FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

DARLENE HOLLINS; CHRISTIAN LEMUS; ALAIN MICHAEL; MARIE ANGELINE FALCONE, Individually and on Behalf of All Others Similarly Situated,

Plaintiffs-Appellants,

and

ANGELA DIAMOS,

Plaintiff,

v.

WALMART INC.; INTERNATIONAL VITAMIN CORPORATION,

Defendants-Appellees.

No. 21-56031

D.C. No. 2:19-cv-05526-SVW-GJS

OPINION

Appeal from the United States District Court
for the Central District of California
Stephen V. Wilson, District Judge, Presiding

Argued and Submitted November 22, 2022
Pasadena, California

Filed May 11, 2023

Before: Danny J. Boggs,[*] Kim McLane Wardlaw, and Sandra S. Ikuta, Circuit Judges.

Opinion by Judge Ikuta;
Partial Dissent by Judge Wardlaw

SUMMARY[**]

Federal Food, Drug, and Cosmetic Act

The panel affirmed the district court's order granting summary judgment for Walmart Inc. in a consumer class action alleging that Walmart's product, Spring Valley Glucosamine Sulfate, contained glucosamine hydrochloride, not glucosamine sulfate or glucosamine sulfate potassium chloride, and that the plaintiffs were allegedly damaged by the misleading labeling.

The Federal Food, Drug, and Cosmetic Act ("FDCA") prohibits the misbranding of any food. A food is deemed to be misbranded if it meets any of the definitions in 21 U.S.C.

[*] The Honorable Danny J. Boggs, United States Circuit Judge for the U.S. Court of Appeals for the Sixth Circuit, sitting by designation.

[**] This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

§ 343. Section 343(q) includes a subsection specific to dietary supplements. To implement this subsection, the Food and Drug Administration ("FDA") promulgated regulations governing the nutrition labeling of dietary supplements. *See* 21 C.F.R. § 101.36. Dietary ingredients such as glucosamine sulfate potassium chloride, for which the FDA has not established a Reference Daily Intake or Daily Reference Values, are governed by § 101.36(b)(3), which provides that such dietary ingredients "shall be declared by their common or usual name." Compliance with this requirement is determined in accordance with specified testing protocols. The FDCA preempts specified state requirements relating to food labeling.

The named plaintiff, Darlene Hollins, alleged that she and other consumers were damaged because "they paid for a product that they would not have purchased had it truthfully disclosed that it did not contain Glucosamine Sulfate." The second amended complaint claimed violations of the California Consumers Legal Remedies Act, the California Unfair Competition Law, the California False Advertising Law, unjust enrichment, restitution, and breach of warranty. The district court held that the methods used by Hollins' expert witness, Dr. Neil Spingarn, raised *Daubert* concerns and were not reliable and appropriate under 21 C.F.R. § 101.9(g)(2) for determining whether Walmart's product was mislabeled. The district court concluded that Walmart had carried its burden of showing that Hollins's state-law claims were preempted by federal law.

Hollins contended that her state-law mislabeling claim, which would require the state to impose the rule that a blend of glucosamine hydrochloride and potassium sulfate cannot be labeled glucosamine sulfate or glucosamine sulfate potassium chloride, is not preempted because such a rule is

identical to the federal rule. The panel held that Hollins's claim that Walmart's product was mislabeled due to being a blend would allow a state to impose a different labeling requirement of Walmart's product than is imposed § 343(q), and is therefore preempted.

Hollins argued that her claim would not allow a state to impose a labeling requirement on Walmart's product different from that imposed by § 343(b). She argued that a label can violate § 343(b) even if the label uses the product's "common or usual name," as determined by federal testing requirements under § 343(q), because such testing requirements apply only to the information provided in the nutrition panel. The panel disagreed. Section 343(s)(2)(B) permits Walmart to label its dietary supplement with the name of its active ingredient, and the "common and usual" name of that ingredient may be determined pursuant to federal testing requirements. The panel held that Hollins's proposed rule to the contrary was preempted. The holding in *Durnford v. MusclePharm Corp.*, 907 F.3d 595 (9th Cir. 2018), did not provide otherwise. Nothing in *Durnford* suggested its analysis applied only to the nutrition panel. This case is governed by *Durnford*'s holding that the manufacturer's method for determining the amount of protein in the supplement was authorized by regulation and therefore preempted Hollins's proposed state-law rule. In addition, the panel rejected the dissent's reliance on *Hawkins v. Kroger Co.*, 906 F.3d 763 (9th Cir. 2018), and held that *Hawkins* was inapposite here.

