APPENDIX A

NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

NOAH BRADACH, On Behalf of Himself and All Others Similarly Situated, Plaintiff-Appellant, v. PHARMAVITE, LLC, Defendant-Appellee.	No. 16-56598 17-55064 D.C. No. 2:14-cv-03218-GHK-AGR MEMORANDUM* (Filed May 17, 2018)

Appeal from the United States District Court
for the Central District of California
George H. King, District Judge, Presiding

Argued and Submitted April 10, 2018
Pasadena, California

Before: BEA and MURGUIA, Circuit Judges, and KEELEY,** District Judge.

Noah Bradach appeals from the district court's dismissal of his class action complaint against Defendant-Appellee Pharmavite LLC. Bradach alleges he and other consumers purchased Pharmavite's Nature

* This disposition is not appropriate for publication and is not precedent except as provided by Ninth Circuit Rule 36-3.

** The Honorable Irene M. Keeley, United States District Judge for the Northern District of West Virginia, sitting by designation.

Made Vitamin E dietary supplements in reliance of the statement "Helps Maintain a Healthy Heart," ("Heart Health statement") which appears on the product's label. Bradach filed a class action lawsuit against Pharmavite contending the statement is false and misleading and asserting Pharmavite's use of the statement violates California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code § 17200, *et seq.*, and Consumers Legal Remedies Act ("CLRA"), Cal. Civ. Code § 1750 *et seq*.

Dietary supplement labeling is primarily governed by federal law. *See Gallagher v. Bayer AG*, No. 14-cv-04601-WHO, 2015 WL 1056480, at *3–7 (N.D. Cal. Mar. 10, 2015). Under federal law, dietary supplement manufacturers' statements on product labels fall into one of two categories. The first is "structure/function" claims, which allow manufacturers to display truthful, non-misleading statements about the benefits the dietary supplement provides. *See Gallagher*, 2015 WL 1056480 at *6; *see also* 21 C.F.R. § 101.93(f). Structure/function claims do not require pre-approval from the Food and Drug Administration ("FDA") so long as the "manufacturer has substantiation that the statements are truthful and not misleading, provides a disclaimer that the statement has not been approved by the FDA, and notifies the FDA of its use of the statement no later than 30 days after its first use." *Gallagher*, 2015 WL 1056480 at *4 n.2 (citing 21 U.S.C. § 343(r)(6)). The second type of permissible statements are disease claims, which are defined as statements that a product can diagnose, mitigate, treat, cure, or

prevent a specific disease or class of diseases. *See Gallagher*, 2015 WL 1056480 at *4; *see also* 21 C.F.R. § 101.93(g). Disease claims require FDA pre-approval. *See Gallagher*, 2015 WL 1056480 at *4 n.3 (citing 21 U.S.C. § 343(r)(3)).

Federal law can preempt state laws that impose different requirements from those dictated by federal statutes and regulations. The Food, Drug, and Cosmetic Act ("FDCA"), as amended by the Nutrition Labeling and Education Act ("NLEA"), contains an express preemption provision. *Gallagher*, 2015 WL 1056480, at *4 (citing 21 U.S.C. § 343-1(a)(5)). Section 343-1(a)(5) makes clear that states are prohibited from legislating food labeling laws that are not identical to federal requirements under 21 U.S.C. § 343(r), including § 343(r)(6). 21 U.S.C. § 343-1(a)(5). As *Gallagher* explained, "preemption only occurs where application of state laws would impose more or inconsistent burdens on manufacturers than the burdens imposed by the FDCA." *Gallagher*, 2015 WL 1056480, at *4.

The parties do not dispute that, on its face, the Heart Health statement is a structure/function claim. Federal law does not preempt state requirements that statements on dietary supplement labels that are structure/function claims and speak about maintaining heart health be accurate and not misleading. *See Gallagher,* 2015 WL 1056480 at *6–7 (citing to 65 Fed. Reg. 1000). However, federal law does preempt state regulation of statements on dietary supplement labels that are disease claims and speak about preventing heart disease when those regulations impose

requirements that differ from the requirements of the FDCA. *See Gallagher*, 2015 WL 1056480 at *6–7.

Here, the district court determined that Bradach lacked standing to assert his claims under the CLRA and UCL because the district court concluded that Bradach's deposition testimony and an interrogatory response indicated that Bradach believed the Heart Health statement was a disease claim and that Bradach's state-law claims were therefore preempted by the FDCA. In turn, the district court determined that Bradach could not serve as the class representative, declined to certify a class, and dismissed the case. After the case was dismissed, the district court awarded Pharmavite $84,862 in costs for a consumer survey Pharmavite commissioned. Bradach appeals both the dismissal of his lawsuit and the district court's subsequent grant of Pharmavite's motion to recover costs.

We have jurisdiction under 28 U.S.C. § 1291. For the reasons discussed below, we reverse the district court on both issues and remand for further proceedings.

1. We review questions of preemption and standing de novo. *See Gingery v. City of Glendale*, 831 F.3d 1222, 1226 (9th Cir. 2016) (citation omitted); *see also Galvez v. Kuhn*, 933 F.2d 773, 776 (9th Cir. 1991).

The record does not support the proposition that Bradach's individual claims are *solely* premised on preempted disease claims. Bradach's testimony reflects that he had a mixed understanding of what Pharmavite's Vitamin E supplement would do.

Bradach understood the Vitamin E product to both *maintain* his heart health and *prevent* heart disease. Courts have recognized that a plaintiff may have claims based on mixed motives and have allowed claims arising in part from non-preempted motives to move forward. *See Sorosky v. Burroughs Corp.*, 826 F.2d 794, 799–800 (9th Cir. 1987); *Ikekwere v. Southwall Techs., Inc.*, No. C-04-00027-JF(PVT), 2005 WL 1683623, at *2–3 (N.D. Cal. 2005). Accordingly, Bradach's claims were not preempted.

Additionally, Bradach has standing to sue Pharmavite because he suffered an injury by buying the supplement when, he contends, he would otherwise not have purchased it had he known the truth about the Heart Health statement, his injury is traceable to the Heart Health statement, and his injury is a redressable through restitution. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992). Further, Bradach has standing to sue under California law because California law "demands no more than the corresponding requirement under Article III" for CLRA and UCL claims. *Reid v. Johnson & Johnson*, 780 F.3d 952, 958 (9th Cir. 2015). Therefore, to the extent the district court dismissed Bradach's claims because it found that he lacked standing, that dismissal was error.

2. The district court declined to certify a class because it determined that Bradach was not a member of the proposed class. We review a district court's class certification ruling for abuse of discretion. *Pulaski & Middleman, LLC v. Google, Inc.*, 802 F.3d 979, 984 (9th Cir. 2015).

The district court rested its denial of class certification on two primary grounds. First, the district court held that, because Bradach's claims were preempted, he was not a member of the proposed class and, thus, he failed the typicality requirement of Federal Rule of Civil Procedure 23. As discussed above, the district court erred when it determined that Bradach's claims were preempted, so this holding was erroneous.

