UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

JAMES KROESSLER, individually and on behalf of all others similarly situated,

Plaintiff,

v.

CVS HEALTH CORPORATION,

Defendant.

Case No.: 19-CV-277-CAB-JLB

ORDER GRANTING DEFENDANT'S MOTION TO DISMISS AND DENYING DEFENDANT'S MOTION TO STRIKE AS MOOT

[Doc. Nos. 9, 10]

This matter comes before the Court on Defendant's motion to dismiss and motion to strike. [Doc. Nos. 9, 10.] The motions have been fully briefed and the Court finds them suitable for determination on the papers and without oral argument. *See* S.D. Cal. CivLR 7.1(d)(1). For the reasons set forth below, Defendant's motion to dismiss [Doc. No. 9] is granted and Defendant's motion to strike [Doc. No. 10] is denied as moot.

I. BACKGROUND

Plaintiff James Kroessler filed a putative consumer class action complaint against Defendant CVS Health Corporation on February 7, 2019, alleging false and misleading advertising of Defendant's CVS Health glucosamine joint health products. [Doc. No. 1 at ¶ 1.] The complaint alleges violations of California's Unfair Competition Law, California Business & Professions Code § 17200, *et. seq*. ("UCL"); California's Consumer Legal

Remedies Act, California Civil Code § 1750, *et. seq*. ("CLRA"); and Breach of Express Warranty. [*Id.* at ¶¶ 96–131.[1]]

Defendant markets, sells, and distributes its line of CVS Health Glucosamine Products (the "Products").[2] [*Id.* at ¶ 2.] The complaint alleges that Defendant represents through the Products' labeling, packaging, and other advertising, that the Products provide "JOINT HEALTH," "assist[] with joint pain, flexibility and mobility," provide "improved joint comfort," increase "range of motion," "strengthen joints," "support flexibility," and "support mobility." [*Id.* at ¶ 3.] Plaintiff contends these statements are designed to induce consumers to believe that Defendant's Products provide meaningful joint health benefits. According to Plaintiff, however, the Products do not support or benefit the health of human joints because glucosamine, the primary ingredient[3] in each of the Products, either alone or in combination with other ingredients, is not effective at supporting or benefitting joint health. [*Id.* at ¶¶ 4–5.]

Plaintiff alleges in his complaint that he "was exposed to and saw Defendant's representations by reading [the Glucosamine Chondroitin Tablets product] label." [*Id.* at ¶ 11.] The label for the Glucosamine Chondroitin Tablets includes the following representations: "JOINT HEALTH," "Supports flexibility & range of motion," "Glucosamine and Chondroitin help support and maintain the structure of joints," "Glucosamine and Chondroitin work to support joint comfort while helping to promote joint mobility," (the "Representations").[4] [Doc. No. 1-2 at 2.]

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[1] Document numbers and page references are to those assigned by CM/ECF for the docket entry.

[2] The CVS Health Glucosamine products at issue include the following variations: (1) CVS Health Glucosamine Chondroitin Tablets; (2) CVS Health Glucosamine Chondroitin Capsules; (3) CVS Health Glucosamine Maximum Strength Tablets; (4) CVS Health Glucosamine MSM Caplets; (5) CVS Health Glucosamine Chondroitin with MSM Tablets; (6) CVS Health Glucosamine Chondroitin with Vitamin D Caplets. [*Id.* at ¶ 14.]

[3] Each of the CVS Health Glucosamine Products contains 1500mg of glucosamine. However, some of the Products in issue contain other primary ingredients in combination with glucosamine. [Doc. No. 1 at ¶¶ 15–16; Doc. No. 1 at note 1–6.]

[4] For purposes of this Order, the Representations are only in reference to the statements on the Glucosamine Chondroitin Tablets product that Plaintiff viewed and relied upon.

