No. _____

In The
Supreme Court of the United States

PHARMAVITE LLC,

Petitioner,

v.

NOAH BRADACH, on behalf of himself and all others similarly situated,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

PETITION FOR WRIT OF CERTIORARI

DANIEL J. CONNOLLY
FAEGRE BAKER DANIELS LLP
2220 Wells Fargo Center
90 South Seventh Street
Minneapolis, MN 55402-3901
(612) 940-9453
Daniel.Connolly@FaegreBD.com

Counsel of Record for Petitioner

COCKLE LEGAL BRIEFS (800) 225-6964
WWW.COCKLELEGALBRIEFS.COM

QUESTIONS PRESENTED

1. Is it a violation of the Supremacy Clause, U.S. CONST. art. VI, cl. 2, for a federal court to certify a class that includes class members asserting state law claims that are expressly preempted by federal statute, where the question of preemption cannot be determined for the class as a whole?

2. Is it a violation of the Supremacy Clause, U.S. CONST. art. VI, cl. 2, for a federal court to certify a class that includes class members asserting state law false labeling claims that are expressly preempted by federal statute, if the federal court does not require individual inquiry into the interpretation of or reliance on the challenged label to determine whether each member's claim is preempted?

3. To avoid violating the Supremacy Clause, U.S. CONST. art. VI, cl. 2, is it necessary to require inquiry into individual class members' interpretation of or reliance on a label statement alleged to be false under state law to determine whether each class member's claims are expressly preempted by federal statute, even if the causation/reliance element of the state claims may be determined on a class-wide basis, without individual inquiry into each class member's reliance on the challenged label?

PARTIES TO THE PROCEEDING AND RULE 29.6 STATEMENT

The Petitioner is Pharmavite LLC, who was Defendant-Appellee below. Pharmavite LLC is owned 100% by Otsuka America, Inc. Otsuka America, Inc. is owned 100% by Otsuka Pharmaceutical Co., Ltd., which is owned 100% by Otsuka Holdings Co., Ltd., a public company.

The Respondent is Noah Bradach, who was Plaintiff-Appellant below. Noah Bradach is an individual, and asserts claims on behalf of himself and others similarly situated.

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The U.S. District Court for the Central District of California denied class certification by unpublished order entered on July 6, 2016. (Attached hereto as Appendix B).

The district court also dismissed Noah Bradach's individual claims as preempted by unpublished order dated August 25, 2016. Although not the subject of this Petition, because this order is cited herein, it is attached hereto as Appendix C.

In a decision that also is not the subject of this Petition (but is cited herein), the district court denied a motion for judgment on the pleadings on December 22, 2015. (Attached hereto as Appendix D).

The Ninth Circuit Court of Appeals reversed and remanded the class certification order and the order dismissing Bradach's individual claims in an unpublished opinion entered on May 17, 2018. (Attached hereto as Appendix A).

The unpublished Order of the Ninth Circuit Court of Appeals denying the timely Petitions for Panel Rehearing and for Rehearing En Banc was entered on July 10, 2018. (Attached hereto as Appendix E).

JURISDICTION

The Ninth Circuit Court of Appeals filed its opinion reversing the district court's denial of class

certification on May 17, 2018 (Appendix A), and on July 10, 2018, filed its opinion denying the timely Petitions for Rehearing En Banc and Panel Rehearing (Appendix E).

This Court has jurisdiction under 28 U.S.C. § 1254(1) to review the Ninth Circuit's decision on a writ of certiorari.

STATUTORY AND REGULATORY PROVISIONS AT ISSUE

1. The Supremacy Clause of the U.S. Constitution, U.S. CONST. art. VI, cl. 2, provides:

> This Constitution, and the laws of the United States which shall be made in pursuance thereof; and all treaties made, or which shall be made, under the authority of the United States, shall be the supreme law of the land; and the judges in every state shall be bound thereby, anything in the Constitution or laws of any State to the contrary notwithstanding.

2. The preemption clause of the Nutrition Labeling and Education Act, 21 U.S.C. § 343 (2012), which amended the Food, Drug, and Cosmetic Act 21 U.S.C. §§ 301–399, provides in pertinent part (at 21 U.S.C. § 343–1(a)(2)):

> National uniform nutrition labeling.
>
> * * *

> . . . [N]o State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food[1] in interstate commerce—
>
> * * *
>
> (2) any requirement for the labeling of food of the type required by [21 U.S.C.] section 343(c), 343(e), 343(i)(2), 343(w), or 343(x) . . . that is not identical to the requirement of such section. . . .

