UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

GORDON NOBORU YAMAGATA, et al., Plaintiffs, v. RECKITT BENCKISER LLC, Defendant.	Case No. 17-cv-03529-VC **ORDER DENYING MOTION FOR SUMMARY JUDGMENT** Re: Dkt. No. 116

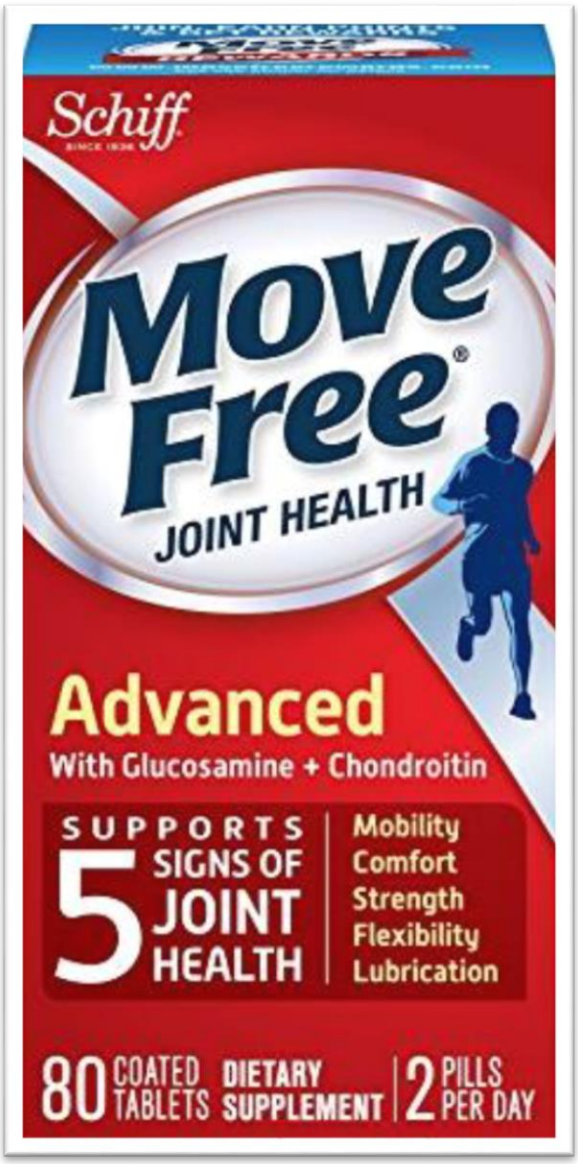
This case is about joint supplements—and, more precisely, the advertising statements printed on their boxes. The plaintiffs have sued the maker of the supplements under state law, contending that the statements on the boxes are misleading. The primary question presented by this summary judgment motion is whether the state law claims are preempted by federal law. If the boxes are best understood as making assertions about the ability of the supplements to alleviate the symptoms of arthritis, those assertions violate federal law, and the state law claims attacking them are not preempted. If the boxes are best understood as not making assertions relating to arthritis, those assertions are authorized by federal law, and the state law claims are preempted. This ruling explains why the boxes are best understood as making assertions regarding arthritis, and seeks in the process to explain why this determination is the judge's to make.

I.