The panel concluded that Hollins's claims were preempted, and Walmart was entitled to judgment as a matter of law.

Judge Wardlaw dissented in part. In her view, Hollins was not required to comply with the FDA's testing requirements with respect to her claims outside of the nutrition facts panel. Challenges to the label under 21 U.S.C. § 343(q) are distinct from those to the nutrition facts panel under 21 U.S.C, § 343(q), such that the 21 C.F.R. § 101.9(g) federal testing requirements do not apply to the label outside of the nutrition panel, and, therefore, these state law claims are not preempted by federal law, and can proceed. She wrote that the majority opinion misapplied *Durnford*, and ran counter to the presumption against preemption.

COUNSEL

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OPINION

IKUTA, Circuit Judge:

Darlene Hollins and three other consumers brought a class-action lawsuit against Walmart Inc. and International Vitamin Corporation under California law.[1] In her complaint, Hollins alleged that Walmart's product, "Spring Valley Glucosamine Sulfate," manufactured by International Vitamin Corporation, contained glucosamine hydrochloride, not glucosamine sulfate or glucosamine sulfate potassium chloride, and claimed she was damaged by the misleading labeling. We hold that Hollins's claims are preempted because they seek to impose state labeling requirements that are not identical to the requirements of applicable federal regulations. Therefore, we affirm the district court's order granting summary judgment for Walmart.

I

We begin by providing the legal background. The Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301–399i, governs (among other things) "fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity." 21 U.S.C. § 341. The Secretary of Health and Human Services has authority to promulgate regulations to enforce the FDCA, 21 U.S.C. § 371(a), and has delegated this authority to the Food and Drug Administration (FDA). *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S.

[1] To avoid confusion, we refer to the consumer plaintiffs in this action as Hollins and refer to the defendants Walmart and International Vitamin Corporation as Walmart.

120, 126 (2000). We first describe the applicable misbranding provisions of the FDCA and then turn to the applicable preemption provisions.

A

The FDCA prohibits the "misbranding of any food." 21 U.S.C. § 331(b). "[A] dietary supplement shall be deemed to be a food within the meaning of [the FDCA]." *Id.* § 321(ff). A food is "deemed to be misbranded" if it meets any of the definitions in 21 U.S.C. § 343.

The parties focus on two of these definitions. First, a food is misbranded "[i]f it is offered for sale under the name of another food." *Id.* § 343(b). For instance, the FDA has indicated that labeling an item "red snapper" when it actually consists of rockfish, "an economically inferior species," is a violation of § 343(b). 59 Fed. Reg. 4142, 4176 (proposed Jan. 28, 1994).

Second, a food is misbranded if its label does not bear nutrition information that meets the requirements set forth in 21 U.S.C. § 343(q) and the regulations promulgated by the FDA pursuant to this section.[2] Section 343(q)(1) lists the nutrition information that must be included on the label, including serving size, calories, the amount of specified nutrients, and a list of nutrients specified by the FDA, while § 343(q)(2) authorizes the FDA to issue regulations regarding additional nutrition information that must be included. The FDA has promulgated regulations delineating

[2] "We refer to the product's packaging as a whole as the 'label.'" *Durnford v. MusclePharm Corp.*, 907 F.3d 595, 598 n.1 (9th Cir. 2018). We refer to the format required by § 101.9(d) for certain nutritional information as the "nutrition panel." *Id.* The nutrition panel is part of the label. *Id.*

the nutrition information that must be included and the format for presenting the information to consumers. *See* 21 C.F.R. § 101.9(c), (d).

