run amok, selling worthless dietary supplements with impunity. That is simply not the case.

Were this Court to uphold the district court's ruling, the government would remain free to administratively challenge the claims of a dietary supplement as lacking substantiation based on the manufacturer's failure to have "competent and reliable scientific evidence" to support them. *See Kwan v. SanMedica Int'l*, 854 F.3d 1088, 1095 (9th Cir. 2017) (discussing *King Bio Pharm.*, 107 Cal. App. 4th at 1344). And both the government *and private plaintiffs* remain free to challenge the claims of a dietary supplement as false in court. *See id.*

In a private suit—like this one—where the manufacturer argues that the claims were substantiated (and the plaintiff's state law claims

were therefore preempted), a capable district judge would still have to determine whether the claims were substantiated by "competent and reliable scientific evidence." There is no reason to believe that judge would ignore FDA guidance as to what constitutes "competent and reliable scientific evidence" in favor of the "any warm body" standard that Plaintiff fears. (AOB 44.) Federal judges are well-versed in *Daubert* principles and have significant experience determining the admissibility of scientific evidence.

If the claims are substantiated, the plaintiff's claims are preempted, but there is no harm to the public. The balancing act of substantiation has worked in precisely the way that Congress intended—the federal framework *encourages and permits* substantiated claims that may benefit a consumer in the marketplace. If the claims are not substantiated, then there is no preemption, and the plaintiff can move forward and attempt to prove falsity at trial. If the plaintiff prevails because the claims truly are false, then the plaintiff may secure an injunction prohibiting such false claims to the benefit of the public. If the plaintiff does not prevail, then the advertising was not false, and

the advertisement need not be enjoined. Either way, the public interest is well-served.

While Plaintiff attempts to paint a picture of dietary supplements as dubious and worthless, dietary supplements are both useful and beneficial to those who take them. Congress agrees. In enacting DSHEA, Congress explicitly found that "dietary supplements are safe within a broad range of intake" and that "the benefits of [supplements] in health promotion and disease prevention have been documented increasingly in scientific studies." DSHEA § 2, 108 Stat. at 4325-26. This is why Congress "expand[ed] the scope of information in dietary supplement labeling by providing for claims to affect the structure or function of the body and the other types of claims authorized by section 403(r)(6) of the act." 65 Fed. Reg. at 1036-37; *accord id.* at 1010, 1022.

At bottom, Plaintiff's "public policy" argument is an apparent repudiation of Congress' belief that the public is best served with more—not fewer—dietary supplements. But, as even Plaintiff must acknowledge, it is the province of Congress to enact laws to meet various legislative goals, which here it did in passing DSHEA and the NLEA. Those laws must be followed. As this Court has repeatedly

recognized—including in the dietary supplement preemption context—Plaintiff's arguments are more appropriately addressed to the legislative branch than the judicial one. *See, e.g., Winter ex rel. U.S. v. Gardens Reg'l Hosp. and Med. Ctr., Inc.,* 953 F.3d 1108, 1117 (9th Cir. 2020) ("'[P]olicy arguments cannot supersede the clear statutory text.' Our role is 'to apply, not amend, the work of the People's representatives.'") (citations omitted); *Dachauer*, 913 F.3d at 848 ("Plaintiff disagrees with the federal statutory scheme for dietary supplements, but we cannot accept his invitation to upend it.").

V

CONCLUSION

The district court's grant of summary judgment for Defendants should be affirmed.

DATED: June 16, 2020

Respectfully submitted,

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STATEMENT OF RELATED CASES

Defendants-Appellees Costco Wholesale Corporation and NBTY, Inc., state, pursuant to Ninth Circuit Rule 28-2.6, that it is not aware of any case related to this appeal.

CERTIFICATE OF COMPLIANCE

I certify that:

1. This brief complies with the length limits permitted by Ninth Circuit Rule 32-1 because the brief contains 11,473 words, excluding the portions exempted by Fed. R. App. P. 32(f), if applicable.

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 it has been prepared in a proportionally spaced typeface (14-point Century Schoolbook) using Microsoft Word 2016.

DATED: June 16, 2020

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