Second, the district court held that the proposed classes failed the ascertainability, commonality, predominance, and superiority elements of Rule 23 because it would be very difficult to determine whether the putative class members viewed the Heart Health statement as a disease claim or a structure/function claim. This determination was based on an error of law and was a per se abuse of discretion. *See United States v. Hinkson*, 585 F.3d 1247, 1260 (9th Cir. 2009) (en banc). Under California law, class members in CLRA and UCL actions are not required to prove their individual reliance on the allegedly misleading statements. Instead, the standard in actions under both the CLRA and UCL is whether "members of the public are likely to be deceived." *Kasky v. Nike, Inc.*, 27 Cal. 4th 939, 951 (2002), *as modified* (May 22, 2002); *see also In re Tobacco II Cases*, 46 Cal. 4th 298, 312 (2009). For this reason, courts have explained that CLRA and UCL claims are "ideal for class certification because they will not require the court to investigate class members' individual interaction with the product." *Tait v. BSH Home Appliances Corp.*, 289 F.R.D. 466, 480 (C.D. Cal. Dec. 20, 2012) (internal quotation marks

omitted). Thus, the district court's conclusion that it would need to inquire into the motives of each individual class member was premised on an error of law.

Accordingly, we remand to the district court for it to reconsider the class allegations.

3. Finally, Bradach appeals the district court's grant of Pharmavite's motion seeking to recover $84,862 for expenses Pharmavite incurred in conducting a consumer survey for its expert report. We review the district court's award of costs and ruling regarding local rules for abuse of discretion. *Kalitta Air L.L. C. v Central Texas Airborne Sys. Inc.*, 741 F.3d 955, 957 (9th Cir. 2013). We review de novo whether the district court had the authority to award costs. *Id.*

Although district courts have discretion under Fed. R. Civ. P. 54(d) "to *refuse* to tax costs in favor of a prevailing party, a district court may not rely on its 'equity power' to tax costs beyond those expressly authorized by [28 U.S.C.] section 1920." *Romero v. City of Pomona*, 883 F.2d 1418, 1428 (9th Cir. 1989), *abrogated on other grounds by Townsend v. Holman Consulting Corp.*, 929 F.2d 1358 (9th Cir. 1990), *amended by* 929 F.2d 1658 (9th Cir. 1990) (emphasis in original). The text of § 1920(4) is narrow, which "suggest[s] that fees are *permitted only for the physical preparation and duplication of documents, not the intellectual effort involved in their production." Id.* (emphasis added).

Here, the district court relied on the language of the Central District of California's Local Rule 54-3.12 and its inherent discretion in making its decision, and

did not consider whether § 1920 permitted it to award the requested costs. A district court's authority to award costs is circumscribed by § 1920. *Id.* Pharmavite seeks to recover the costs of conducting a consumer survey—which is akin to the intellectual effort of producing the survey, not merely the physical preparation and duplication of documents. This is not the type of cost § 1920(4) contemplates. *Id.* Accordingly, the district court erred in granting Pharmavite's motion seeking to recover the costs of producing the consumer survey.

REVERSED AND REMANDED.

APPENDIX B

E-FILED

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES – GENERAL

Case No.	CV 14-3218-GHK (AGRx)	Date	July 6, 2016
Title	*Noah Bradach, et al. v. Pharmavite LLC*		

Presiding: The Honorable	**GEORGE H. KING, U.S. DISTRICT JUDGE**	
Beatrice Herrera Deputy Clerk	N/A Court Reporter/ Recorder	N/A Tape No.

Attorneys Present for Plaintiff:	Attorneys Present for Defendants:
None	None

Proceedings: (In Chambers) Order re: Renewed Motion for Class Certification [Dkt. 181]

This matter is before us on Plaintiffs Noah Bradach ("Bradach") and Laura Corbett's ("Corbett")[1] above-captioned Motion ("Motion"). [Dkt. 181.] We have considered the papers filed in support of and in opposition to this Motion and deem this matter appropriate for resolution without oral argument. L.R. 7-15. As the Parties are familiar with the facts, we will

[1] Bradach and Corbett will be collectively referred to as "Plaintiffs."

repeat them only as necessary. Accordingly, we rule as follows:

I. Background

Defendant Pharmavite LLC ("Defendant" or "Pharmavite") manufactures and distributes various dietary supplements under the brand name "Nature Made," including vitamin E supplements produced in multiple sizes and doses. (Third Consolidated Amended Class Action Complaint ("TAC") ¶¶ 1, 14-15.) Nearly every major food, drug, and mass retail store in the country sells these vitamin E supplements. (*Id.* ¶ 15.) The front label of each bottle of the supplements bears the statement "Helps Maintain a Healthy Heart." (*Id.* ¶ 16.) The back label makes this statement, albeit less conspicuously, and also notes "[t]hese statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease." (*Id.* ¶¶ 4, 30, fig. "Back.") Plaintiffs allege that they viewed "Helps Maintain a Healthy Heart" on Pharmavite's vitamin E supplements and purchased at least one bottle of the supplements in reliance on this statement. (*Id.* ¶ 12.) The operative TAC brings the following two claims rooted in the alleged falsity of the "Helps Maintain a Healthy Heart" statement: (1) violation of California's unfair competition law ("UCL"), and (2) violation of California's Consumer Legal Remedies Act ("CLRA").

Plaintiffs now seek to certify a class for these claims. Plaintiffs request that we appoint Bradach as

class representative and specifically state that they are "not presently moving to have Laura Corbett jointly appointed class representative." (Mot. at 1 n.1.) They also seek appointment of the law firms Bonnett, Fairbourn, Friedman & Balint, P.C.; Boodell & Domanskis, LLC; and Goldman Scarlato & Penny P.C. as Class Counsel. (*Id.* at 1.)

II. Legal Standard

A motion for class certification is governed by Federal Rule of Civil Procedure 23, and the party seeking certification "bears the burden of demonstrating that [he] has met each of the four requirements of Rule 23(a) and at least one of the requirements of Rule 23(b)." *Zinser v. Accufix Research Inst., Inc.*, 253 F.3d 1180, 1186 (9th Cir. 2001).

Bradach must establish that the following Rule 23(a) prerequisites are met for the proposed class:

1. the class is so numerous that joinder of all members is impracticable;

2. there are questions of law or fact common to the class;

3. the claims or defenses of the representative party are typical of the claims or defenses of the class; and

4. the representative party will fairly and adequately protect the interests of the class.

Fed. R. Civ. P. 23(a)(1)-(4). Though not specifically mentioned in Rule 23(a), ascertainability is also a threshold prerequisite to class certification. *See Thomas & Thomas Rodmakers, Inc. v. Newport Adhesives & Composites, Inc.*, 209 F.R.D. 159, 163 (C.D. Cal. 2002). Because Bradach seeks to certify a Rule 23(b)(3) class, he must additionally show predominance and superiority.