Attached to Plaintiff's complaint are images of the other five products' labels. [Doc. No. 1-2 at 1–7.] The label for the Glucosamine Chondroitin Capsules includes: "SUPPORTS JOINT FLEXIBILITY & MOBILITY," "Promotes healthy joint structure & function," "Glucosamine . . . supports cartilage, ligaments, tendons, bones, eyes, nails, and heart valves," "Chondroitin helps maintain healthy joint flexibility and lubrication." [Doc. No. 1-2 at 3.] The label for the Glucosamine Maximum Strength Tablets includes: "JOINT HEALTH," "Nourishes cartilage and promotes comfortable joint movement," "Supplementing with Glucosamine can support flexibility and comfort with joint movement." [*Id.* at 4.] The label for the Glucosamine MSM Caplets includes: "JOINT HEALTH," "Supports cartilage health & joint comfort," "Glucosamine + MSM is an effective supplement combination that helps support maximum flexibility, range of motion and joint health," "Together, this duo promotes healthy cartilage and collagen development to support fluid joint movement." [*Id.* at 5.] The label for Glucosamine Chondroitin with MSM Tablets includes: "JOINT HEALTH," "Supports healthy cartilage & joint comfort," "Glucosamine Chondroitin with MSM helps to support and maintain joint function." [*Id.* at 6.] The label for Glucosamine Chondroitin with Vitamin D Caplets includes: "JOINT HEALTH," "Supports flexibility & range of motion with added bone support," "This triple strength product gives you more value added supplementation for supporting joint health," "As an essential nutrient, Vitamin D supports proper bone health." [*Id.* at 7.] Each product also states that individual results may vary and includes a disclaimer that the product is not intended to diagnose, treat, cure, or prevent any disease. [*Id.* at 1–7.]

Plaintiff alleges that on or around March 15, 2017, at a CVS retail store in El Cajon, California, he purchased the CVS Health Glucosamine Chondroitin Tablets product in reliance on the representations made by Defendant on that specific product's label. [Doc. No. 1 at ¶ 11.] Plaintiff contends that the product he purchased, like all of the Products at issue, do not provide the promised, advertised benefits. [*Id.*] Had he known the truth about Defendant's alleged misrepresentations and omissions at the time of purchase, Plaintiff asserts he would not have purchased the product. [*Id.*]

Further, the complaint alleges Defendant expressly and impliedly advertises that the Products treat and provide relief from symptoms of osteoarthritis, including joint pain and joint stiffness. [*Id.* at ¶ 19.] Plaintiff contends the front labeling for each of the Products is materially identical and communicates the same advertising message of joint health benefits. [*Id.* at ¶¶ 22.] In support of his allegations, Plaintiff cites to numerous clinical trials and studies which he alleges demonstrate that the Products' primary ingredients, specifically glucosamine, alone or in combination with other ingredients in the Products, are ineffective at supporting or benefiting joint health. [*Id.* at ¶ 28.]

Plaintiff seeks to represent a Multistate Class defined as "[a]ll persons in California and other states with similar laws[5], who purchased any of Defendant's CVS Health Glucosamine Products for personal use between January 19, 2016, and the date notice is disseminated." [*Id.* at ¶ 86.] Plaintiff also seeks to represent a California Senior Class defined as "[a]ll senior citizens who purchased in the state of California any of Defendant's CVS Health Glucosamine Products for personal use between January 19, 2016, and the date notice is disseminated." [*Id.*] In the alternative to the Multistate Class, Plaintiff also seeks to represent a California-Only Class defined as "[a]ll persons who purchased in the state of California any of Defendant's CVS Health Glucosamine Products for personal use between January 19, 2016, and the date notice is disseminated." [*Id.* at ¶ 87.] The complaint's prayer for relief includes, among other things, an order enjoining Defendant from continuing the unlawful practices, requiring Defendant to engage in a "corrective advertising campaign," and an award of restitution, disgorgement, and damages for Plaintiff and the class. [*Id.* at 37.]

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[5] Plaintiff preliminarily avers other states with similar consumer fraud laws under the facts of this case include, but are not limited to: Florida (Fla. Stat. §§ 501.201, *et seq.*); Illinois (815 Ill. Comp. Stat. Ann. §§ 505/1, *et seq.*); Massachusetts (Mass. Gen. Laws Ch. 93A, *et seq.*); Michigan (Mich. Comp. Laws §§ 445.901, *et seq.*); Minnesota (Minn. Stat. §§325F.67, *et seq.*); Missouri (Mo. Rev. Stat. §§ 407.010, *et seq.*); New Jersey (N.J. Stat. §§ 56:8-1, *et seq.*); New York (N.Y. Gen. Bus. Law §§ 349, *et seq.*; and Washington (Wash. Rev. Code §§ 19.86.010, *et seq.*) (collectively, the "Class States").