Section 343(q) includes a subsection specific to dietary supplements. *See* 21 U.S.C. § 343(q)(5)(F). This subsection provides that a dietary supplement product "shall comply with the requirements of [§ 343(q)(1) and (2)] in a manner which is appropriate for the product and which is specified in regulations" of the FDA, and lists the nutrition information to be provided. *Id.*

To implement this subsection, the FDA has promulgated regulations governing the nutrition labeling of dietary supplements. *See* 21 C.F.R. § 101.36. Under the regulations, dietary ingredients such as glucosamine sulfate potassium chloride, for which the FDA has not established a Reference Daily Intake or Daily Reference Values, are governed by § 101.36(b)(3), which provides that such dietary ingredients "shall be declared by their common or usual name." *Id.* § 101.36(b)(3)(i). Compliance with this "common or usual name" requirement is determined in accordance with specified testing protocols. As explained in the regulations,

> Compliance with [§ 101.36] will be determined in accordance with § 101.9(g)(1) through (g)(8), (g)(10), and (g)(11), except that the sample for analysis shall consist of a composite of 12 subsamples (consumer packages) or 10 percent of the number of packages in the same inspection lot,

> whichever is smaller, randomly selected to be representative of the lot.

Id. § 101.36(f)(1).

Under § 101.9(g)(2) (one of the sections referenced in § 101.36(f)(1) that is relevant to this case), 12 subsamples must "be analyzed by appropriate methods as given in the 'Official Methods of Analysis of the AOAC International,' or, if no AOAC method is available or appropriate, by other reliable and appropriate analytical procedures." The AOAC "is a comprehensive collection of chemical and microbiological methods of analysis" which "have undergone rigorous scientific review and validation to determine the performance characteristics for the intended analytical application and fitness for purpose." 81 Fed. Reg. 33742, 33748–49 (May 27, 2016).

If there is no AOAC official method available or appropriate for a particular dietary supplement, the manufacturer may use an alternative methodology. FDA, *Guidance for Industry: Nutrition Labeling Manual – A Guide for Developing and Using Data Bases* (1998), 1998 WL 34327548, at *15. An alternate method used "to support a nutrient declaration value" must have "appropriate validation" unless the method was previously validated by collaborative studies. 58 Fed. Reg. 2079, 2109 (Jan. 6, 1993). According to the FDA, validation means "demonstrating performance characteristics such as accuracy, precision, sensitivity, selectivity, limit of detection, limit of quantitation, linearity, range, and ruggedness, to ensure that results are meaningful." FDA, *Guidelines for the Validation of Chemical Methods in Food, Feed, Cosmetics, and Veterinary Products* (3rd ed. 2019), at 4. Certified reference materials, which are reference

samples issued by an authoritative body to provide one or more specified property values, are a tool used to validate the accuracy of a test method. *Id*. at 6, 17; *see also* FDA, *Guidance for Industry: Nutrition Labeling Manual – A Guide for Developing and Using Data Bases* (1998), 1998 WL 34327548, at *16 (stating that determining the accuracy of a new test method requires using "a material or a standard with a certified concentration of the analyte being measured").

Methods that are validated are often referred to as "compendial" test methods. As defined in the FDCA, an "official compendium" includes "the official United States Pharmacopoeia [(USP)]." 21 U.S.C. § 321(j). The European Pharmacopeia (EP) is a compendial standard recognized in the European Union and observed by the United States.[3]

In sum, a dietary supplement such as glucosamine sulfate potassium chloride is deemed misbranded if it is sold under the name of a different food or dietary supplement, 21 U.S.C. § 343(b), or does not provide the "common or usual name" of its dietary ingredient, 21 C.F.R. § 101.36(b)(3)(i), as determined in accordance with a validated test method.

[3] The European Pharmacopeia "is the primary source of official quality standards for medicines and their ingredients in Europe." European Pharmacopoeia, 11th Edition, www.edqm.eu/en/european-pharmacopoeia-ph.-eur.-11th-edition. The United States is not a member of the EP but has observer status. EUR-Lex, *European Pharmacopoeia* (June 4, 2014), https://eur-lex.europa.eu/EN/legal-content/summary/european-pharmacopoeia-eur-lex.html. The European Pharmacopoeia maintains a certified reference standard of glucosamine sulfate potassium chloride.

B

The FDCA preempts specified state requirements relating to food labeling. Two such preemption provisions are relevant here. First, "no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce . . . any requirement for the labeling of food of the type required by section 343(b) . . . of this title [requiring that the food not be offered under the name of another food] that is not identical to the requirement of such section." 21 U.S.C. § 343-1(a)(3).