3. The regulations thereunder, 21 C.F.R. § 100.1(c)(4), provide in relevant part:

> "[N]ot identical to" . . . means that the State requirement directly or indirectly imposes obligations or contains provisions concerning the . . . labeling of food . . . that:
>
> (i) Are not imposed by or contained in the applicable provision (including any implementing regulation) of [21 U.S.C. § 343]; or
>
> (ii) Differ from those specifically imposed by or contained in the applicable provision (including any implementing regulation) of [21 U.S.C. § 343].

4. The structure/function provisions of the Nutrition Labeling and Education Act, 21 U.S.C. § 343 (2012), which amended the Food, Drug, and Cosmetic

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[1] The Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(ff), provides that "a dietary supplement shall be deemed to be a food within the meaning of this Act."

Act, 21 U.S.C. §§ 301–399, provide in pertinent part (at 21 U.S.C. § 343(r)(6)):

> (6) For purposes of paragraph (r)(1)(B), a statement for a dietary supplement may be made if—
>
> > (A) the statement . . . describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, . . .
> >
> > (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."
> >
> > > A statement under this subparagraph may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. . . .

5. The regulations thereunder, 21 C.F.R. § 101.93, provide:

> Sec. 101.93 Certain types of statements for dietary supplements.
>
> * * *

> (f) *Permitted structure/function statements.* Dietary supplement labels or labeling may . . . bear statements that describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans . . . provided that such statements are not disease claims under paragraph (g) of this section. If the label or labeling of a product marketed as a dietary supplement bears a disease claim as defined in paragraph (g) of this section, the product will be subject to regulation as a drug unless the claim is an authorized health claim for which the product qualifies.
>
> (g) *Disease claims.* . . .
>
> > (2) FDA will find that a statement about a product claims to diagnose, mitigate, treat, cure, or prevent disease (other than a classical nutrient deficiency disease) under 21 U.S.C. 343(r)(6) if it meets one or more of the criteria listed below. These criteria are not intended to classify as disease claims statements that refer to the ability of a product to maintain healthy structure or function, unless the statement implies disease prevention or treatment. . . .

6. Federal Rule of Civil Procedure Rule 23(b)(3) provides, in pertinent part:

> (b) TYPES OF CLASS ACTIONS. A class action may be maintained if Rule 23(a) is satisfied and if:
>
> * * *

> (3) the court finds that the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy. . . .

STATEMENT OF THE CASE

Wanting to protect himself from heart disease, plaintiff Noah Bradach alleges he purchased Nature-Made® brand vitamin E, which is manufactured and sold by defendant Pharmavite LLC ("Pharmavite"). Bradach claims that he bought the vitamin in reliance upon one of the several statements on the product's label—"Helps Maintain a Healthy Heart"—which Bradach interpreted to mean "prevents heart disease." Shortly after making his purchase, Bradach's attorney (from a different case in which Bradach was the named plaintiff in a putative class action) informed Bradach that vitamin E purportedly does not prevent heart disease. Bradach, accordingly, filed a putative class action alleging that Pharmavite violated two California statutes—the Consumer Legal Remedies Act, California Civil Code §§ 1750 *et seq*. ("CLRA"), and the Unfair Competition Law, California Business and Professions Code §§ 17200 *et seq*. ("UCL")—by including the allegedly false statement on its vitamin E labels.

Pharmavite's vitamin labels are subject to the comprehensive requirements of the Food, Drug and

Cosmetic Act, 21 U.S.C. §§ 301–399 ("FDCA"), as amended by the Nutrition Labeling and Education Act, 21 U.S.C. § 343 ("NLEA"), as well as the regulations issued thereunder by the federal Food and Drug Administration ("FDA"). The NLEA expressly preempts state laws that impose labeling requirements different from or in addition to the requirements set forth in the FDCA/NLEA and the implementing regulations. 21 U.S.C. § 343–1(a)(5); *see also* 21 C.F.R. § 100.1(c)(4).

The NLEA and governing regulations distinguish between two types of statements, or claims, on vitamin labels: "disease" claims and "structure/function" claims. A disease claim is one that explicitly or implicitly claims to mitigate, treat, cure, or prevent disease. 21 U.S.C. § 343(r)(6); 21 C.F.R. § 101.93(g)(2). A structure/function claim is one that does not claim to mitigate, treat, cure, or prevent disease, but instead describes the ways in which a nutrient or dietary ingredient affects the structure or the function of the human body or a part thereof. 21 U.S.C. § 343(r)(6)(A); 21 C.F.R. § 101.93(f). By definition, disease claims and structure/function claims are mutually exclusive; a label claim can be one or the other, but not both.

