

NOT FOR PUBLICATION

FILED

UNITED STATES COURT OF APPEALS

FEB 1 2022

FOR THE NINTH CIRCUIT

MOLLY C. DWYER, CLERK
U.S. COURT OF APPEALS

SANDRA SEEGER, individually and on
behalf of all others similarly situated,

Plaintiff-Appellant,

v.

REXALL SUNDOWN, INC.,

Defendant-Appellee.

No. 20-55486

D.C. No.

3:17-cv-01243-BEN-JLB

MEMORANDUM*

Appeal from the United States District Court
for the Southern District of California
Roger T. Benitez, District Judge, Presiding

Argued and Submitted September 3, 2021
Pasadena, California

Before: BENNETT and R. NELSON, Circuit Judges, and EZRA,** District Judge.

Sandra Seegert appeals the district court's order granting summary judgment for Rexall Sundown, Inc. ("Rexall"). We have jurisdiction under 28 U.S.C. § 1291,

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

** The Honorable David A. Ezra, United States District Judge for the District of Hawaii, sitting by designation.

and we affirm in part, reverse in part, and remand.¹

Seegert purchased Osteo Bi-Flex Triple Strength (“Osteo Bi-Flex”), a dietary supplement manufactured by Rexall that contains a glucosamine compound and a proprietary ingredient called Joint Shield 5-LOXIN Advanced (“5-Loxin”). Rexall claims on the product label that Osteo Bi-Flex “Shows Improved Joint Comfort within 7 Days!” and “supports joint comfort.” Rexall also claims that Osteo Bi-Flex “helps strengthen joints while helping maintain joint cartilage,” and helps to strengthen joints, support flexibility, and support mobility. Seegert alleges, however, that Osteo Bi-Flex and its ingredients do not provide any of these benefits. Thus, Seegert filed this class action suit against Rexall, claiming violations of California’s Unfair Competition Law (“UCL”) and Consumers Legal Remedies Act (“CLRA”). *See* Cal. Bus. & Prof. Code § 17200; Cal. Civ. Code § 1770(a).

Both parties submitted expert testimony. Seegert submitted the declarations of Dr. Farshid Guilak and Dr. Timothy McAlindon. Dr. Guilak conducted an in vitro study on pig cartilage and concluded that Osteo Bi-Flex and 5-Loxin “have no effect on cartilage function, in the presence or absence of inflammation.” Dr. McAlindon reviewed many studies and meta-analyses of the ingredients in Osteo Bi-Flex and concluded that the product doesn’t “support[] mobility, support[] flexibility,

¹ We grant Seegert’s and Rexall’s motions to take judicial notice. We deny as moot Rexall’s motion to strike portions of Seegert’s excerpts of record because the relevant portions of the excerpts of record are already sealed.

strengthen[] joints, or maintain[] joint cartilage . . . for people with or without arthritis.” Both of Seegert’s experts also critiqued the studies that Rexall relied on to support its statements, as well as the testimony of Rexall’s expert witnesses. Both parties moved to exclude opposing expert testimony.

The district court granted summary judgment for Rexall. The court held that Rexall’s statements on Osteo Bi-Flex used the correct terms to constitute permissible structure/function claims under the Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 343. Thus, the district court held that Seegert’s state law claims were preempted by the FDCA’s express preemption provision. The district court also rejected Seegert’s argument that Rexall’s statements, even though they looked like acceptable structure/function claims, made implicit disease claims and thus violated the FDCA. Instead, the court found that “the representations do not suggest treatment or prevention of a disease,” and so “the representations are proper structure/function claims according to the federal requirements.”

We review the district court’s grant of summary judgment de novo. *Ass’n des Éleveurs de Canards et d’Oies du Québec v. Becerra*, 870 F.3d 1140, 1145 (9th Cir. 2017). We must decide, viewing the evidence in the light most favorable to the nonmoving party, whether there are any genuine issues of material fact and whether the district court correctly applied the law. *Id.* We also review questions of preemption and statutory interpretation de novo. *Id.*

Structure/function claims are statements that “describe[] the role of a nutrient or dietary ingredient intended to affect the structure or function in humans.” 21 U.S.C. § 343(r)(6)(A). Section 343(r) allows a manufacturer to make structure/function claims about dietary supplements if: (1) the manufacturer “has substantiation that such statement is truthful and not misleading,” (2) the statement contains a prominent disclosure that the statement has not been pre-approved by the FDA and “is not intended to diagnose, treat, cure or prevent any disease,” and (3) the statement is not a disease claim. *Id.* § 343(r)(6)(B), (C). Section 343-1(a)(5) expressly preempts any state requirement respecting a structure/function claim that “is not identical to the requirement of § 343(r).”