III. Analysis

A. Preemption

As an initial matter, Pharmavite argues that we should deny certification because Plaintiffs' claims—as phrased in the Class Certification Motion—are preempted. (Opp'n at 5.) This argument closely matches the preemption argument already resolved in Pharmavite's Motion for Judgment on the Pleadings. [*See* Dkt. 170.] We reject this argument for the reasons set forth in our December 22, 2015 Order addressing Pharmavite's Motion for Judgment on the Pleadings. [*See id.*]

B. Validity of Bradach's Claims

As Pharmavite notes, Bradach's testimony reveals problems with the viability of his personal claims. The TAC states that "Bradach was exposed to and saw Pharmavite's heart health representation by reading the label of Pharmavite's vitamin E product, and that he bought the vitamin E product "in reliance on Pharmavite's heart health representation." (TAC ¶ 12.1.) "Had [] Bradach known the truth about Pharmavite's

misrepresentations and omissions, he would not have purchased" the product. (*Id*.) In his deposition, Bradach elaborated on this purchase decision, explaining that he thought that Pharmavite's vitamin E supplements would "help maintain [his] healthy heart." (Markowitz Decl., Ex. 15 at 103:12-15 ("Q: What exactly did you think that the Nature Made Vitamin E was going to do for you? A: I thought it was going to help maintain my healthy heart at the time.").) However, Bradach clarified that, to him, this phrase meant "preventing heart disease." (*Id.* at 104:18-25 ("A [Bradach]: I believe – I believe that it would – it would help maintain my healthy heart – Q: That to you – A: – that I believe that I have. Q: And to that – That, to you, means preventing heart disease, right? A: It does.").) In his responses to Pharmavite's interrogatories, Bradach stated that the concern that he intended Pharmavite's vitamin E supplements to address was "to keep his heart healthy, which to him meant keeping his heart free from heart disease."[2] (*Id.*, Ex. 26 at 13.)

Pharmavite contends that Bradach's testimony shows that he has no valid claims. However, the exact

[2] Pharmavite's interrogatory asked, "Identify all health concerns that You intended the Nature Made® Vitamin E supplements to address, including the specific location on Your body of any concern, the length of time of the concern, and whether or not You have ever sought any medical treatment related to the health concern." (Markowitz Decl., Ex. 26 at 13.) Bradach responded that "his concern was to keep his heart healthy, which to him meant keeping his heart free from heart disease," and that "[i]n this regard, Plaintiff does not recall reading any general disclaimer on the label about the product not being intended to prevent, treat, or cure disease." (*Id.*)

contours of Pharmavite's argument to this effect are unclear. To the extent Pharmavite suggests that Bradach lacks Article III standing to bring his UCL and CLRA claims against Pharmavite, we disagree. Pharmavite has confused Article III standing with the validity of the claims.

To establish constitutional standing, a plaintiff must show (1) he suffered injury in fact, (2) there is a "causal connection between the injury and the conduct complained of," i.e., the injury is fairly traceable to the challenged action of the defendant, and (3) it is likely that the injury will be redressed by a favorable decision. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). Bradach has satisfied these elements as (1) he suffered injury by purchasing a product he would not have purchased had he known the truth of the "Helps Maintain a Healthy Heart" statement; (2) the injury is fairly traceable to the alleged falsity of "Helps Maintain a Healthy Heart"; and (3) the injury will be redressed by a favorable decision for Bradach because he will receive restitution for his purchase. Pharmavite itself acknowledges the existence of such standing. (*See* Opp'n at 7 (noting that Bradach bought Pharmavite's product "because he believed ['Helps Maintain a Healthy Heart'] means 'prevents heart disease,' and that "[t]his is the only basis for which he personally has standing to assert any claims").)

However, Pharmavite is correct that Bradach's claims are preempted. Bradach's deposition statements reveal that his alleged injury—his purchase of Pharmavite's vitamin E supplements in reliance on

"Helps Maintain a Healthy Heart"—is based on his interpretation of "Helps Maintain a Healthy Heart" as meaning "prevent[s] heart disease." (*See* Markowitz Decl., Ex. 15 at 104:18-25.) In other words, Bradach is asserting a false disease claim, and as explained in our December 22, 2015 Order addressing Pharmavite's Motion for Judgment on the Pleadings, the Nutrition Labeling and Education Act expressly preempts claims based on a false disease claim characterization of "Helps Maintain a Healthy Heart." [*See* Dkt. 170.] Thus, Bradach's claims are preempted as a matter of law.

Moreover, to maintain non-preempted claims, the proposed class must proceed on a theory that "Helps Maintain a Healthy Heart" is false for structure/function reasons—i.e., that the statement is false because the supplements do not help the structure or function of the heart. As explained, Bradach does not assert a structure/function claim. Thus, Bradach is not and cannot be a member of the proposed class.

Bradach argues that Pharmavite "confuses his personal interpretations of [Pharmavite's] label and the reasons for his purchase with the nature of the *legal* claim he brings in this case." (Reply at 7.) This argument does not address the preemption issues described above. As both Bradach and the class must advance non-preempted false structure/function claims for such claims to survive, each class member's interpretation of "Helps Maintain a Healthy Heart"—including Bradach's—matters in determining the viability of his or her claims.

Bradach next argues that Pharmavite "mischaracterizes [his] testimony." (*Id.*) "Contrary to [Pharmavite's] argument that he believed vitamin E supplements would prevent heart disease, [Bradach] testified that he believed Defendant's vitamin E supplements would 'help maintain [his] healthy heart[,]' which he understood to mean that it would help him be 'free of heart disease.'" (*Id.*) "It therefore cannot be denied that [Bradach] relied upon [Pharmavite's] false structure/function ['Helps Maintain a Healthy Heart'] representation in purchasing [Pharmavite's] product." (*Id.* at 7-8.) This argument is also unpersuasive. First, we fail to see a material difference between an interpretation that "Helps Maintain a Healthy Heart" means that a product will help a person be free of heart disease and an interpretation that "Helps Maintain a Healthy" heart means that a product will prevent heart disease—the interpretations are identical. Additionally, Bradach ignores his own express affirmation that he interpreted "help maintain my healthy heart" to mean "preventing heart disease." (*See* Markowitz Decl., Ex. 15 at 104:18-25 ("A [Bradach]: I believe – I believe that it would – it would help maintain my healthy heart . . . Q: . . . That, to you, means preventing heart disease, right? A: It does.").) Thus, Bradach's statements show that he adopted a preempted false-disease claim interpretation of "Helps Maintain a Healthy Heart."

Finally, Bradach asserts that "[w]hat Plaintiff's erroneous belief was about the eventual benefits that taking [Pharmavite's] supplement might provide—

post-purchase—is irrelevant." (Reply at 8.) "The only thing that is relevant is that Plaintiff relied upon Defendant's false ['Helps Maintain a Healthy Heart'] structure/function claim in making his purchase." (*Id.*) Bradach is incorrect. As explained above, his interpretation of "Helps Maintain a Healthy Heart" determines whether his claims are preempted. His statements show his claims are preempted, and that he is not a member of the proposed class.

In sum, while Bradach has Article III standing to assert UCL and CLRA claims against Pharmavite, he only has standing to assert claims that are preempted. Bradach's individual claims are therefore invalid. Further, as the proposed class cannot assert preempted claims, Bradach is not a member of the proposed class. "In order to satisfy the typicality or adequacy requirements, Plaintiffs must be members of the class they seek to represent." *Williams v. Oberon Media, Inc.*, 2010 WL 8453723, at *6 (C.D. Cal. Apr. 19, 2010); *see also Estate of Felts v. Genworth Life Ins. Co.*, 250 F.R.D. 512, 524 (W.D. Wash. 2008) ("Class membership is a minimal prerequisite to a finding of typicality."). Thus, neither the typicality nor adequacy requirements are satisfied. Class certification is therefore unwarranted.