"Helps maintain a healthy heart" is a structure/function claim, as Bradach and Pharmavite both agree. As such, it does not imply that vitamin E can prevent, treat, cure, or mitigate heart disease. The FDA, in its guidance for manufacturers, offers similar statements as examples of structure/function claims, including: "helps maintain cardiovascular function and a healthy

circulatory system." 65 FR 1000 at 1012.[2] Manufacturers may include structure/function claims on vitamin labels so long as the manufacturer has substantiation that the vitamin provides a benefit to the function or the structure of the body part or system at issue. 21 U.S.C. § 343(r)(6)(C). Pharmavite has substantiation that vitamin E benefits the function and structure of the heart.[3] It thus included the structure/function claim "helps maintain a healthy heart" on its vitamin E labels.[4]

In a decision not appealed, the U.S. District Court for the Central District of California held in this case that, in light of the NLEA's express preemption of state laws' imposition of labeling requirements different

[2] Another FDA example of a structure/function claim is: "supports the cardiovascular system by inhibiting leukotriene and thromboxane synthesis, substances associated with platelet aggregation." 65 FR 1000 at 1030.

[3] Among other things, as Pharmavite's experts explained in their reports filed with the district court, vitamin E is an antioxidant that protects the heart from damage by free radicals; reduces inflammation (essential to the maintenance of the arteries that carry blood to the heart); inhibits an enzyme involved in cell growth and differentiation (a process important to the functioning of vascular smooth muscle cells); helps suppress genes that cause blood cell components to bind to the wall of blood vessels; modulates enzymes that promote blood vessel expansion; and modulates other enzymes in a manner that discourages blood platelets from aggregating in clumps.

[4] Pharmavite at all times has also included the following statement on all of the NatureMade vitamin E labels, as required by 21 U.S.C. § 343(r)(6)(C): "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)(C).

from or in addition to the requirements of the FDCA/NLEA and implementing regulations, because "helps maintain a healthy heart" is a structure/function claim and not a disease claim, it can violate the CLRA and UCL only if "helps maintain a healthy heart" is false *as a structure/function claim—i.e.*, if vitamin E does not help maintain the function or structure of the heart, regardless of whether vitamin E can prevent heart disease. (Appendix D at pp. App.40–App.41). The district court held that using a "disease claim characterization" of the challenged label claim "helps maintain a healthy heart" in a CLRA or UCL claim "would effectively impart requirements onto the structure/function claim that are inconsistent with the FDCA's provisions," and "Plaintiffs' state law claims would be preempted under the NLEA's express preemption provision." (*Id.*).

Following this decision, Bradach moved under Rule 23 of the Federal Rules of Civil Procedure for an order certifying a nationwide and/or California class of NatureMade vitamin E consumers asserting claims under the CLRA and UCL. The district court denied Bradach's motion on the ground, *inter alia*, that "[w]hether 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," which will require "an individualized inquiry into each consumer's interpretation" of the label "to determine whether each consumer has non-preempted claims. Such individualized inquiries would predominate over

any other issues common to the class." (Appendix B at p. App.20). "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." (*Id*. at p. App.15).

The Ninth Circuit reversed, holding that "the district court's conclusion that it would need to inquire into the motives of each individual class member" to determine if each was asserting a claim expressly preempted by federal statute "was premised on an error of law." (Appendix A at p. App.6). Relying on a decision by the California Supreme Court which considered only non-preempted claims (because the preempted claims were stripped out of the case before the decision was rendered), the Ninth Circuit stated that California courts allow the causation element of CLRA and UCL claims to be satisfied for the entire class by showing that "members of the public are likely to be deceived"; to prove causation, individual inquiries are not required to determine whether each class member relied on the challenged statement in making his or her purchase. (Appendix A at pp. App.6–App.7, citing *Kasky v. Nike, Inc.*, 27 Cal. 4th 939, 951 (2002), *as modified* (May 22, 2002), and *In re Tobacco II Cases*, 46 Cal. 4th 298, 312 (2009)). Accordingly, and even though the *Tobacco II* decision was made after the preempted claims were stripped out of the case (and the *Kasky* decision did not involve preempted claims), the Ninth Circuit extrapolated that no similar inquiry

should be required to determine whether any individual class member is asserting a claim expressly preempted by federal statute in violation of the Supremacy Clause of the U.S. Constitution. (Appendix A at pp. App.6–App.7).[5]

REASONS FOR GRANTING THE PETITION

In light of the growing number of false labeling class actions that have been filed in recent years, the Court's review is warranted to settle the important question of federal law: is it a violation of the Supremacy Clause, U.S. CONST. art. VI, cl. 2, for a federal court to certify a class that includes class members asserting state law claims that are expressly preempted by federal statute, where the question of preemption cannot be determined for the class as a whole?

