UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

TODD GREENBERG,

Plaintiff,

v.

TARGET CORPORATION, et al.,

Defendants.

Case No. 17-cv-01862-RS

ORDER GRANTING SUMMARY JUDGMENT

I. INTRODUCTION

Plaintiff Todd Greenberg brings this putative class action against Defendants Target Corporation, International Vitamin Corporation, and Perrigo Company of South Carolina, Inc. (collectively "Defendants"), alleging the labeling for their biotin dietary supplement is misleading in violation of California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §§ 17200, *et seq.*, and California's Consumers Legal Remedies Act ("CLRA"), Cal. Civ. Code §§ 1750, *et seq*. Greenberg seeks certification of a multistate UCL class or, in the alternative, a California-only UCL class and a California-only CLRA class under Federal Rule of Civil Procedure 23(b)(2) and (3). Defendants move for summary judgment, asserting Greenberg cannot establish reasonable reliance, his claims fail as a matter of law because they are expressly and impliedly preempted by the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 343(r)(6), 343-1(a)(5), in light of the Ninth Circuit's recent decision in *Dachauer v. NBTY, Inc.*, 913 F.3d 844 (9th Cir. 2019), and the First Amendment bars Greenberg's claims for monetary relief. For the reasons discussed below, Defendants' motion is granted and Greenberg's motion for class certification is

therefore denied without prejudice.

II. BACKGROUND

International Vitamin Corporation and Perrigo Company of South Carolina, Inc. manufactured and sold at wholesale biotin supplements, which were then marketed and sold at retail by Target under the Up & Up brand. Greenberg challenges three products sold to retail consumers during the putative class period: biotin 1000 mcg, biotin 5000 mcg, and biotin 10,000 mcg (collectively, the "Biotin Supplements"). Biotin is the only active ingredient in the Biotin Supplements. All supplements at issue stated on their front labels "helps support healthy hair and skin," with asterisks at the end directing readers to a disclaimer: "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." (Second Amended Complaint ("SAC") ¶ 21.) The supplements provide far more than the estimated daily value the vast majority of people require, ranging from 333% to 3,333% of the daily value.

Biotin is a nutrient that plays a cellular and biochemical role in the support of healthy hair, skin, nails, and energy. Only a finite amount of biotin, however, is required for normal bodily functions and any surplus of the nutrient is unused by the body. The average person ingests more than enough biotin from his or her normal daily diet in the United States. Thus, once an individual consumes a sufficient amount of biotin, which is easily met by the general population in their everyday diets, the remainder becomes functionally superfluous and cannot convey any additional health benefits.

In approximately 2000, Greenberg was diagnosed with a condition that caused him to lose hair all over his body. For several years, Greenberg pursued various treatments and self-medication to treat his disease, including consuming biotin supplements years before purchasing the Up & Up brand at issue here. In May 2015, Greenberg purchased a 5000 mcg bottle of Up & Up brand biotin from a Target store. He represents that he purchased the supplement both with the hope that it would help with his disease in some way by fostering hair growth, in addition to "receiv[ing] the benefits that were advertised on the label[.]" (Syverson Decl., Ex. B, Greenberg

Depo. at 166:12-13.) Several weeks after purchasing the supplement, he was informed by a friend that the supplement does not provide any benefits. Greenberg subsequently filed this lawsuit, alleging that as the general population would derive no health benefits from biotin supplements in any form, let alone the mega doses of the Biotin Supplements in this case, Defendants' representations that their supplements "helps support healthy hair and skin" is false, misleading, and reasonably likely to deceive the public.

III. LEGAL STANDARD

The purpose of summary judgment "is to isolate and dispose of factually unsupported claims or defenses[.]" *Celotex v. Catrett*, 477 U.S. 317, 323-24 (1986). Summary judgment is therefore proper where the pleadings, discovery, and affidavits demonstrate that there is "no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Material facts are those which may affect the outcome of the case. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A dispute as to a material fact is genuine if there is sufficient evidence for a reasonable jury to return a verdict for the nonmoving party. *Id.*

The party moving for summary judgment bears the initial burden of identifying those portions of the pleadings, discovery, and affidavits which demonstrate the absence of a genuine issue of material fact. *Celotex*, 477 U.S. at 323. Where the moving party will have the burden of proof on an issue at trial, it must affirmatively demonstrate that no reasonable trier of fact could find other than for the moving party. In contrast, on an issue for which the opposing party will have the burden of proof at trial, the moving party need only point out "that there is an absence of evidence to support the nonmoving party's case." *Id.* at 325.