We begin with Seegert’s argument that Rexall’s representations are implied disease claims and not structure/function claims. “A statement claims to diagnose, mitigate, treat, cure, or prevent disease if it claims, explicitly or *implicitly*, that the product . . . [h]as an effect on the characteristic signs or symptoms of a specific disease or class of diseases, using scientific or lay terminology” 21 C.F.R. § 101.93(g)(2)(ii) (emphasis added). In *Kroessler v. CVS Health Corp.*, 977 F.3d 803 (9th Cir. 2020), we considered representations that a glucosamine-based supplement “supports flexibility & range of motion” and “supports cartilage health & joint comfort,” *id.* at 806, and concluded that they were structure/function claims, not implied disease claims, *see id.* at 816. We see no material difference between

the structure/function claims in *Kroessler* and Rexall's representations. Rexall does not represent that Osteo Bi-Flex "reduces joint pain" or affects any other characteristic symptom of osteoarthritis. *See* 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, 1016 (Jan. 6, 2000). Nor do any other representations on Osteo Bi-Flex's label suggest that the product treats disease symptoms. And although we may consider extra-label evidence in determining whether a representation is an implied disease claim, *Kroessler*, 977 F.3d at 816, the extrinsic evidence Seegert submitted is not relevant to our inquiry. Thus, we affirm the district court's finding that Rexall's representations are structure/function claims, not implied disease claims. To the extent that Seegert argues Rexall's representations are false or misleading because they present implied disease claims, her state law claims are preempted.

But the district court erred when it construed § 343-1(a)(5) as preempting plaintiff's state law claims whenever the manufacturer's statement *is* a structure/function claim. "The FDCA does not preempt California false advertising causes of action simply because the challenged label contains a proper structure/function claim; instead, preemption applies only if the plaintiff's legal claims and factual allegations would hold a defendant to a different 'substantiation' standard than the FDCA." *Kroessler*, 977 F.3d at 813. Thus, the district court must

decide whether there is a triable issue on substantiation, which requires looking at Seegert's evidence. *See Dachauer v. NBTY, Inc.*, 913 F.3d 844, 849 (9th Cir. 2019) ("Because the FDCA and California law have the same labeling requirement with respect to failing to disclose an increased risk of death, § 343-1(a)(5) does not preempt this particular aspect of Plaintiff's case. Thus, we address whether Plaintiff created a genuine issue of material fact as to whether the immune-health claim is misleading."). If a reasonable jury could conclude that Rexall failed to substantiate its claims, then Seegert's state law claims are not preempted. *See id.*

On appeal, Rexall argues that we should still affirm the district court's preemption decision because Seegert's evidence is mismatched against the structure/function claims. *See id.* Rexall contends that Seegert's evidence (1) concerns disease outcomes when Rexall's structure/function claims do not purport to treat disease, and (2) relies on studies involving different formulations of the ingredients in Osteo Bi-Flex. But "[o]nly admissible evidence may be considered in deciding a motion for summary judgment," *Miller v. Glenn Miller Prods., Inc.*, 454 F.3d 975, 988 (9th Cir. 2006), and we do not yet know whether Seegert's evidence is admissible because the district court has not ruled on the parties' *Daubert* motions. Because *Daubert* affords a measure of discretion to the district court, *see Murray v. S. Route Mar. SA*, 870 F.3d 915, 923 (9th Cir. 2017), it would be inappropriate for us to decide the admissibility of Seegert's evidence in the first

instance on appeal. Thus, we reverse the district court's finding of preemption and remand so that it can decide the admissibility of Seegert's evidence and, if the evidence is admissible, determine whether there is a triable issue on substantiation.

AFFIRMED in part, REVERSED in part, and REMANDED.