[5] In a decision not appealed here, the Ninth Circuit also reversed the district court's dismissal of Bradach's personal claims. (Appendix A at pp. App.4–App.5). The district court dismissed Bradach's claims based on his discovery responses and testimony that he purchased NatureMade vitamin E because he believed the challenged label statement meant that the vitamin E would prevent heart disease. (Appendix C). Bradach testified that he bought the vitamin E for this purpose and this purpose only, and that he would not have bought the vitamin E if he had known that it would not prevent heart disease. Citing no evidence, the Ninth Circuit concluded that Bradach had "mixed motives" in buying the vitamin E: he believed it would prevent heart disease and also believed that it would help maintain his healthy heart in ways unrelated to heart disease. (Appendix A at pp. App.4–App.5). Based on this finding, the Ninth Circuit concluded that "Bradach's claims were not preempted." (*Id.*).

Review is warranted to enforce the Supremacy Clause of the U.S. Constitution and confirm that there is no exception thereto allowing absent class members to assert state law claims that are expressly preempted by federal statute, even where such claims may not be asserted by named plaintiffs. The Ninth Circuit decision violates the Supremacy Clause.

A. The Supremacy Clause precludes state law claims that are preempted by federal law.

The Supremacy Clause of the United States Constitution empowers Congress to enact legislation that preempts state law. *See Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 211 (1824) ("In every such case, the act of Congress, or the treaty, is supreme; and the law of the State, though enacted in the exercise of powers not controverted, must yield to it."); *Law v. General Motors Corp.*, 114 F.3d 908, 909 (9th Cir. 1997) ("The Supremacy Clause empowers Congress to supplant decentralized, state-by-state regulation with uniform national rules.").

Federal law can preempt state law by express statutory command. *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383, 119 L. Ed. 2d 157, 112 S. Ct. 2031 (1992). In the FDCA and the NLEA, Congress created a comprehensive scheme for the regulation and oversight of food, vitamin, and supplement products, including the uniform national labeling of such products. As the Ninth Circuit acknowledged in this case, the FDCA/NLEA expressly preempts "application of state

laws [which] would impose more or inconsistent burdens on manufacturers than the burdens imposed by the FDCA." (Appendix A at p. App.3, citing *Gallagher v. Bayer AG*, No. 14-cv-04601-WHO, 2015 WL 1056480, at *3–7 (N.D. Cal. Mar. 10, 2015)).

The Seventh Circuit explained the reason for the FDCA/NLEA's uniform labeling rules and express preemption of differing state rules:

> It is easy to see why Congress would not want to allow states to impose disclosure requirements of their own on packaged food products, most of which are sold nationwide. Manufacturers might have to print 50 different labels, driving consumers who buy food products in more than one state crazy.

Turek v. General Mills, Inc., 662 F.3d 423, 426 (7th Cir. 2011).

Because the FDCA/NLEA and regulations thereunder define and regulate structure/function claims as mutually exclusive from disease claims, trying to impose disease claim standards on a structure/function claim under California's CLRA or UCL—including by interpreting a structure/function claim to be an implied-disease-prevention claim and alleging injury under the CLRA and UCL because the vitamin purportedly does not prevent disease—runs directly afoul of the FDCA/NLEA's express preemption provision. As the district court held, and as the Ninth Circuit did not dispute, "any legal claim based on a false disease characterization of the ["help maintain a healthy heart"]

Statement—*i.e.,* that the Statement is false because Pharmavite's vitamin E supplements do not prevent or cure heart disease—is preempted." (Appendix C at p. App.28). This is because a "false disease claim characterization" of the structure/function claim "helps maintain a healthy heart" "would effectively impart requirements onto the structure/function claim that are inconsistent with the FDCA's provisions." (Appendix D at p. App.41).