Second, "no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce . . . any requirement for nutrition labeling of food that is not identical to the requirement of section 343(q) of this title [requiring certain nutrition information to be on the food's label]." *Id.* § 343-1(a)(4).[4]

A state law is "not identical to the requirement of" a specified section if "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 [FDCA or applicable federal regulation] . . . or [d]iffer from those specifically imposed by or contained in the applicable provision" of the FDCA or applicable federal regulation. 21 C.F.R. § 100.1(c)(4). Because the FDCA "preempts state-law requirements for claims about dietary supplements that

[4] Section 343-1(a)(4) applies to requirements that are "not identical to the requirement[s] of [§] 343(q)," which sets forth requirements for the "label or labeling" of food generally. *Cf.* Dissent at 31 (arguing that § 343-1(a)(4) applies only to information contained in a nutrition panel).

differ from the FDCA's requirements," *Dachauer v. NBTY, Inc.*, 913 F.3d 844, 848 (9th Cir. 2019), "private plaintiffs may bring only actions to enforce violations of '*state laws* imposing requirements identical to those contained in the FDCA.'" *Kroessler v. CVS Health Corp.*, 977 F.3d 803, 808 (9th Cir. 2020) (citation omitted). Therefore, "a state-law misbranding claim" that would allow "a state to impose requirements . . . different from those permitted under the FDCA . . . is preempted." *Durnford*, 907 F.3d at 603. "[W]e do not invoke any presumption against pre-emption" where, as here, "the statute 'contains an express pre-emption clause.'" *Puerto Rico v. Franklin Cal. Tax-Free Tr.*, 579 U.S. 115, 125 (2016) (quoting *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 594 (2011)).

II

We now turn to the facts of this case. In her second amended complaint, Hollins asserted that Walmart's product labeled "Spring Valley Glucosamine Sulfate" contained glucosamine hydrochloride, not glucosamine sulfate or glucosamine sulfate potassium chloride. Hollins asserted that glucosamine sulfate potassium chloride is comprised of glucosamine, sulfate, potassium, and chloride bonded to form a single crystal, but Walmart's glucosamine sulfate instead consists of a blend of glucosamine hydrochloride and potassium sulfate. Hollins based this conclusion on tests of 13 bottles of Walmart's product, using a test method called Fourier-transform infrared spectroscopy (FTIR). According to Hollins, the dietary supplement marketed by Walmart contains glucosamine hydrochloride, and therefore cannot

be labeled either "glucosamine sulfate" or "glucosamine sulfate potassium chloride."[5]

According to the second amended complaint, although glucosamine is sold in two commercial formulations, glucosamine sulfate and glucosamine hydrochloride, only glucosamine sulfate has demonstrated clinical effectiveness for certain conditions, so consumers are willing to pay more for this formulation. Therefore, Hollins claimed that she and other consumers were damaged because "they paid for a product that they would not have purchased had it truthfully disclosed that it did not contain Glucosamine Sulfate." Based on these allegations, the second amended complaint claimed violations of the California Consumers Legal Remedies Act, the California Unfair Competition Law, the California False Advertising Law, unjust enrichment, restitution, and breach of warranty.

In October 2020, Walmart moved for summary judgment on the ground that Hollins's claims were based on a testing protocol that was different than the protocol required by federal law, and her claims were therefore preempted. Specifically, Walmart claimed that Hollins's testing methodology deviated from federal requirements under 21 C.F.R. § 101.9(g), because it was not performed on 12 packages of Walmart's product from the same lot at issue and because Walmart's product was tested by FTIR testing,

[5] At the time the lawsuit commenced, the label identified Walmart's product as "Glucosamine Sulfate," and listed the active ingredient as "Glucosamine Sulfate Potassium Chloride 1000mg (1 g)." During the pendency of the lawsuit, the label was changed to identify Walmart's product as "Glucosamine Sulfate Potassium Chloride" and listed the same active ingredient. Hollins does not attribute any significance to this change and has forfeited any argument on that ground, contrary to the dissent. Dissent at 27.

rather than by the AOAC International Official Method 2005.01.