Even assuming that Bradach is a typical and adequate representative of the class, however, other issues—discussed below—would preclude class certification.

C. Ascertainability

"The requirement of an ascertainable class is met as long as the class can be defined through objective criteria." *Guido v. L'Oreal, USA, Inc.*, 2013 WL 3353857, at *18 (C.D. Cal. July 1, 2013). "A class is sufficiently defined and ascertainable if it is administratively feasible for the court to determine whether a particular individual is a member." *Keegan v. Am. Honda Motor Co.*, 284 F.R.D. 504, 521 (C.D. Cal. 2012) (internal quotation marks omitted); *see also Parkinson v. Hyundai Motor Am.*, 258 F.R.D. 580, 593 (C.D. Cal. 2008) (reasoning that a proposed class was ascertainable where "the proposed class definition allows prospective plaintiffs to determine whether they are class members with a potential right to recover"). A class that includes members who were not harmed by a defendant's alleged wrongdoing is "both imprecise and overbroad" and does not satisfy the ascertainability requirement. *See Red v. Kraft Foods, Inc.*, 2012 WL 8019257, at *3 (C.D. Cal. Apr. 12, 2012).

As Pharmavite asserts, the proposed class is overbroad. The proposed class potentially includes members, such as Bradach, who have no non-preempted claims. There is no common or class-based way to determine whether a particular purchaser of Pharmavite's vitamin E supplements has non-preempted claims. An individualized inquiry would be needed for such determination. Such inquiry would place a massive administrative burden on the courts that would nullify any benefits of a class action. The ascertainability requirement is not met. *See Tietsworth v. Sears*

Roebuck & Co., 2012 WL 1595112, at *14 (N.D. Cal. May 4, 2012) (concluding that the ascertainability requirement was not met where, "[b]ecause of the way that the classes are defined, it appears that 'ascertaining class membership would require unmanageable individualized inquiry").

D. Commonality and Predominance

Commonality requires a plaintiff to demonstrate that "class members have suffered the same injury," by showing their claims "depend upon a common contention." *Dukes*, 564 U.S. at 349-50. "That common contention, moreover, must be of such a nature that it is capable of classwide resolution—which means that determination of its truth or falsity will resolve an issue that is central to the validity of each one of the claims in one stroke." *Id.* "[C]ommonality only requires a single significant question of law or fact." *Mazza v. Am. Honda Motor Co.*, 666 F.3d 581, 589 (9th Cir. 2012).

Predominance "tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation." *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 623 (1997). It focuses on the relationship between the common and individual issues, requiring that the common issues be qualitatively substantial in relation to the issues peculiar to individual class members. *See Hanlon v. Chrysler Corp.*, 150 F.3d 1011, 1022 (9th Cir. 1998). "The predominance inquiry under Rule 23(b)(3) is 'similar to,' but more demanding than, the commonality inquiry under Rule 23." *Steven Ades & Hart*

Woolery v. Omni Hotels Mgmt. Corp., 2014 WL 4627271, at *8 (C.D. Cal. Sept. 8, 2014). It "requires that plaintiff demonstrate common questions predominate as to each cause of action for which plaintiff seeks class certification." *Petersen v. Costco Wholesale Co.*, 312 F.R.D. 565, 579 (C.D. Cal. 2016). "In order to determine whether common issues predominate, the Court neither decides the merits of the parties' claims or defenses nor does it decide whether the plaintiffs are likely to prevail on their claims. Rather, the Court must determine whether plaintiffs have shown that there are plausible classwide methods of proof available to prove their claims." *Wolph v. Acer Am. Corp*., 272 F.R.D. 477, 487 (N.D. Cal. 2011) (internal quotation marks omitted).

Whether a given consumer has non-preempted false structure/function claims will depend on how the consumer interpreted "Helps Maintain a Healthy Heart" when the consumer purchased the supplements. As Bradach has offered no evidence that consumers uniformly interpret the statement in a particular manner, he has failed to show that this interpretation question would be common to the class. To the contrary, an individualized inquiry into each consumer's interpretation of "Helps Maintain a Healthy Heart" would be required to determine whether each consumer has non-preempted claims. Such individualized inquiries would predominate over any other issues common to the class.

Moreover, an individualized inquiry into each consumer's interpretation of "Helps Maintain a Healthy

Heart" would be required to determine the materiality of the statement. "While a named plaintiff in a UCL class action [ ] must show that he or she suffered injury in fact and lost money or property as a result of the unfair competition, once the named plaintiff meets that burden, no further individualized proof of injury or causation is required to impose restitution liability against the defendant in favor of absent class members." *See In re Steroid Hormone Prod. Cases*, 181 Cal. App. 4th 145, 154 (2010). "[A] presumption, or at least an inference, of reliance arises wherever there is a showing that a misrepresentation was material." *In re Tobacco II Cases*, 46 Cal. 4th 298, 327 (2009). "Thus, so long as plaintiffs establish that defendants' omissions and misrepresentations are 'material,' they may bring a UCL claim on behalf of a class without individualized proof of reliance." *Guido v. L'Oreal, USA, Inc.*, 284 F.R.D. 468, 475 (C.D. Cal. 2012). Unlike the UCL, "the CLRA requires a showing of actual injury as to each class member." *In re Steroid Hormone Prod. Cases*, 181 Cal App. 4th at 154. But, "a plaintiff may demonstrate that a defendant's alleged deceptive conduct caused . . . damage to the class by showing that the alleged misrepresentation would have been *material* to reasonable persons." *Jones v. ConAgra Foods, Inc*., 2014 WL 2702726, at *15 (N.D. Cal. June 13, 2014) (internal quotation marks and citation omitted) (emphasis in the original). "If the trial court finds that material misrepresentations have been made to the entire class, an inference of reliance arises as to the class." *In re Vioxx Class Cases*, 180 Cal. App. 4th 116, 129 (2009). Thus, both the UCL and CLRA "allow plaintiffs to establish

materiality and reliance (i.e., causation and injury) by showing that a reasonable person would have considered the defendant's representation material." *In re NJoy Inc. Consumer Class Action Litig.*, 120 F. Supp. 3d 1050, 1103 (C.D. Cal. 2015).

"A misrepresentation is judged to be material if a reasonable man would attach importance to its existence or nonexistence in determining his choice of action in the transaction in question." *In re Tobacco II Cases*, 46 Cal. 4th at 327 (internal quotation marks omitted). "Materiality of the misrepresentation is an objective standard that is susceptible to common proof." *Wolph*, 272 F.R.D. at 488. Though materiality is an objective inquiry, this does not "suggest that predominance would be shown in every California UCL case." *See Stearns v. Ticketmaster Corp.*, 655 F.3d 1013, 1020 (9th Cir. 2011), *abrogated on other grounds by Comcast Corp. v. Behrend*, 133 S. Ct. 1426 (2013). "If the misrepresentation or omission is not material as to all class members, the issue of reliance 'would vary from consumer to consumer' and the class should not be certified." *Id.* at 1022-23; *see also In re Vioxx Class Cases*, 180 Cal. App. 4th at 129 ("[I]f the issue of materiality or reliance is a matter that would vary from consumer to consumer, the issue is not subject to common proof, and the action is properly not certified as a class action.").