On March 19, 2019, Defendant moved to dismiss Plaintiff's claims pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6) [Doc. No. 9], and to strike Plaintiff's multistate class claims pursuant to Federal Rule of Civil Procedure Rule 12(f). [Doc. No. 10.] Plaintiff filed his oppositions to the motions [Doc. Nos. 12, 13] on April 9, 2019, and Defendant filed its replies [Doc. Nos. 15, 16] on April 16, 2019. Along with their motions, both parties filed requests for Judicial Notice. [Doc. Nos. 11, 14.]

II. LEGAL STANDARD

A. Motion to Dismiss for Lack of Subject Matter Jurisdiction under Rule 12(b)(1)

Federal Rule of Civil Procedure Rule 12(b)(1) allows a party to move to dismiss based on the court's lack of subject matter jurisdiction. Fed. R. Civ. P. 12(b)(1). Plaintiff has the burden of establishing that the court has subject matter jurisdiction. *Assoc. of Med. Colls. v. U.S.*, 217 F.3d 770, 778–79 (9th Cir. 2000). In a class action at least one of the named plaintiffs must meet the Article III standing requirements. *Bates v. United Parcel Servs., Inc.*, 511 F.3d 974, 985 (9th Cir. 2007). Article III requires that: "(1) at least one named plaintiff suffered an injury in fact, (2) the injury is fairly traceable to the challenged conduct, and (3) the injury is likely to be redressed by a favorable decision." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992) (quotation marks and citations omitted).

B. Motion to Dismiss for Failure to State a Claim under Rule 12(b)(6)

Under Federal Rule of Civil Procedure Rule 12(b)(6), a party may bring a motion to dismiss based on the failure to state a claim upon which relief may be granted. Fed. R. Civ. P. 12(b)(6). A Rule 12(b)(6) motion challenges the sufficiency of a complaint as failing to allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). For purposes of ruling on a Rule 12(b)(6) motion, the court "accept[s] factual allegations in the complaint as true and construe[s] the pleadings in the light most favorable to the nonmoving party." *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008). "[D]ismissal may be based on

either a lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory." *Johnson v. Riverside Healthcare Sys.*, 534 F.3d 1116, 1121 (9th Cir. 2008) (internal quotations and citations omitted).

III. REQUEST FOR JUDICIAL NOTICE

At the motion to dismiss stage a court may consider materials incorporated into the complaint or matters of public record, without converting the motion to dismiss into a motion for summary judgment. *Coto Settlement v. Eisenberg.*, 593 F.3d 1031, 1038 (9th Cir. 2010) (citation omitted); *see also* Federal Rules of Evidence 201(b): "The court may judicially notice a fact that is not subject to reasonable dispute because it: (1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned."

Defendant asks the Court to take judicial notice of eleven exhibits, consisting primarily of its product ingredient lists available on its website and various scientific opinions by the European Food Safety Authority ("EFSA"). Plaintiff asks the Court to take judicial notice of two letters from the U.S. Department of Health & Human Services to dietary supplement manufacturers, both available online. Neither party has opposed the others' request or challenged the documents' authenticity. FRE 201(b)(2). Accordingly, the Court takes judicial notice of both Plaintiff's and Defendant's exhibits.

IV. DISCUSSION

Defendant moves to dismiss on the following grounds: (1) Plaintiff's CLRA and UCL state law claims are preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA") as amended by the Nutrition Labeling and Education Act ("NLEA"); (2) Plaintiff lacks standing to pursue injunctive relief; (3) Plaintiff only purchased one of the six Products identified and therefore lacks standing to assert any claims, including any putative class claims, relating to Products he did not purchase; and (4) the complaint fails to state a claim under the CLRA and UCL because it is not pled with specificity under Federal Rule of Civil Procedure 9(b); Defendant also moves to strike Plaintiff's multistate class allegations because Plaintiff fails to allege sufficient facts connecting non-California

putative class members' claimed injuries to California, and because the multistate class definition violates due process. The Court first addresses whether Plaintiff's claims are expressly preempted under the NLEA and holds that Plaintiff's claims are expressly preempted. Therefore, the Court does not reach Defendant's motion to dismiss on its remaining grounds and Defendant's motion to strike is denied as moot.