B. The Supremacy Clause of the U.S. Constitution does not permit individuals to recover on preempted claims merely because they are absent class members.

For nearly 200 years, it has been the law of this Court that an act of Congress preempting state laws "is supreme; and the law of the State, though enacted in the exercise of powers not controverted, must yield to it." *Gibbons*, 22 U.S. at 211. There is no exception to the Supremacy Clause allowing preempted state law claims to be asserted by absent class members.

In this case, without regard for the Supremacy Clause, the Ninth Circuit opined 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" to prove the element of causation/reliance. (Appendix A at p. App.6). Rather, the "standard in actions under both the CLRA and UCL is whether 'members of the public are likely to be deceived.'" (*Id*., citing *Kasky v. Nike,*

Inc., 27 Cal. 4th 939, 951 (2002), *as modified* (May 22, 2002)).

However, the fact that state courts have obviated the need for individual inquiries to prove an element of a state law claim in situations where no preempted claims are being asserted by absent class members is of no relevance to whether absent class members may assert state law claims that are expressly preempted by federal statute. The Ninth Circuit's reversal of the district court's order denying class certification failed to recognize that the Supremacy Clause requires a determination as to whether each class member's claims are preempted, which would require individual inquiries into issues of interpretation. All of this is in direct violation of both the Supremacy Clause of the U.S. Constitution and Rule 23 of the Federal Rules of Civil Procedure.

In holding that individual inquiry is not required to determine whether class members' claims are expressly preempted by federal statute, the Ninth Circuit relied on the California Supreme Court's decision in *In re Tobacco II Cases*, 46 Cal. 4th 298, 312 (2009), that individual class members are not required to prove reliance in UCL cases. (Appendix A at p. App.6). In *In re Tobacco II Cases*, however, the California Supreme Court did not hold—and could not have held without violating the Supremacy Clause—that absent class members can assert preempted claims. Preemption was not at issue at that stage of the case.

Earlier in the same case, the California Supreme Court explicitly acknowledged the limitation imposed by the Supremacy Clause on whether, and to what extent, absent class members could recover under the UCL. Before the dispute resolved by the 2009 decision ever got to the Supreme Court, the California Supreme Court first affirmed summary adjudication of the UCL claims of those plaintiffs that were preempted by federal law. *See In re Tobacco II Cases*, 46 Cal. 4th 298, 310, fn.5 (2009) ("allegations within the UCL cause of action that pertained to defendants' targeting of minors in advertising were struck as preempted by federal law"), citing *In re Tobacco II Cases*, 41 Cal. 4th 1257, 1262, 63 Cal.Rptr.3d 418, 163 P.3d 106 (2007); *see also In re Tobacco II Cases*, 41 Cal. 4th at 1275–76 (UCL claims could not proceed to the extent preempted by federal law). Accordingly, in the 2009 decision cited by the Ninth Circuit, the California Supreme Court did not have before it the situation presented in this case: where some, but not all, absent class members want to recover on claims expressly preempted by federal law. The California Supreme Court decision in 2009 on which the Ninth Circuit relied thus did not allow preempted claims by absent class members, and the 2007 and 2009 decisions by the California Supreme Court acknowledge that such claims could not proceed. Because of that, in the 2009 decision (where preempted claims were no longer in issue), the court did not have to confront the same issues of predominance, commonality, superiority, and manageability as are present

here as a result of the preempted claims by absent class members.[6]

C. Class certification should not be permitted in federal court where the issue of preemption cannot be determined on a class-wide basis.

Rule 23 of the Federal Rules of Civil Procedure provides that a class may be certified only where "the questions of law or fact common to class members predominate over any questions affecting only individual members." Fed.R.Civ.P. 23(b)(3).

Predominance "tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation." *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 623 (1997). When, for example, a determination as to whether class members' claims are preempted "can be resolved on a class-wide basis without any individualized inquiries," there is no bar to class certification. *Ward v. United Airlines, Inc.*, No. C 15-02309 WHA, 2016 U.S. Dist. LEXIS 38896, at *16 (N.D. Cal. Mar. 23, 2016). Instead, as the *Ward* court summarized:

> The possibility that the putative class may lose on preemption or constitutional grounds does not preclude certification of the class. "A common contention need not be one that will be answered, on the merits, in favor of the

[6] The other case cited by the Ninth Circuit, *Tait v. BSH Home Appliances Corp.*, 289 F.R.D. 466, 480 (C.D. Cal. Dec. 20, 2012), similarly did not raise issues of preemption.