While Bradach asserts that "Helps Maintain a Healthy Heart" is material to consumers, he offers no evidence on how consumers interpret this statement. Instead, Bradach merely proclaims that "[t]he law does

not require Plaintiffs to prove *how* a reasonable consumer would interpret the meaning of 'helps maintain a healthy heart,'" but only that "the representation is material to the reasonable consumer." (Reply at 10.) Bradach's focus is misplaced. If individualized questions exist regarding how consumers interpret "Helps Maintain a Healthy Heart," then whether a consumer considered the statement material would also be an individualized inquiry. In other words, with no evidence that consumers in the class interpret "Helps Maintain a Healthy Heart" in a uniform way, the question of *what* interpretation consumers find material will vary from consumer to consumer notwithstanding whether the consumers actually find a given interpretation material. *See Jones*, 2014 WL 2702726, at *14 ("Here, there is a lack of cohesion among the class members . . . because 'even if the challenged statements were *facially* uniform, consumers' *understanding* of those representations would not be.'" (emphasis in the original)). The individual questions of consumers' interpretation of "Helps Maintain a Healthy Heart" would predominate in the litigation, as the Parties would need to examine every consumer individually to ultimately determine how each consumer interpreted the statement. *See Astiana v. Kashi Co.*, 291 F.R.D. 493, 508 (S.D. Cal. 2013) (concluding that materiality issues did not predominate where plaintiffs failed "to sufficiently show that 'All Natural' has any kind of uniform definition among class members"); *In re ConAgra Foods, Inc.*, 302 F.R.D. 537, 576-77 (C.D. Cal. 2014) ("*ConAgra I*") (concluding that the predominance requirement was not met where, among other things,

plaintiffs failed to offer evidence linking "consumers' understanding of '100% Natural' to the specific issue raised in this case—i.e., whether consumers believe the label means the product contains no genetically modified organisms or GMO ingredients"); *Thurston v. Bear Naked, Inc.*, 2013 WL 5664985, at *8 (S.D. Cal. July 30, 2013) (reasoning that the predominance requirement was not met for a particular class because the plaintiffs failed to, among other things, "sufficiently show that 'natural' has any kind of uniform definition among class members"); *cf. In re ConAgra Foods, Inc.*, 90 F. Supp. 3d 919, 1019 (C.D. Cal. 2015) ("*ConAgra II*") (concluding that the predominance requirement was satisfied where "plaintiffs [] made a sufficient showing for purposes of class certification that the '100% Natural' claim is material and that consumers generally understand it, inter alia, as a representation that Wesson Oils do not contain GMOs").

Thus, individualized issues will predominate over any issues common to the class.[3] The predominance requirement is therefore not met.

E. Superiority

The superiority inquiry under Rule 23(b)(3) turns on the question of whether "classwide litigation of common issues will reduce litigation costs and promote greater efficiency." *Valentino v. Carter-Wallace, Inc.*, 97

[3] Other predominance problems may also exist such as Bradach's failure to provide a damages model attributable to his theory of liability.

F.3d 1227, 1234 (9th Cir. 1996). In determining superiority, courts must consider the four factors of Rule 23(b)(3). *Zinser*, 253 F.3d at 1190. They are: (1) "the class members' interests in individually controlling the prosecution or defense of separate actions"; (2) "the extent and nature of any litigation concerning the controversy already begun by or against class members"; (3) "the desirability or undesirability of concentrating the litigation of the claims in the particular forum"; and (4) "the likely difficulties in managing a class action." Fed. R. Civ. P. 23(b)(3)(A)-(D).

As explained in the "Ascertainability" section, (*see supra* Section III.C), the proposed class would be extremely difficult to manage. There is no common way to determine if class members have non-preempted structure/function claims against Pharmavite without having each member testify as to his or her interpretation of "Helps Maintain a Healthy Heart" at the time of purchase. As obtaining such testimony would be costly, time-consuming, burdensome, and would defeat the very purpose of classwide litigation, it does not satisfy the superiority requirement.

IV. Conclusion

For the foregoing reasons, Plaintiffs' Renewed Motion for Class Certification is **DENIED**.

Additionally, Bradach appears to have asserted only preempted false disease claims. He is hereby **ORDERED to SHOW CAUSE** in writing, within **14 days**

hereof, why his claims should not be dismissed as preempted.

IT IS SO ORDERED.

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APPENDIX C

E-FILED

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES – GENERAL

Case No.	CV 14-3218-GHK (AGRx)	Date	August 25, 2016
Title	*Noah Bradach, et al. v. Pharmavite LLC*		

Presiding: The Honorable	**GEORGE H. KING, U.S. DISTRICT JUDGE**	
Paul Songco Deputy Clerk	N/A Court Reporter/ Recorder	N/A Tape No.

Attorneys Present for Plaintiff:	Attorneys Present for Defendants:
None	None

Proceedings: (In Chambers) Order re: Plaintiff's Response to Order to Show Cause [Dkt. 203]

On July 6, 2016, we issued an order denying class certification in this matter. [Dkt. 202.] We noted that Plaintiff Noah Bradach ("Bradach" or "Plaintiff') "appears to have asserted only preempted false disease claims" and accordingly ordered Bradach to show cause why his claims should not be dismissed as preempted. [*Id.*] Bradach timely responded on July 19, 2016. [Dkt. 203.] On August 2, 2016, Defendant

Pharmavite LLC ("Pharmavite" or "Defendant") filed an opposition to Bradach's response. [Dkt. 209.]

Ultimately, we conclude that Bradach's claims are preempted. As all Parties agree, "Helps Maintain a Healthy Heart" (the "Statement") is a structure/function claim. [*See* Dkt. 170 at 3.] As explained in our December 22, 2015 Order re: Pharmavite's Motion for Judgment on the Pleadings, this means that any legal claim based on a false disease characterization of the Statement—i.e., that the Statement is false because Pharmavite's vitamin E supplements do not prevent or cure heart disease—is preempted. Bradach testified that, when he purchased Pharmavite's supplements, he did so thinking that they would "help maintain [his] healthy heart." [Dkt. 190-1, Ex. 15 at 103:12-15.] Bradach explained that, to him, this phrase meant "preventing heart disease." [*Id.* at 104:18-25.] Thus, Bradach purchased Pharmavite's supplements thinking that they would prevent heart disease.

This testimony reveals that Bradach has no standing to assert a legal claim based on a false structure/function claim characterization of the Statement. Were Bradach to proceed on such a theory, his injury would not be fairly traceable to the challenged action because his decision to buy the supplements was not influenced by the alleged wrongdoing—the purported falsity of the Statement with regards to the supplements' effect on the structure/function of his heart. Instead, Bradach only has standing to assert a legal claim based on a false disease claim characterization of the Statement—that the Statement is false because it does not

prevent heart disease. Because Bradach purchased the supplements thinking that the Statement meant that the supplements would prevent heart disease, his injury is traceable only to such alleged wrongdoing. But, such legal claims are preempted. Thus, Bradach only has standing to bring a preempted claim and must be dismissed from this action.