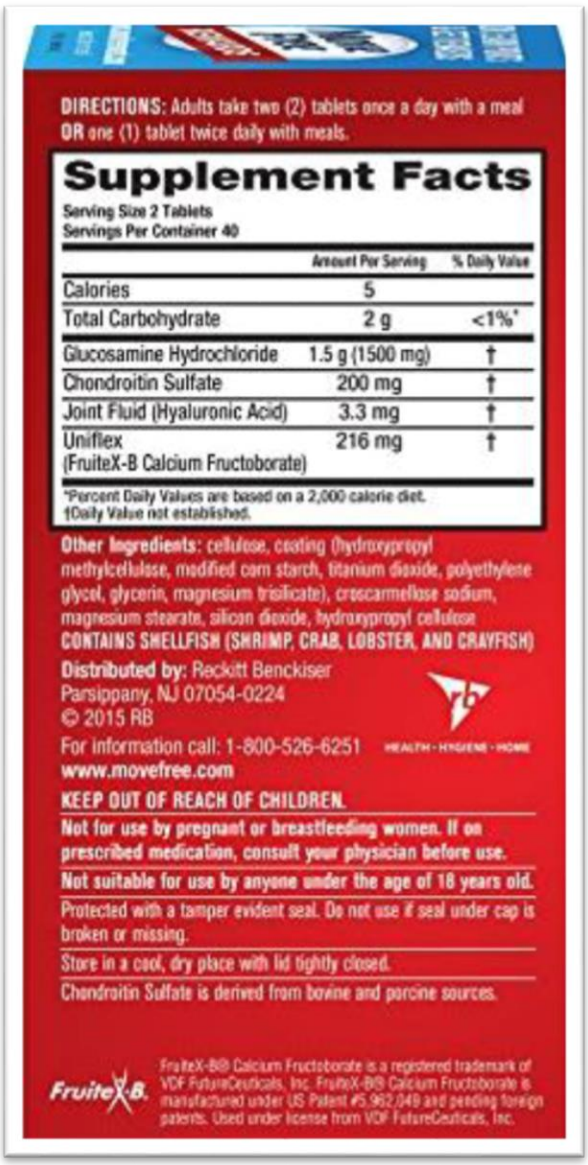
The plaintiffs bought joint supplements sold under the name Move Free Advanced. They have sued Reckitt Benckiser, the company that sells the supplements. The plaintiffs argue that the statements printed on the Move Free Advanced packaging violate California and New York

laws against false or misleading advertising. Their principal contention is that the packaging misled them into thinking that the products help alleviate the symptoms of arthritis. These images show a typical box:

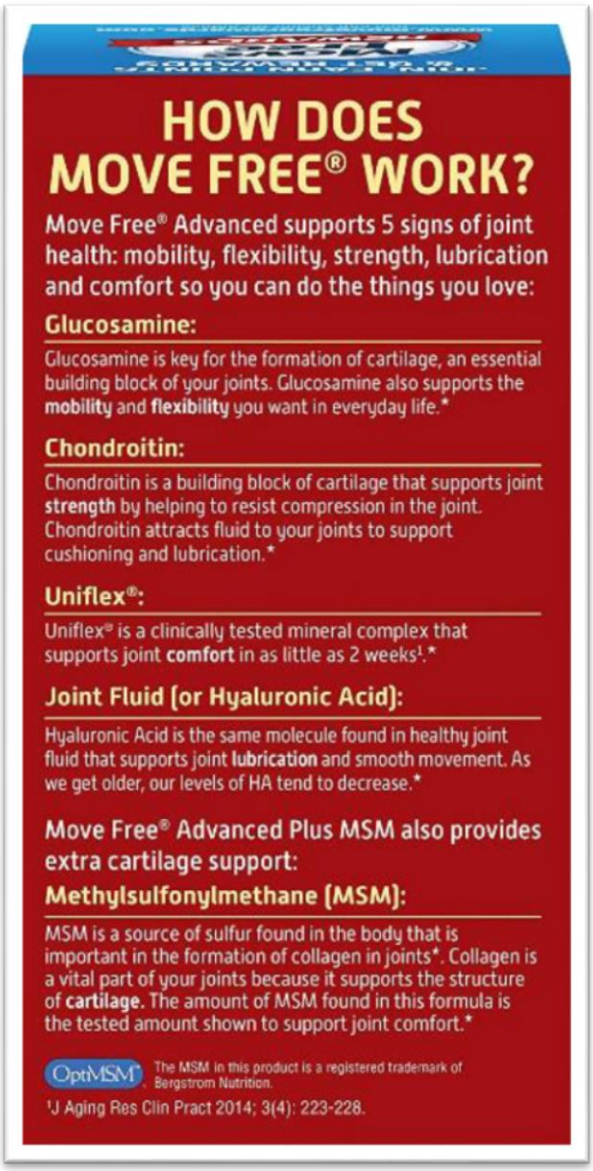
Front

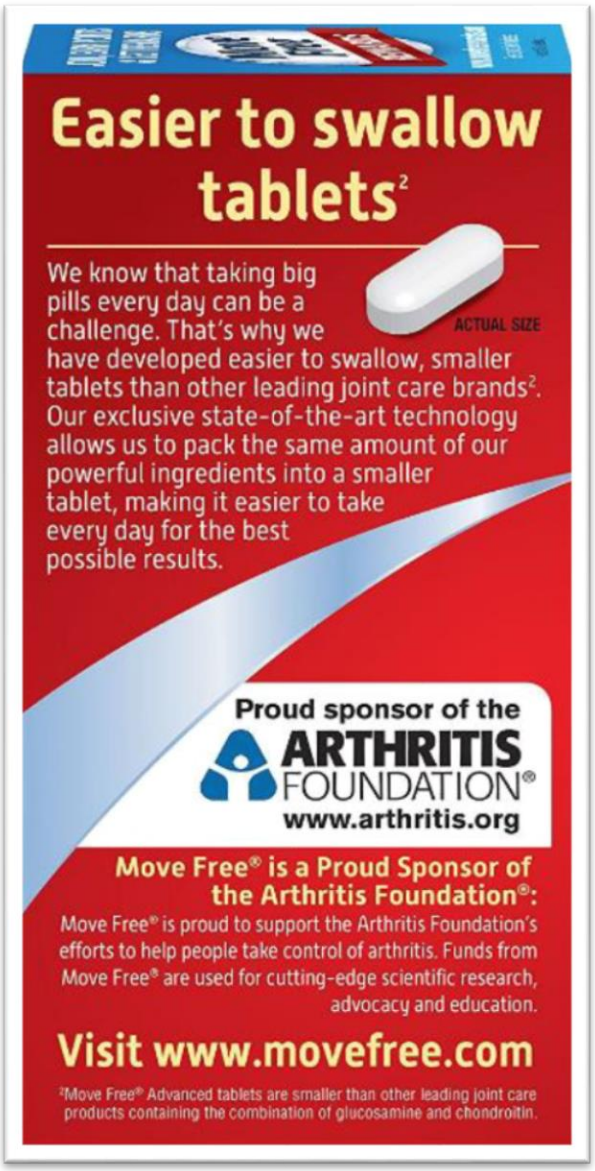


Back



Side **Side**





The Court certified two classes—one of California buyers and one of New York buyers. Reckitt now moves for summary judgment on three grounds. It argues first that the plaintiffs' claims are preempted by the federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717 (1938), as amended by the Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417. It next argues that the products work as advertised and so the state-law consumer-protection claims could not go forward even if they were not preempted. Finally, the company argues that

the plaintiffs could not proceed on a "full refund" theory of damages even if the claims survived summary judgment, because the supplements were not worthless.

II.

The plaintiffs' claims are not preempted. The Food, Drug, and Cosmetic Act contains provisions governing what manufacturers may print on dietary supplement labels, and it preempts state-law claims attacking labels that comply with its rules. The key constraint, for the purposes of this litigation, is a ban on statements implying that the supplement mitigates, treats, prevents, or cures a specific disease or class of diseases. Some of the assertions on the Move Free Advanced labels do just that, and so they are not protected by the preemption provision.

A.

Federal law distinguishes between two types of advertising statements that might appear on supplement labels; it allows one type and forbids the other. Manufacturers may make statements "describing the role of a nutrient or dietary ingredient intended to affect the structure or function in humans." 21 U.S.C. § 343(r)(6). But manufacturers must take care not to make statements implying that the supplement can "diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases."[1] *Id.*

The statute refers to these statements as "claims," and so does the FDA in its implementing regulations. The distinction is between "structure/function claims" and "disease claims." Courts use this language too, but doing so results in rulings that are hard to follow. For people reading these rulings, it's easy to lose track of when "claim" means a statement on a package and when it means a cause of action in the lawsuit. To avoid that confusion, this ruling

[1] The FDA allows a limited number of these statements as "health claims"—either "authorized" (unqualified) or "qualified" —but neither type of claim is relevant to this litigation. (An example of an unqualified claim is, "Adequate calcium and vitamin D as part of a healthful diet, along with physical activity, may reduce the risk of osteoporosis in later life.") The FDA has approved only 12 unqualified health claims since 1990. *See Questions and Answers on Health Claims in Food Labeling*, Food and Drug Administration (March 10, 2020), https://www.fda.gov/food/food-labeling-nutrition/questions-and-answers-health-claims-food-labeling.

will describe statements on packages as "statements," reserving the label "claims" for the actual legal claims asserted by plaintiffs in consumer protection cases.