The district court denied the motion, because Walmart had not established that AOAC Method 2005.01 was the appropriate method for determining whether Walmart's product was glucosamine sulfate potassium chloride or glucosamine hydrochloride. The AOAC Method 2005.01 is "[a]pplicable to the analysis of glucosamine in raw materials and dietary supplements containing glucosamine sulfate and/or glucosamine hydrochloride." However, the district court deemed it unclear whether the method was appropriate for distinguishing between glucosamine sulfate (or glucosamine sulfate potassium chloride) and glucosamine hydrochloride. Nor had Walmart met its burden of showing that Hollins's test methodology was not "reliable and appropriate." Instead, the court granted Hollins's discovery request to obtain 12 samples from a single lot in order to conduct testing in compliance with federal law, *see* 21 C.F.R. § 101.9(g)(2), for the purpose of establishing that Walmart's product was not glucosamine sulfate or glucosamine sulfate potassium chloride.

After Hollins obtained the 12 samples from the same lot and conducted testing, the district court held an evidentiary hearing. At the hearing, Hollins's expert witness, Dr. Neil Spingarn, testified that he tested 12 unopened bottles from the same lot using FTIR, X-Ray Diffraction (XRD), and Energy Dispersive X-Ray Spectroscopy (EDX). According to Spingarn, the tests showed that Walmart's product contained a blend of glucosamine hydrochloride and potassium sulfate, rather than a single crystal of glucosamine sulfate potassium chloride.

On cross-examination, Spingarn agreed that the FDA requires the use of a compendial test method to validate a labeling claim. He agreed that the USP standard was a compendial test method. He also agreed that either a single crystal or a blend would satisfy the USP standards for glucosamine sulfate potassium chloride, and therefore Walmart's product would qualify as glucosamine sulfate potassium chloride under the USP method. Spingarn also admitted that he had purchased the EP certified reference standard of glucosamine sulfate potassium chloride, and had confirmed that Walmart's product was indistinguishable from that standard. He argued, however, that the EP's certified reference standard was mislabeled because it was a blend, not a single crystal.

With respect to Spingarn's three test methods (FTIR, XRD, and EDX), Spingarn conceded that he had not published his methods, submitted them for peer review, or documented them in a standard operating procedure. He agreed that his methods were neither validated nor accepted by the FDA to validate label claims for either glucosamine sulfate or glucosamine hydrochloride dietary supplements, and were not considered compendial methods. Finally, Spingarn conceded that he had not found (nor was he aware of anyone finding) any product or material that met his criteria of being a single crystal of glucosamine sulfate potassium chloride rather than a blend.

After the evidentiary hearing, the district court granted Walmart's summary judgment motion. The court concluded that Spingarn's methods raised *Daubert* concerns and were not "reliable and appropriate" under 21 C.F.R. § 101.9(g)(2) for determining whether Walmart's product was mislabeled. The court concluded that Walmart had carried its burden of

showing that Hollins's state-law claims were preempted by federal law. Hollins timely appealed.

III

We review de novo a district court's grant of summary judgment, *Martinez v. City of Clovis*, 943 F.3d 1260, 1269 (9th Cir. 2019), and "questions of preemption." *Silvas v. E*Trade Mortg. Corp.*, 514 F.3d 1001, 1004 (9th Cir. 2008) (citation omitted); *see also Kroessler*, 977 F.3d at 807.

On appeal, Hollins argues that the district court erred in holding that Walmart carried its burden of proving, as a matter of law, that Hollins's claims are preempted. Hollins contends that her state-law mislabeling claim, which would require the state to impose the rule that a blend of glucosamine hydrochloride and potassium sulfate cannot be labeled glucosamine sulfate or glucosamine sulfate potassium chloride, is not preempted because such a rule is identical to the federal rule. "FDCA preemption, like all federal preemption, is an affirmative defense," *Durnford*, 907 F.3d at 603 n.8 (citation omitted), as to which the defendant bears the burden of proof. To prevail on summary judgment, Walmart has to show that, as a matter of law, Hollins's proposed state rule would impose labeling requirements different than those imposed by § 343(b) and § 343(q), and is therefore preempted.[6] *See* 21 U.S.C. § 343-1(a)(3), (4).