Plaintiff asserts that his claims are not preempted if "(1) Defendant's 'Helps Maintain a Healthy Heart' statement is a structure/function claim (as opposed to a disease claim), and (2) Plaintiff alleges that the [S]tatement is false or misleading." (OSC Response at 4.) Plaintiff is incorrect. It is not enough for Plaintiff to merely allege that the Statement is false or misleading. As explained above, the reasons why the Statement is false matter for determining whether a given claim is preempted. If Plaintiff asserts that the Statement is false because the supplements do not prevent heart disease, then such claims are preempted.

Plaintiff also alleges that "where a consumer challenges such claims under the UCL or CLRA, . . . the focus is on the 'actions of the defendants'—not on 'the subjective state of mind of class members.' (*Id.* (quoting *Waller v. Hewlett-Packard Co.,* 295 F.R.D. 472, 480 (S.D. Cal. 2013).) Plaintiff claims that what Bradach "personally believed to be the manner in which Defendant's vitamin E supplements might help him maintain a healthy heart is not a fact required to prove his CLRA or UCL claim." (*Id.* at 6.) Were this a typical UCL and CLRA case, it may be true that Bradach's understanding of the Statement's meaning would not

effect the validity of his claims. But, unlike the typical UCL and CLRA case, Bradach's case presents unique concerns regarding preemption. Claims based on certain theories are preempted, while claims based on other theories are not. Because of these preemption concerns, Bradach cannot simply assert that the Statement is false. He must assert that the Statement is false because the supplements do not maintain the structure/function of the heart. To the extent that Bradach argues that the Statement is false because the supplements do not prevent heart disease, his claims are preempted. Bradach's reasons for purchasing the supplements inform whether he has standing to assert non-preempted claims. Thus, unlike usual UCL and CLRA claims, Bradach's beliefs regarding the Statement's meaning are relevant to evaluating the viability of his claims.

Plaintiff argues that "[b]y going further than its determination that Plaintiff purchased Defendant's vitamin E supplements in reliance on the allegedly 'Helps Maintain a Healthy Heart' misrepresentation and considering Plaintiffs understanding of how Defendant's supplements work to help maintain a healthy heart, the Court has imposed a new burden upon CLRA and UCL plaintiffs," by "requiring that plaintiffs asserting such claims . . . be able to articulate how the product works or how the representation is false or misleading." (*Id.* at 14.) However, this purported "new burden" is merely a byproduct of the unique preemption concerns in this case. Because a false disease characterization of the statement is

preempted, a Plaintiff's theory of recovery matters in determining whether the Plaintiff possess a cognizable claim. In other words, because of the preemption issue in this case, merely suffering injury as a result of the purported false Statement is not enough to state a claim for relief—the claim must also be based on a non-preempted theory. As explained above, Plaintiff's testimony reveals that he only has standing to proceed on a theory that is preempted.

The defect with Bradach's claims is not that he did not suffer an injury. As stated in our class certification order, Bradach has suffered an injury—he purchased a product he otherwise would not had he known the purported truth of the Statement. Instead, the problem with Bradach's claims is that the injury he suffered is fairly traceable to a false disease claim theory of the Statement, which is preempted. Such preemption concerns did not exist in cases such as *Pulaski & Middleman, LLC v. Google, Inc.*, 802 F.3d 979 (9th Cir. 2015), and *Hinojos v. Kohl's Corp.*, 718 F.3d 1098 (9th Cir. 2013). Thus, while it may be true, as Bradach contends, that his claims were "'conclusively' established when . . . he saw, relied, and purchased Defendant's supplements based upon Defendant's 'Helps Maintain a Healthy Heart' representation," (OSC Response at 7), such claims are preempted in light of his testimony as to why he purchased the supplements.

Plaintiff also argues that we impermissibly relied on Bradach's testimony to answer the "legal question of whether Plaintiffs claims are preempted." (*Id.* at 8.) "It is well-settled that a plaintiff need not have

personal knowledge of the basis for his legal claims particularly when they involve complicated issues of what constitutes a structure/function claim versus a disease claim." (*Id.*) Plaintiff misunderstands our consideration of Bradach's testimony. We did not rely on Bradach's statements to determine whether he thought his legal claim to be based on a false structure/function theory or a false disease claim theory. Instead we considered Bradach's testimony to determine how he relied on the Statement, which in turn determined whether he has standing to bring non-preempted claims.

Bradach further asserts that whether the supplements improve the structure/function of the heart is assessed by, among other things, the absence of heart disease. According to Bradach, this means that "Plaintiffs consideration of this as a potential benefit of taking Defendant's vitamin E supplements does not transform his legal claims regarding Defendant's structure/function misrepresentation into a preempted legal claim regarding a disease misrepresentation." (*Id.* at 11-12.) But, even assuming that the absence or presence of heart disease can be used as evidence of whether the supplements improve the structure/function of the heart, this does not change the fact that Bradach did not interpret the Statement to mean that the supplements would improve the structure/function of his heart. Instead, Bradach believed the statement meant that the supplements would prevent heart disease. Thus, as mentioned, Bradach only has standing

to proceed on a preempted theory that the Statement is false for false disease claim reasons.

Bradach next contends that "[t]he totality of Plaintiff's testimony shows that he understood [the Statement] to be a structure/function claim." (*Id.* at 13.) Bradach notes that, in response to what he understood the Statement to mean, he "explained that he understood [the] [S]tatement to mean just exactly what it said, that taking Defendant's vitamin E supplement would help him maintain his healthy heart." (*Id.* at 14.) "Given this testimony, it is not possible to conclude that Plaintiff only bought the supplement to treat heart disease that he did not even have." (*Id*.) Bradach's argument is unpersuasive. Though he may have testified that he thought the Statement meant that the supplements would help him maintain his healthy heart, he also testified that to him, this phrase meant "preventing heart disease." [Dkt. 190-1, Ex. 15 at 104:18-25 ("A [Bradach]: I believe—I believe that [the supplement] would—it would help maintain my healthy heart[.] . . . Q: And to that—[t]hat, to you, means preventing heart disease, right? A: It does.").][1]

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[1] Plaintiff also states that "even if the Court interprets Plaintiff's testimony as asserting a disease claim, the Court here, at most, should sever that part of Plaintiff's testimony and allow him to proceed on the testimony where he stated that he believed Defendant's supplements would help maintain the health of his heart—as this testimony clearly establishes his reliance upon Defendant's misrepresented structure/function claim." (OSC Response at 16.) This argument is meritless. To truncate Plaintiff's testimony in this fashion would deprive his testimony of context. These are not two independent statements that form independent

Based on the foregoing, we conclude that Bradach's claims are preempted as a matter of law and accordingly **DISMISS** Bradach's individual claims **with prejudice**.

IT IS SO ORDERED.

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bases for his claims. His second statement—that he believed "help maintain my healthy heart" to mean "preventing heart disease"—is merely an explanation of what he meant when he testified that he believed the supplements would help maintain his healthy heart. It would be inappropriate to divorce one statement from the other in this context.

APPENDIX D

E-FILED

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES – GENERAL

Case No.	CV 14-3218-GHK (AGRx)	Date	December 25, 2016
Title	*Noah Bradach, et al. v. Pharmavite LLC*		

Presiding: The Honorable	**GEORGE H. KING, CHIEF U.S. DISTRICT JUDGE**	
Beatrice Herrera Deputy Clerk	N/A Court Reporter/ Recorder	N/A Tape No.