A. Preemption under the FDCA as amended by the NLEA

First, Defendant contends Plaintiff's state law false advertising claims are preempted under the FDCA 21 U.S.C. § 301 *et seq*., as amended by the NLEA, 21 U.S.C. § 343 *et seq.* [Doc. No. 9-1 at 18–20.] The NLEA expressly preempts any state law that establishes "any requirement respecting any claim of the type described in section 343(r)(1) of this title made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title." 21 U.S.C. § 343-1(a)(5). The NLEA also provides that no state may "directly or indirectly establish . . . any requirement for the labeling of food that is not identical" to the federal requirements. 21 U.S.C. § 343-1(a)(5). The phrase "not identical to" means "that the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food [that] . . . [a]re not imposed by or contained in the applicable [federal regulation] . . . or [d]iffer from those specifically imposed by or contained in the applicable [federal regulation]." 21 C.F.R. § 100.1(c)(4).

The NLEA distinguishes between "*structure/function claims*" and "*disease claims*" that manufacturers make about their products. A structure/function claim "describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans" or "characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function," but "may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases." 21 U.S.C. § 343(r)(6). A disease claim, conversely, "claims to diagnose, mitigate, treat, cure, or prevent disease," either explicitly or implicitly (such as by claiming that a product treats a disease's "characteristic signs or symptoms"). 21 C.F.R. § 101.93(g)(2)(ii). Structure/function claims must meet three requirements: (1) the manufacturer has

substantiation that the statement is truthful and not misleading; (2) the statement contains a prominent disclaimer that the Food and Drug Administration ("FDA") has not evaluated the statement and that the product "is not intended to diagnose, treat, cure, or prevent any disease"; and (3) the statement itself does not "claim to diagnose, mitigate, treat, cure, or prevent" disease. 21 U.S.C. § 343(r)(6).

Defendant contends that the challenged Representations are all permissible structure/function claims that comply with federal labeling requirements for dietary supplements, meaning Plaintiff's state law false advertising claims are expressly preempted. [Doc. No. 9-1 at 19–20.] Plaintiff counters that (1) the Representations are not proper structure/function claims because they suggest effects on characteristic signs and symptoms of osteoarthritis; and (2) regardless of whether the Representations are structure/function claims or disease claims, the Representations are false and misleading and therefore his state law claims are not inconsistent with the federal requirements. [Doc. No. 13 at 13.] Although the FDCA requires manufacturers to have substantiation for their structure/function claims, California law does not allow private plaintiffs to demand substantiation for advertising claims. *Dachauer v. NBTY, Inc.*, 913 F.3d. 844, 847 (9th Cir. 2019) (citing *Nat'l Council Against Health Fraud, Inc. v. King Bio Pharm., Inc.*, 107 Cal.App.4th 1336, 1344 (2003)).

Defendant relies on the guidance issued by the FDA discussing acceptable structure/function claims and analogizes this case to *Dachauer*. The FDA has published guidance in the Federal Register discussing, among other things, acceptable structure/function claims. *Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body*, 65 Fed. Reg. 1000–01 (Jan. 6, 2000). In relevant part, the FDA states that "'joint pain' is characteristic of arthritis . . . [but] [t]he claim 'helps support cartilage and joint function,' on the other hand, would be a permissible structure/function claim, because it relates to maintaining normal function rather than treating joint pain." *Id.* at 1016–17. "The guidance recognizes that structure/function claims may use general terms such as

'strengthen,' 'improve,' and 'protect,' as long as the claims 'do not suggest disease prevention or treatment.'" *Dachauer*, 913 F.3d. at 847 (*citing* 65 Fed. Reg. at 1028.)