> class. It only must be of such a nature that it is capable of classwide *resolution*."

Ward, 2016 U.S. Dist. LEXIS 38896, at *16 (quoting *Alcantar v. Hobart Services*, 800 F.3d 1047, 1053 (9th 2015).

The Ninth Circuit's violation of the Supremacy Clause cannot be rectified by trying to segregate the preempted from the non-preempted claims. In this case, the issue of preemption cannot be determined on a class-wide basis because, as the Ninth Circuit and district court both recognized, whether a class member's state law claim is preempted depends on how he or she understood the "Helps Maintain A Healthy Heart" statement on the label. That is, in finding that Bradach had "mixed motives" for buying the Nature-Made vitamin E because he purportedly purchased it (i) to prevent heart disease and (ii) to maintain his healthy heart, the Ninth Circuit confirmed that a plaintiff's "understanding" of the challenged label statement and "motive" for buying the product will determine whether the plaintiff's state law claim is expressly preempted. The Ninth Circuit opined that where a plaintiff's state claims are "based on mixed motives" for purchasing the product, the "claims arising in part from non-preempted motives [can] move forward." (Appendix A at p. App.5). Conversely, claims arising solely from preempted motives—*i.e.*, state law claims premised on characterizing a structure/function claim as an implied disease prevention claim—are expressly preempted by the NLEA because they impart requirements inconsistent with the federal statutes

and governing regulations. The Ninth Circuit's holding that such individualized inquiries are not required to determine whether claims are preempted because they are not required to prove an element of the claims is erroneous.

As the district court correctly found, "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." (Appendix B at p. App.20).

As numerous district courts have similarly held, class certification in inappropriate where individual inquiries would be required to determine whether class members' claims are preempted. For example, in *Sellers v. Rushmore Loan Mgmt. Servs., LLC*, 2017 U.S. Dist. LEXIS 203736 (M.D. Fla. Dec. 12, 2017), the court noted that individualized inquiries had been required on summary judgment to analyze the viability of the named plaintiffs' claims, including whether the claims were preempted by the Bankruptcy Code. *Id*. at **9–10. Thus, the court concluded, "if the Court certified Plaintiffs' proposed class, such individualized inquiries would be required for every class member to determine whether . . . the Bankruptcy Code precluded and/or preempted the [claims]. Such a course of action—which Plaintiffs' proposed class definition mandates—is the type of extensive individualized factual inquiry that is too burdensome to allow class certification." *Id*. (footnote omitted).

Similarly, in *Cima v. WellPoint Health Networks, Inc.*, 250 F.R.D. 374, 383–84 (S.D. Ill. 2008), the court noted that it would be presented with the question whether the putative class members' state law claims "with respect to the group insurance plans in the class are preempted by federal laws," and concluded that, "given that the claims of the proposed class in this case likely are honeycombed with issues of ERISA preemption, the Court finds that predominance and manageability are not satisfied."

Likewise, in *Gawry v. Countrywide Home Loans, Inc.*, 640 F. Supp. 2d 942, 953 (E.D. Ohio 2009), the court denied class certification in part because the defendant planned to raise as a defense that two federal bank and loan statutes preempt the claims of the putative class. The court held that it "necessarily will have to delve into the specific details of each individual transaction" to determine whether preemption is applicable; this "fact-driven individualized inquiry . . . obviously runs contrary to the class action purpose of utilizing common evidence to efficiently adjudicate disputes," and "weighs against class certification." *Id*. at 954. *See also Lazaroff v. Blue Cross & Blue Shield of Conn., Inc.*, 1989 U.S. Dist. LEXIS 19175, **10–11, 1989 WL 235958 (D.Conn. Jan. 11, 1989) (declining to certify a class where some members "may have claims that are preempted by ERISA" and others may have claims that are not preempted).

The Ninth Circuit's failure to similarly recognize that the individual inquiry needed to determine whether putative class members' claims are

preempted renders certification improper under Rule 23(b)(3) demonstrates the need for a definitive and binding ruling by this Court.

CONCLUSION

For the foregoing reasons, this Court is requested to issue a writ of certiorari to the Court of Appeals for the Ninth Circuit.

Respectfully submitted,

DANIEL J. CONNOLLY
FAEGRE BAKER DANIELS LLP
2220 Wells Fargo Center
90 South Seventh Street
Minneapolis, MN 55402-3901
(612) 940-9453
Daniel.Connolly@FaegreBD.com