Attorneys Present for Plaintiff:	Attorneys Present for Defendants:
None	None

Proceedings: **(In Chambers) Order re:** Pharmavite LLC's Motion for Judgment on the Pleadings [Dkt. 153]

This matter is before us on Defendant Pharmavite LLC's ("Defendant" or "Pharmavite") Motion for Judgment on the Pleadings ("Motion"). We have considered the papers filed in support of and in opposition to the Motion and deem this matter appropriate for resolution without oral argument. L.R. 715. As the Parties are familiar with the facts, we will repeat them only as necessary. Accordingly, we rule as follows:

I. Background

Defendant Pharmavite LLC ("Defendant" or "Pharmavite") manufactures and nationally distributes various dietary supplements under the brand name "Nature Made." (Third Consolidated Amended Class Action Complaint ("TAC") ¶¶ 1, 14.) Among the dietary supplements that Defendant manufactures are vitamin E supplements, which it produces in multiple sizes and doses. (*Id.* ¶¶ 14-15.) Nearly every major food, drug, and mass retail outlet store in the country sells Defendant's vitamin E supplements. (*Id.* ¶ 15.)

The front label of each bottle of Defendant's vitamin E supplements prominently bears the statement "Helps Maintain a Healthy Heart" (the "Statement"). (*Id.* ¶ 16.) This Statement is also presented less conspicuously on each bottle's back label. (*Id.* ¶ 30.) Also on the back of the bottle is the statement "[t]hese statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease." (*Id.*¶¶ 4, 30, fig. "Back.") Plaintiffs Noah Bradach and Laura Corbett (collectively, "Plaintiffs") allege that they viewed the Statement on Defendant's vitamin E supplements and purchased at least one bottle of the supplements in reliance on this statement. (*Id.* ¶ 12.) However, Plaintiffs assert that the vitamin E supplements they purchased "did not and could not" help maintain their heart health as represented because "the vast weight of scientific evidence and the consensus in the scientific community is that Vitamin E supplements do not provide any heart health benefits." (*Id*.)

The operative TAC brings the following two claims rooted in the alleged falsity of the "Helps Maintain a Healthy Heart" Statement: (1) violation of California's unfair competition law ("UCL"), and (2) violation of California's Consumer Legal Remedies Act ("CLRA"). On November 9, 2015, Defendant filed the instant Motion, which alleges that dismissal of the TAC is proper under Federal Rule of Civil Procedure 12(c) because both of Plaintiffs' state law claims are preempted by the federal Food, Drug, and Cosmetic Act ("FDCA"). [Dkt. 153.] For the following reasons, we deny Defendant's Motion.

II. Legal Standard

A party may move for judgment on the pleadings "[a]fter the pleadings are closed—but early enough not to delay trial." Fed. R. Civ. P. 12(c). Our analysis of a Rule 12(c) Motion is "substantially identical to analysis under Rule 12(b)(6), because, under both rules, a court must determine whether the facts alleged in the complaint, taken as true, entitle the plaintiff to a legal remedy." *Chavez v. United States*, 683 F.3d 1102, 1108 (9th Cir. 2012) (internal quotation marks omitted). This means that, in examining a Rule 12(c) Motion, "[w]e must accept all factual allegations in the complaint as true and construe them in the light most favorable to the non-moving party." *Fleming v. Pickard*, 581 F.3d 922, 925 (9th Cir. 2009). "Judgment on the pleadings is properly granted when, accepting all factual allegations in the complaint as true, there is no issue of material fact in dispute, and the moving party

is entitled to judgment as a matter of law." *Chavez*, 683 F.3d at 1108 (internal quotation marks and alterations omitted). Under this standard, a "defendant is not entitled to judgment on the pleadings if the complaint raises issues of fact, which, if proved, would support recovery." *Casiano v. Deutsche Bank Nat'l Trust Co.*, 2011 WL 836659, at *2 (C.D. Cal. Feb. 28, 2011). A defendant can base a Rule 12(c) Motion on an affirmative defense if the "affirmative defense is obvious on the face of a complaint." *Rivera v. Pen & Sons Farms, Inc.*, 735 F.3d 892, 902 (9th Cir. 2013). To determine if judgment on the pleadings is proper we consider the complaint in its entirety, materials incorporated into the complaint by reference, and matters of which we may take judicial notice. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322-23 (2007).

III. Structure/Function Claims and Disease Claims

As amended by the Dietary Supplement Health and Education Act ("DSHEA"), the FDCA "establish standards with respect to dietary supplements." *See* Pub. L. No. 103-417, 108 Stat. 4325 (1994). Specifically, it provides that a statement for a dietary supplement may be made if

> (A) the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a

> nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient, (B) the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading, and (C) the statement contains, prominently displayed and in boldface type, the following: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

21 U.S.C. § 343(r)(6)(A)-(C). Claims of this type are known as "structure/function" claims. *See* 21 C.F.R. § 101.93(f). "Such structure/function claims do not require FDA pre-approval," so long as they comply with the requirements listed above. *See Hughes v. Ester C Co.*, 99 F. Supp. 3d 278, 282 (E.D.N.Y. 2015).

The DSHEA also describes "disease claims," which are statements that "claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases." *See* 21 U.S.C. § 343(r)(6); 21 C.F.R. § 101.93(g). Unlike structure/function claims, disease claims can only be placed on dietary supplements after obtaining prior approval from the FDA. *See* 21 U.S.C. § 343(r)(5)(D); *see also Gallagher v. Bayer AG*, 2015 WL 1056480, at *5 (N.D. Cal. Mar. 10, 2015) ("*Gallagher I*") (noting that disease claims are "subject to prior approval by the FDA").

IV. Preemption

Under the Supremacy Clause, "state laws that conflict with federal law are without effect." *McClellan v. I-Flow Corp.*, 776 F.3d 1035, 1039 (9th Cir. 2015) (internal quotation marks and citation omitted); *see also Lopez v. Wash. Mut. Bank, FA*, 302 F.3d 900, 906 (9th Cir. 2002) ("Federal regulations have no less preemptive effect than federal statutes."). "Congress may preempt state law by so stating in express terms." *Bank of Am. v. City & Cty. of S.F.*, 309 F.3d 551, 558 (9th Cir. 2002). The FDCA, as amended by the Nutritional Labeling Education Act ("NLEA"), contains an express preemption provision that preempts state law claims that "would impose more or inconsistent burdens on manufacturers than the burdens imposed by the FDCA."[1] *Gallagher I*, 2015 WL 1056480, at *4. "The NLEA is clear, however, that if state law seeks to impose liability consistent with the FDCA, the law is not preempted." *Salazar v. Honest Tea, Inc.*, 74 F. Supp. 3d 1304, 1311 (E.D. Cal. 2014).

Defendant argues that this NLEA preemption provision preempts Plaintiffs' UCL and CLRA claims. Defendant first asserts that the Statement "Helps Maintain a Healthy Heart" is a structure/function

[1] Specifically, the NLEA preempts any state law or claim that is inconsistent with "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, except a requirement respecting a claim made in the label or labeling of food which is exempt under section 343(r)(5)(B) of this title." 21 U.S.C. § 343-1(a)(5).

claim under the FDCA. Plaintiffs agree with this assertion. (*See* Opp'n at 12.) Defendant further argues, however, that (1) Plaintiffs' state law claims characterize this structure/function Statement as a false disease claim, thereby preempting the state law claims; and (2) Plaintiffs also fail to sufficiently plead that the Statement is a false structure/function claim because the TAC's supporting studies only discuss vitamin E's effectiveness at preventing heart disease.