As applied here, the NLEA's preemption provision preempts Plaintiff's CLRA, UCL and breach of express warranty claims. The Representations at issue include: "JOINT HEALTH," "Supports flexibility & range of motion," "Glucosamine and Chondroitin help support and maintain the structure of joints," "Glucosamine and Chondroitin work to support joint comfort while helping to promote joint mobility." Plaintiff alleges Defendant's Representations are improper structure/function claims because they suggest effects on characteristic signs and symptoms of osteoarthritis. Plaintiff contends that the FDA noted that "reduces joint paint" is a disease claim and the FDA has issued warning letters to advertisers of glucosamine supplements who advertise their products will do things like "improve joint mobility." [Doc. No. 13 at 14–15.] However, the Representations do not purport to "reduce" or "improve" anything nor do they mention "joint pain." The Representations do not suggest treatment or prevention of a disease and satisfy the requirements under the NLEA for structure/function claims. Therefore, the Representations are proper structure/function claims according to the federal requirements. *See* 65 Fed. Reg. at 1016–17.

Plaintiff also contends that regardless of whether the Representations are structure/function claims or disease claims, the Representations are false and misleading and therefore his state law claims are not inconsistent with the federal requirements. However, the Ninth Circuit in *Dachauer* held that to the contrary it matters very much. "Plaintiff's argument would vitiate the FDCA's distinction between disease claims and structure/function claims. The FDA allows manufacturers of supplements to make general claims . . . and to substantiate them with evidence that a supplement has some structural or functional effect on a given part of the human body." *Dachauer*, 913 F.3d. at 848 (citing 65 Fed. Reg. at 1012). Unlike in *Dachauer*, where the court held that the NLEA did not preempt plaintiff's claim that the defendant's structure/function claim about immune health was misleading because the supplements *increased* the risk of all-cause mortality, Plaintiff

makes no such claim here. The FDCA regulations state that a food label "shall be deemed to be misleading if it fails to reveal facts" that are "[m]aterial with respect to consequences which may result from use of the article" under normal conditions of use or the conditions of use that the label prescribes. 21 C.F.R. § 1.21(a)(2).

Plaintiff does not argue that Defendant's Representations are false or misleading because Defendant fails to reveal material facts with respect to consequences from taking Defendant's Products. While Plaintiff cites to numerous studies and clinical trials to demonstrate that glucosamine and other primary ingredients in the Products are ineffective at supporting or benefiting joint health, the federal requirements only require that the manufacturer has "substantiation that the statement is truthful and not misleading." 21 U.S.C. § 343(r)(6). The FDCA does not define the term "substantiation," however FDA guidance advances a common sense interpretation of "substantiation," as meaning "competent and reliable scientific evidence." See *Kaufman v. CVS Caremark Corp.*, 836 F.3d 88, 93 (1st Cir. 2016). Plaintiff's citation to studies does not equate to Defendant lacking competent and reliable scientific evidence of its own that establishes the necessary substantiation. Furthermore, California law does not allow private plaintiffs to demand substantiation for advertising claims. *Dachauer*, 913 F.3d. at 847. Plaintiff's breach of express warranty claim is premised on the same theory that the Representations are false and misleading. However, because Defendant's Representations are proper structure/function claims as permitted by the federal requirements, Plaintiff's breach of express warranty claim would also seek to impose state-law requirements that differ from the federal requirements. Accordingly, Plaintiff's state law false advertising claims under the CLRA, UCL, and breach of express warranty are preempted and therefore are **DISMISSED with prejudice**.[6]

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[6] The Court does not find that any amendment to this claim could possibly cure the deficiency. As a general rule, a court freely grants leave to amend a complaint which has been dismissed. Fed.R.Civ.P. 15(a). However, leave to amend may be denied when "the court determines that the allegation of other facts consistent with the challenged pleading could not possibly cure the deficiency." *Schreiber Distrib.*

V. CONCLUSION

For the reasons explained above, Defendant's motion to dismiss [Doc. No. 9] is **GRANTED** and Defendant's motion to strike [Doc. No. 10] is **DENIED as moot**.

It is **SO ORDERED**.

Dated: May 16, 2019

Hon. Cathy Ann Bencivengo
United States District Judge

Co. v. ServWell Furniture Co., Inc., 806 F.2d 1393, 1401 (9th Cir. 1986) (citing *Bonanno v. Thomas*, 309 F.2d 320, 322 (9th Cir. 1962)).