Once the moving party meets its initial burden, the nonmoving party must go beyond the pleadings and, by its own affidavits or discovery, set forth specific facts showing that there is a genuine issue for trial. Only disputes over material facts matter. "Factual disputes that are irrelevant or unnecessary will not be counted." *Anderson*, 477 U.S. at 248. The court must draw all justifiable inferences in favor of the non-moving party, including questions of credibility and of

the weight to be accorded particular evidence. *Id.* at 255. It is not the task of the court, however, to scour the record in search of a genuine issue of triable fact. *Keenan v. Allan*, 91 F.3d 1275, 1279 (9th Cir. 1996). The nonmoving party has the burden of identifying, with reasonable particularity, the evidence that precludes summary judgment. *Id.* If the nonmoving party fails to make this showing, "the moving party is entitled to a judgment as a matter of law." *Celotex*, 477 U.S. at 322.

IV. DISCUSSION

Defendants assert Greenberg's claims fail as a matter of law because they are expressly and impliedly preempted by the FDCA, 21 U.S.C. §§ 343(r)(6), 343-1(a)(5), in light of the Ninth Circuit's recent decision in *Dachauer*, 913 F.3d 844. In *Dachauer*, the court held section 343-1(a)(5) preempted plaintiff's claims under the UCL and CLRA against a manufacturer's structure/function claims with regard to its vitamin E dietary supplement. *Dachauer*, 913 F.3d at 848. In that case, plaintiff contended the structure/function claims that the vitamin E dietary supplement supported cardiovascular *health* were false because it did not prevent cardiovascular *disease*. *Id.* at 846.

The FDCA 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 Ninth Circuit in *Dachauer* held the statute preempts state law requirements for claims about dietary supplements that differ from the FDCA's requirements. *Dachauer*, 913 F.3d at 847-48. For dietary supplements, the FDCA distinguishes between "disease claims" and "structure/function 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," and is prohibited from claiming 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). In light of this regulatory scheme, *Dachauer* held that plaintiff's claims were preempted because he sought to support his allegations that the manufacturer's structure/function claims were false with evidence regarding the supplement's inability to treat or prevent disease: a requirement that was not identical to the requirement of section 343(r). *Dachauer*, 913 F.3d at 848.

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). 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, 1000-01 (Jan. 6, 2000). 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." *Id.* at 1028. For example, a product that represents it treats "joint pain" would constitute an impermissible disease claim, as joint pain is a characteristic symptom of the disease osteoarthritis ("arthritis"), while "support cartilage and joint function" is a permissible structure/function claim. *Id.* at 1016-17. The guidance further explains that manufacturers of supplements can substantiate structure/function claims with evidence of an effect on a small aspect of the related structure/function, rather than with evidence of an effect on the main disease that consumers might associate with a given bodily structure or function. *See id.* at 1012 ("For example, to substantiate the claim 'supports mood,' it is not necessary to study the effects of a substance on clinical depression. Instead, it is quite possible to assess the effects of a substance on mood changes that do not constitute clinical depression.").

Greenberg's claims are expressly preempted by the FDCA. Greenberg is correct in that

Dachauer's fact pattern is not identical to his case. The Ninth Circuit there held plaintiff's claims were preempted only to the extent he sought to prove the dietary supplement's label was false using evidence that did not disprove the claim. *Dachauer*, 913 F.3d at 848. In other words, his evidence regarding the dietary supplement's inability to treat or prevent disease did not address its claim to affect human structure or function which was the subject of plaintiff's challenge. There is no such mismatch here. Greenberg is alleging that Defendants' structure/function claims regarding the Biotin Supplements are false and misleading based on evidence that any form of supplemental biotin is superfluous for the general public, i.e., has no effect on human structure or function. Nevertheless, *Dachauer*'s ultimate holding that a plaintiff's claims are preempted where he seeks to support his allegations that a manufacturer's structure/function claims are false with evidence that is not required for substantiation of a structure/function claim under section 343(r) remains controlling here, as the evidence Greenberg relies upon regarding the superfluous effect that supplemental biotin has on the general population is not required to state a valid structure/function claim under federal regulations. *Dachauer*, 913 F.3d at 848.

The nutrient Biotin, the only active ingredient in the Biotin Supplements, does indeed affect human structure or function, a fact that Greenberg's expert, Barry Wolf, concedes. Congress has expressly specified that sellers of dietary supplements can "describe[] the role of a nutrient . . . intended to affect the structure or function in humans[.]" 21 U.S.C. § 343(r)(6). The FDA, in turn, has promulgated regulations blessing terms like "promote," "maintain," and "support," so long as the seller does not suggest disease prevention or treatment or use for a serious health condition that consumers cannot evaluate. 65 Fed. Reg. at 1014. As the First Circuit explained in the context of a challenge to the representations of a vitamin E dietary supplement, "any nutrient or ingredient that, for example, the heart needs might be described as supporting heart health, even if taking the supplement form of the nutrient actually does nothing to improve the health of one's heart, as long as the claimed beneficial function is substantiated and the description of the nutrient's role is not misleadingly incomplete." *Kaufman v. CVS Caremark Corp.*, 836 F.3d 88, 96 (1st Cir. 2016). Although Greenberg plausibly suggests that the drawing

of such a distinction between biotin's function and its supplement's superfluous impact on the general population likely tricks many consumers who unwittingly think that such a product will reduce the likelihood of poor hair and skin health, this is a form of puffery the statute and regulations allow. 65 Fed. Reg. at 1010 (noting Congress's desire to increase the number of claims that could be made for dietary supplements without subjecting them to drug regulation); *see also Kaufman*, 836 F.3d at 96.