The difference between the two types of advertising statements matters for preemption purposes. If a company follows the specific rules for making "structure/function" statements, this means it has complied with federal law, and any claims under state law are preempted. *See* § 343-1(a)(5). In contrast, implied disease statements are prohibited by federal law, and therefore are not protected by the preemption provision.[2]

B.

There has been confusion in this case about whether the preemption question—that is, the question whether the labels make implied disease statements or merely structure/function statements—could be decided by a jury. Perhaps because the question is partly a factual one, the parties have briefed it as though summary judgment should be denied if a genuine factual dispute is involved. Thus, the plaintiffs argued in their briefs that summary judgment on preemption grounds should be denied because there's a genuine factual dispute about whether the labels make disease statements or structure/function statements; Reckitt argued in its brief that summary judgment should be granted because no reasonable factfinder could conclude that the labels make disease claims. But that's the wrong way to look at it. Preemption is a question of law, and so it's for the Court to decide fully on summary judgment, even if the resolution of a

[2] The plaintiffs say that claims challenging the truthfulness of structure/function statements are not preempted because federal law prohibits false or misleading statements on supplement labels. *See* 21 U.S.C. § 343(a) (providing that a "food"—a term that here includes dietary supplements—"shall be deemed to be misbranded . . . if its labeling is false or misleading in any particular"). Any state-law laws against false or misleading advertising would be consistent with this federal requirement, they argue, and therefore not preempted. That argument is not correct. The statutory preemption provision applicable to structure/function claims preempts state-law requirements "not identical to the requirements of section 343(r)." 21 U.S.C. § 343-1(a)(5). The absolute prohibition on false or misleading statements that plaintiffs point to appears in section 343(a), not section 343(r). Section 343(r) instead requires manufacturers to have "substantiation that [a structure/function] statement is truthful and not misleading." 21 U.S.C. § 343(r)(6)(B). Accordingly, the plaintiffs may not rely on the more demanding requirements of section 343(a) to sustain claims attacking the truthfulness of structure/function statements.

factual dispute is involved.

The Supreme Court said as much last term in *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019), a case involving state-law failure-to-warn claims against a drug manufacturer. The preemption analysis in that case turned on whether the FDA would have approved a change to a drug label. The lower court had held that the question of hypothetical FDA approval was for the jury, but the Supreme Court reversed. It explained first that "a judge, not the jury, must decide the preemption question," and second that "courts may have to resolve subsidiary factual disputes that are part and parcel of the broader [preemption] question." *Id.* at 1676, 1680.

In this case as in *Merck*, the factual questions underlying the preemption determination are "subsumed within an already tightly circumscribed legal analysis." *Id.* at 1680. According to the FDA, the key factor distinguishing a structure/function statement from an implied disease statement is "whether the labeling suggests that the product will produce a change in the characteristic signs or symptoms of a specific disease or class of diseases." *See* 65 Fed. Reg. 1016. Although that inquiry is factual in nature, it is bounded by the FDA's regulations, which list a series of ten criteria (one with five subparts) relevant to the determination. *See* 21 C.F.R. § 101.93(g). And the FDA has further constrained the decision by providing examples of statements that would fall on either side of the line: A statement that a supplement "reduces joint pain," for example, is off limits; a statement that it "helps support cartilage and joint function" is not. *See* 65 Fed. Reg. 1015–17. Why? Joint pain is a characteristic symptom of arthritis, says the FDA, and so statements about relieving joint pain impliedly claim to mitigate the disease of arthritis. *Id.* That may seem like a stretch, and it may even seem that the specific reference to cartilage and joint function draws a closer link to arthritis than does the broader "joint pain." But the idea that the FDA's dictates may conflict with intuitions only confirms that this preemption determination, while fact-based, depends ultimately on application of the law.[3]

[3] In supplemental briefing, without explicitly agreeing with the Court's position, the parties stipulated that the Court could decide "the factual dispute that is subsumed within the preemption

C.