A. Do Plaintiffs' State Law Claims Characterize the Statement as a Structure/Function Claim?

Defendant contends that Plaintiffs' state law claims apply a false disease claim characterization to the Statement, which the Parties agree is a structure/function claim. Such a characterization would effectively impart requirements onto the structure/function claim that are inconsistent with the FDCA's provisions. Accordingly, Plaintiffs' state law claims would be preempted under the NLEA's express preemption provision. *See Gallagher I*, 2015 WL 1056480, at *7 ("[P]laintiffs' claims based on the argument that 'supports heart health' is an impermissible disease claim are preempted. . . ."). Plaintiffs argue that their state law claims simply characterize the Statement as a false structure/function claim, not a false disease claim. So characterized, these state law claims would

be consistent with the FDCA's requirements,[2] and therefore not preempted. *See id.* ("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.").

As Defendant points out, several portions of the TAC seem to characterize the Statement as a false disease claim. (*See* TAC ¶ 2 ("[L]arge scale randomized controlled clinical trials ('RCTs') have conclusively shown that Vitamin E supplements such as those sold by Defendant do not prevent [cardiovascular disease] and thus the consensus in the scientific community is that Vitamin E supplements do not provide any heart health benefits and most certainly do not 'help maintain a healthy heart")) Nevertheless, other portions of the TAC characterize the Statement as a false structure/function claim. (*See id.* ¶¶ 5 ("Large scale RCTs have demonstrated that Vitamin E supplements, like Pharmavite's Products, do not provide any cardiovascular or heart health benefits. Thus, the sole 'active' ingredient in the Products, Vitamin E, does not work as represented by Pharmavite in that it does not help maintain a healthy heart. Pharmavite's heart health representation is false, misleading, and reasonably likely to deceive the public."); 12 ("The Vitamin E 400 I.U. Plaintiff Bradach purchased did not and could not help maintain his heart health as represented because, as discussed herein, the vast weight of scientific

[2] The FDCA "already subjects all food claims, including structure/function claims on dietary supplements, to [a] 'truthful and non-misleading' standard." *See* 65 Fed. Reg. 100-01 at 1003.

evidence and the consensus in the scientific community is that Vitamin E supplements do not provide any heart health benefits.");[3] 16 ("Pharmavite's heart health representation is false, misleading and deceptive.").) Thus, as a whole and for purposes of this Motion for Judgment on the Pleadings, the TAC sets forth allegations that at least plausibly characterize the Statement as a false structure/function claim. Such claims are not preempted.

B. Do Plaintiffs Sufficiently Plead that the Statement Is a False Structure/Function Claim?

"[S]tructure/function claims cannot be proved false by pointing only to evidence of a product's ability to treat or prevent disease." *Gallagher v. Bayer AG*, 2015 WL 4932292, at *4 (N.D. Cal. Aug. 18, 2015) ("*Gallagher II*"). Defendant argues that the scientific studies included in the TAC only show "that vitamin E does not prevent heart disease," which can only support a false disease claim theory and accordingly cannot support a false structure/function claim theory. (*See* Reply at 11-12); *see also Gallagher II*, 2015 WL 4932292, at *4 (noting that, to sufficiently state a false structure/function claim, a plaintiff must "explicitly plead—with support to scientific evidence—that [the defendant's claims] are false as structure/function claims").

The TAC presents several scientific studies to support its claims. While some of these studies appear to

[3] The TAC alleges similar claims for Plaintiff Corbett.

simply discuss vitamin E's effect on cardiovascular disease, others seem to suggest that vitamin E might actually harm the heart. (*See, e.g.*, TAC ¶¶ 24 (citing the Lonn, et al. study, which concludes that "long-term Vitamin E supplementation does not prevent cardiovascular events, and in fact, may increase the risk for heart failure"); 25 (citing multiple meta-analyses that have concluded that "people who take a dosage of 15mgs or more of Vitamin E supplements are more likely to die than those taking a placebo"); 27 (citing the expert report of Dr. Miller, which indicates that there is "an increased risk of mortality associated with high dose vitamin E supplementation (>400 UI) reported in two-meta analyses of all trials combined").) Studies showing that vitamin E harms the heart support the assertion that the structure/function Statement "Helps Maintain a Healthy Heart" is false. A vitamin cannot logically help maintain a healthy heart if it actively damages the heart. *See Gallagher II*, 2015 WL 4932292, at *5 (reasoning that studies that included "some indications that vitamin supplements actually harm heart health" were " inconsistent with [the defendant's] claim that its products support heart health"). Assuming the truth of these studies for the purposes of this Motion and drawing all inferences in Plaintiffs' favor, these studies "make it not only 'possible,' but 'plausible' that [vitamin E] do[es] not improve heart health more generally." *Id.* Thus, Plaintiffs have sufficiently stated a false structure/function claim at this stage.

V. Conclusion

For purposes of this Motion, Plaintiffs have plausibly pled that Defendant's "Helps Maintain a Healthy Heart" Statement is a false structure/function claim. Plaintiffs' state law claims are therefore not preempted by the FDCA, and Defendant's Motion for Judgment on the pleadings is **DENIED**.[4]

As discovery for both Plaintiff Bradach and Plaintiff Corbett is complete for purposes of class certification, we hereby **ORDER** the Parties to meet and confer, in accordance with Local Rule 7-3, regarding the class certification motion. Should Plaintiffs elect to file a class certification motion, they **SHALL** do so no later than **February 8, 2016**. Any class certification motion **SHALL** fully comply with the Federal Rules of Civil Procedure and the Local Rules. After ruling on the class certification motion, we will set a status conference to schedule additional proceedings.

IT IS SO ORDERED.

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[4] Because the Parties' requests for judicial notice are unnecessary for our resolution of this Motion, these requests are **DENIED**. *See Rizzo v. Ins. Co. of State of Pa.*, 969 F. Supp. 2d 1180, 1186 n.1 (C.D. Cal. 2013) ("The Court also declines to consider both parties' most recent requests for judicial notice as the documents submitted are unnecessary to the Court's analysis.").

APPENDIX E

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NOAH BRADACH, On Behalf of Himself and All Others Similarly Situated, Plaintiff-Appellant, v. PHARMAVITE, LLC, Defendant-Appellee.	No. 16-56598 D.C. No. 2:14-cv-03218-GHK-AGR Central District of California, Los Angeles ORDER (Filed Jul. 10, 2018)

Before: BEA and MURGUIA, Circuit Judges, and KEELEY,* District Judge.

The panel has voted to deny the petition for panel rehearing. Judges Bea and Murguia voted to deny the petition for rehearing en banc, and Judge Keeley recommended denying the petition for rehearing en banc.

The full court has been advised of the petition for rehearing and rehearing en banc and no judge has requested a vote on whether to rehear the matter en banc. Fed. R. App. P. 35.

The petition for panel rehearing and the petition for rehearing en banc are DENIED (Docs. 33, 34).

* The Honorable Irene M. Keeley, United States District Judge for the Northern District of West Virginia, sitting by designation.