In contrast, cases involving structure/function claims where the manufacturer lacks the required substantiation or that misleadingly fails to disclose the harmful aspects of the nutrient's structure/function are not preempted. In *Dachauer*, for example, the Ninth Circuit concluded plaintiff's claims with respect to the supplement's representations which failed to disclose an increased risk of death were not preempted by section 343-1(a)(5). *Dachauer*, 913 F.3d at 849; *see also* 21 U.S.C. § 343(a) (prohibiting structure/function statements regarding dietary supplements that are false or misleading); *Hawkins v. Kroger Co.*, 906 F.3d 763, 772 (9th Cir. 2018) ("Because the FDA regulations do not authorize the contested statement, [plaintiff's] labeling claims are not preempted . . . ."). Similarly, this Court in *Mullins* found plaintiff had successfully raised triable issues of fact regarding, among other things, that the manufacturer's structure/function claims regarding its dietary supplement were false and misleading based on evidence that the active ingredient was ineffective in providing any health benefits to anyone, i.e., had no effect on human structure or function. *Mullins v. Premier Nutrition Corp.*, 178 F. Supp. 3d 867, 875-76 (N.D. Cal. 2016). Greenberg advances no such claims here, instead contending that while the nutrient biotin affects human structure or function, the supplement at issue will impact the health of only a small proportion of the population.[1]

Greenberg identifies no federal regulation requiring a dietary supplement to substantiate its structure/function claims with evidence that the supplement, as opposed to the nutrient, will have

[1] Greenberg's concession that 0.00138% of the population suffers from rare genetic conditions that *require* them to consume biotin supplements in order to maintain their health further belies his contention that Defendants' structure/function claims are false.

the practical effect of impacting the health of a sizeable proportion of the general public. As a result, his claims are preempted, as he is seeking to impose a requirement on the labeling of dietary supplements that is different from that mandated by federal regulations. *Dachauer*, 913 F.3d at 848. Greenberg insists that since biotin deficiency is rare, the challenged statement is necessarily misleading by not disclosing that very rarity. The FDCA, however, instructs that a disclosure of "the prevalence of [a classical nutrient deficiency] disease in the United States" on a dietary supplement is only required if "the statement claims a benefit related to [such] disease." 21 U.S.C. § 343(r)(6). Greenberg offers no evidence that the Biotin Supplements claimed any benefit related to a classical nutrient deficiency disease. Moreover, the cases he relies upon to demonstrate that other courts have permitted similar claims against other biotin supplements to survive summary judgment are readily distinguishable, as none of them considered whether the claims were preempted. *Jensen v. Natrol, LLC*, No. 17-cv-03193-VC (N.D. Cal. July 25, 2019) (slip op.); *Alvarez v. NBTY, Inc.*, No. 17-cv-00567-BAS-BGS, 2019 WL 2238632 (S.D. Cal. May 22, 2019). It is Greenberg's burden to introduce evidence demonstrating that Defendants' claims are unsubstantiated and therefore misleading. *Mullins*, 178 F. Supp. 3d at 892. He has failed to do so here and therefore his claims are expressly preempted as a matter of law. In light of this ruling, it is not necessary to consider Defendants' arguments regarding implied preemption, whether Greenberg can establish reasonable reliance, or whether the First Amendment bars Greenberg's monetary claims.[2]

V. CONCLUSION

For the foregoing reasons, Defendants' motion for summary judgment is granted and Greenberg's motion for class certification is denied without prejudice.[3]

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[2] On August 28, 2019, Greenberg filed an *ex parte* request for leave to file a supplemental submission in support of his Opposition. (Dkt. 122.) Since nothing in the supplemental submission alters the above analysis, the application is denied.

[3] The various sealing motions (Dkt. 91, 98, 102, 107, 113, 121) are denied, as the parties fail to satisfy the compelling reasons standard of *Kamakana v. City & Cty. of Honolulu*, 447 F.3d 1172, 1178-79 (9th Cir. 2006) to justify sealing any information in the current record.

IT IS SO ORDERED.

Dated: August 29, 2019

RICHARD SEEBORG
United States District Judge

United States District Court
Northern District of California