Under this federal framework, the Move Free Advanced labels imply that the supplement can mitigate, treat, or prevent arthritis. For starters, the labels say that the product "supports joint comfort"—an assertion that is dangerously close to a statement that a supplement "reduces joint pain." The Court would have trouble articulating a meaningful difference between the two. But even if that statement did not cross the line on its own, the FDA has determined that the statements need to be considered in context, taking the whole label into account. *See* 21 C.F.R. § 101.93(g). So even when an advertising statement is best viewed as a structure/function statement in isolation, it can improperly imply an effect on a disease if other parts of the label associate the supplement with a disease. The product name, any pictures or symbols, citations to journal articles, and statements about the formulation of the product, if printed on the label, are all relevant. *Id.*

The advertisements here contain elements closely associated with arthritis, and this association colors the meaning of the label's statements. Most prominent is the Arthritis Foundation logo, accompanied by the following statement: "Move Free™ is a Proud Sponsor of the Arthritis Foundation®: Move Free™ is proud to support the Arthritis Foundation's efforts to help people take control of arthritis." The "support" referred to is quite clearly financial, but the logo and statement nonetheless draw an explicit link between the supplement and arthritis. And that link is relevant to whether other statements on the packaging imply that the supplement will have an effect on arthritis. Also relevant is the citation to a journal article in the "Journal of Aging and Research," along with the choice to highlight glucosamine and chondroitin on the front of the box. According to the Merck Manual, cited by the FDA as an authority on disease characteristics, osteoarthritis is "nearly universal . . . by age 80," so a citation to an aging journal on a joint supplement label is suggestive of arthritis.[4] And according to industry marketing

question" on the basis of the materials already submitted for summary judgment. *See* Parties' Joint Submission in Response to Order Requiring Supplemental Briefing, Dkt. No. 147, at 2.

[4] *Osteoarthritis*, Merck Manual Professional Version (March 8, 2020),

research, about half of arthritis sufferers view "glucosamine &/or chondroitin" as "the most effective arthritis treatment." Mot. for Class Certification, Ex. 8, at 15. There are surely marketing benefits to triggering associations with arthritis, but there are risks, too. In the context of these elements, which (at minimum) trigger associations with arthritis, any assertion that the product "supports joint comfort" is an implied disease statement. For the same reason, the statement that the product "supports 5 signs of joint health: mobility, flexibility, strength, lubrication, and comfort" is also an implied disease statement.

A note on scope: the effect of this determination is limited to the federal preemption question. The state law claims require adjudication of a related but distinct question: whether the labels make false or misleading statements about the effect of the products on joints. Adjudication of that question is not constrained by the FDA's rules governing the distinction between implied disease statements and structure/function statements, nor is it constrained by this Court's conclusion that the MoveFree products contain implied disease statements. In other words, the federal preemption ruling does not require Reckitt to concede that the labels imply under state law that the supplement will mitigate arthritis.

III.

Because the claims are not preempted, the next question is whether a reasonable jury could conclude that Reckitt's labels contain false or misleading statements in violation of New York and California law. *See* N.Y. Gen. Bus. Law § 349 (allowing a private right of action to