We begin with Hollins's contention that her claim would not impose a different labeling requirement on Walmart's product than is imposed by § 343(q). According to Hollins, under § 343(q), a blended version of glucosamine sulfate

[6] Hollins does not invoke any other subsection of § 343 to support her claim.

potassium chloride (such as Walmart's product) may not be identified on the label as glucosamine sulfate or glucosamine sulfate potassium chloride, because such a label does not meet the federal regulatory requirement that the ingredients be declared by "their common or usual name," 21 C.F.R. § 101.36(b)(3)(i). We disagree. A product's "common or usual name" is determined by testing using an AOAC method, or "by other reliable and appropriate procedures." *Id.* § 101.9(g)(2). In an effort to establish that a blended version of glucosamine sulfate potassium chloride does not meet federal requirements, Spingarn used test methods (FTIR, XRD, and EDX) that he conceded were not validated or accepted by the FDA for use in this context. Instead of supporting Hollins's argument, Spingarn's testing indicated that Walmart's product met the EP's certified reference standard for glucosamine sulfate potassium chloride, which supports Walmart's position that glucosamine sulfate or glucosamine sulfate potassium chloride are the "common or usual name" of the product under federal law. Moreover, Spingarn conceded that the blended form of glucosamine sulfate potassium chloride would satisfy the USP compendial standard, another indication that Walmart was using the "common or usual name" of the dietary supplement on its label. *See* 60 Fed. Reg. 67194, 67201 (proposed Dec. 28, 1995) (stating that if a "dietary ingredient is covered by an official compendium, FDA would expect that the dietary ingredient's common or usual name to be drawn from that source").[7] Although Spingarn argues that

[7] The dissent concedes that Hollins cannot prove the distinction between glucosamine sulfate potassium chloride and glucosamine hydrochloride with potassium sulfate "through a validated testing and sampling method as required under 21 C.F.R. § 101.9(g)(2)." Dissent at 25, 27. The dissent nevertheless argues that there is a distinction between these

the EP reference standard was itself mislabeled, this allegation is irrelevant for purposes of determining what federal law requires. In short, Hollins's claim that Walmart's product was mislabeled due to being a blend would allow a state to impose a different labeling requirement on Walmart's product than is imposed by § 343(q), and is therefore preempted. *See* 21 U.S.C. § 343-1(a)(4).

We next turn to Hollins's argument that her claim would not allow a state to impose a labeling requirement on Walmart's product different from that imposed by § 343(b). In making this claim, Hollins argues that a blend of glucosamine hydrochloride and potassium sulfate is mislabeled if it is offered under the name of glucosamine sulfate or glucosamine sulfate potassium chloride because such a label offers a product "for sale under the name of another food" in violation of the labeling requirements in § 343(b). Hollins argues that a label can violate § 343(b), even if the label uses the product's "common or usual name" as determined by federal testing requirements under § 343(q), *see* 21 U.S.C. § 101.9(g)(2), because such testing requirements apply only to the information provided in the

formulations, based on diagrams taken from the National Institutes of Health's website. Dissent at 24, Appendix A. Because such diagrams "were not part of the record before the district court and are not part of the record before us," *Nevius v. Sumner*, 852 F.2d 463, 470 (9th Cir. 1988), and because they shed no light on the molecular structure of the glucosamine sulfate potassium chloride at issue here, they are irrelevant to our analysis.

nutrition panel.[8] Hollins and the dissent rely on *Durnford* to support this theory. Dissent at 25–27.

We disagree. As explained above, Spingarn's testing and concessions indicated that under federal law, glucosamine sulfate or glucosamine sulfate potassium chloride are common or usual names for the blended formulation of glucosamine sulfate. Logically, using the "common or usual" name of a product to identify the product on the label does not constitute offering that product for sale "under the name of another food," in violation of § 343(b). Hollins cites nothing contrary to this common-sense conclusion. Moreover, this conclusion is supported by the labeling requirements in 21 U.S.C. § 343(s), which require a dietary supplement to be labeled with the name of each active ingredient (i.e., each ingredient "for use . . . to supplement the diet," *id.* § 321(ff)(1)(E)), and with the term "dietary supplement," which "may be modified with the name of such ingredient." *Id.* § 343(s)(2)(A)(i), (B). Thus, Section 343(s)(2)(B) permits Walmart to label its dietary supplement with the name of its active ingredient, and the "common and usual" name of that ingredient may be determined pursuant to federal testing requirements. Hollins's proposed rule to the contrary is preempted. *See id.* § 343-1(a)(3).