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https://www.merckmanuals.com/professional/musculoskeletal-and-connective-tissue-disorders/joint-disorders/osteoarthritis-oa; *see also Osteoarthritis*, Merck Manual Consumer Version (March 8, 2020), https://www.merckmanuals.com/home/bone,-joint,-and-muscle-disorders/joint-disorders/osteoarthritis-oa ("Arthritis due to damage of joint cartilage and surrounding tissues becomes very common with aging."); *id.* ("Osteoarthritis . . . often begins in the 40s and 50s and affects almost all people to some degree by age 80."); 65 Fed. Reg. 1016 ("FDA and manufacturers may look to medical texts and other objective sources of information about disease to determine whether a label implies treatment or prevention of disease by listing the characteristic signs and symptoms of a disease or class of diseases."); *id.* ("FDA also believes that 'joint pain' is characteristic of arthritis. According to the Merck Manual, joint tenderness is the most sensitive physical sign of rheumatoid arthritis.").

enjoin and recover damages from "[d]eceptive acts or practices in the conduct of any business"); *id.* §§ 350-A, 350-E (allowing a right of action for "false advertising," which includes "labeling . . . of a commodity . . . if such advertising is misleading in a material respect"); Cal. Business & Professional Code §§ 17200–17208, 17500–17508 (allowing causes of action under the Unfair Competition Law and the False Advertising Law for "deceptive, untrue or misleading advertising"); Cal. Civ. Code §§ 1750–1784 (prohibiting, as part of California's Consumers Legal Remedies Act, manufacturers from "representing that goods . . . have . . . characteristics [or] benefits" that they do not have," and allowing a private cause of action to recover for violations).

Reckitt's motion rests on the purported benefits of calcium fructoborate alone, and not on the effects of glucosamine or chondroitin (which apparently are now thought by at least some experts not to have any positive effects on joints). But there is a triable issue of fact as to whether the calcium fructoborate provides the advertised benefits. *See* Defendant's Motion for Summary Judgment, Dkt. No. 116-1, at 10 & n.6. The company has provided some evidence based on randomized control trials that calcium fructoborate can benefit joints. *See* Declaration of Zbigniew Pietrzkowski, Dkt. No. 116-3. The plaintiffs, for their part, have supplied evidence to the contrary. One expert called the methodology and reliability of the calcium fructoborate studies into question. *See* Expert Report of David Madigan, Dkt No. 126-29. Another cultured pig cartilage in various concentrations of calcium fructoborate and found no positive effect. *See* Expert Report of Farshid Guilak, Dkt. No. 126-30. While each party's studies are flawed in some respects, they are not so divorced from reliable scientific methods as to be inadmissible. The motions to strike the expert reports cited here are therefore denied. Because a jury could decide from the evidence that calcium fructoborate either does or does not produce the advertised benefits, summary judgment is denied. *See Sonner v. Schwabe N. Am., Inc.*, 911 F.3d 989, 993 (9th Cir. 2018); *In re Roundup Products Liability Litigation*, 390 F. Supp. 3d 1102, 1109 (N.D. Cal. 2018).

IV.

Finally, the plaintiffs may proceed with their full-refund theory of damages. Reckitt argues that even if the supplements do not help joints, they are not worthless because some of the ingredients can provide benefits unrelated to joint health. But people purchase joint supplements for the advertised joint health benefits. *See* Mot. for Class Certification, Ex. 41, at 8 (indicating that all of the 65 Move Free users surveyed took supplements to either to prevent or treat joint problems or to maintain joint health). If the plaintiffs received none of the advertised joint health benefits, they are entitled to a full refund. *See Mullins v. Premier Nutrition Corp.*, 178 F. Supp. 3d 867, 899 (N.D. Cal. 2016) (explaining that a full refund for "Joint Juice" – "for all intents and purposes a liquid pill" – would be appropriate if the advertised joint-health claims were false); *Farar v. Bayer AG*, Case No. 14-cv-04601-WHO, at *16 (N.D. Cal. Nov. 15, 2017) (denying summary judgment on a full-refund damages theory because, "[l]ike Joint Juice, defendants' One A Day products are literally pills, and plaintiffs testified that they purchased the products only for their touted health benefits").

V.

Accordingly, Reckitt's motion for summary judgment is denied in full. The motions to strike the opinions and reports of Drs. Guilak and Pietrzkowsi are denied. The motion to strike the opinion and report of Dr. Grande is denied as moot.

IT IS SO ORDERED.

Dated: March 30, 2020

VINCE CHHABRIA
United States District Judge