Durnford does not hold otherwise. Contrary to Hollins's and the dissent's argument, *Durnford*'s conclusion did not rest on any distinction between federal requirements for information in the nutrition panel or information elsewhere

[8] This argument is contrary to her argument before the district court, where Hollins conceded that all of her claims, not just the claims regarding the information provided in the nutrition panel, were subject to federal testing requirements in accordance with 21 C.F.R. § 101.9.

on the label. In *Durnford*, a consumer brought state-law claims against a manufacturer of a nutritional supplement for false or misleading statements about protein contained in one of its products. 907 F.3d at 597. The consumer claimed that the protein in the supplement was augmented by nitrogen-spiking agents, and argued that two types of claims on the label were misleading: (1) the claim that the product contained 40 grams of protein per serving, and (2) the claim that the protein was from "hydrolyzed beef protein and lactoferrin." *Id.* at 598–99. These claims appeared on the nutrition panel as well as in a description of the product's "5-stage mass delivery system" elsewhere on the label. *Id.* at 598. On appeal, we held that the district court correctly dismissed the first claim based on the amount of protein. *Id.* at 601–03. We reasoned that federal regulations, *see* 21 C.F.R. § 101.9(c)(7), permitted the manufacturer's method for determining the amount of protein, and because the "regulations have the same preemptive effect as a statute," they "foreclose the possibility of liability under state law for nitrogen spiking," 907 F.3d at 602. In reaching this conclusion, we did not distinguish between information on the nutrition panel or information elsewhere on the label.

We reversed the district court's dismissal of the consumer's second claim, that the product's label misled him into believing that the protein came entirely from hydrolyzed beef protein and lactoferrin, rather than partly from nitrogen-spiking agents. *Id.* at 603–04. Because the consumer's argument did not go "to the amount of protein, but to its composition," there were no federal testing requirements on point, and so the claim was not preempted. *Id.* at 603.

Nothing in *Durnford* suggests its analysis applied only to the nutrition panel, and indeed, the same information

about the quantity and source of protein was available both in the panel and elsewhere on the label. *Id*. at 598.[9] Therefore, our case is governed by *Durnford*'s holding that the manufacturer's method for determining the amount of protein in the supplement was authorized by regulation and therefore preempted the plaintiff's proposed state-law rule. *Id.* at 602 (citing 21 C.F.R. § 101.9(c)(7)). (We allowed the claim regarding the *source* of protein to go forward only because there were *no* federal testing requirements for identifying protein composition.) Here, as in *Durnford*, federal law permits Walmart to identify its product as glucosamine sulfate potassium chloride, and Hollins's proposed state rule that a blend of glucosamine hydrochloride and potassium sulfate cannot be labeled glucosamine sulfate or glucosamine sulfate potassium chloride is not identical to the federal rule. And as we held in *Durnford*, such a rule is preempted as a matter of law. 21 U.S.C. § 343-1(a)(3), (4).

In arguing against the conclusion that FDA regulations preempt Hollins's state-law mislabeling claims, the dissent

[9] The dissent's claim that *Durnford* made a distinction between "misrepresentations on the *nutrition panel*," which were preempted, and a "misrepresentation on the *rest of the label*," which was not, Dissent 26, takes the language in the opinion out of context. In fact, *Durnford* considered only the distinction between the label's information about the *amount* of protein and the *source* of the protein. 907 F.3d at 602–04. The opinion did not put any weight on the location of the information. Thus, *Durnford* explained that "[u]nder Durnford's theory of misbranding, whether or not there was compliance with the FDA's 12-sample testing protocol does not matter," because the testing protocol is relevant only to "the proper means of calculating protein *content* in dietary supplements," and "Durnford's protein *composition* theory [was] not concerned with the total amount of protein in the Supplement; it [was] concerned with the source of that protein." *Id.* at 603–04.

raises a new argument not made by either party. According to the dissent, *Hawkins v. Kroger Co.*, 906 F.3d 763 (9th Cir. 2018) supports the argument that regulatory requirements applicable to the nutrition panel are not applicable to information elsewhere on the label. Dissent at 28. But *Hawkins* is inapposite here. *Hawkins* involved two inconsistent FDA regulations governing a label's claims about the amount of trans fat in a product. One regulation mandated that the nutrition panel follow certain "rounding rules" with respect to nutrient levels, *id.* at 772, including the rule that "[i]f the serving contains less than 0.5 gram [of trans fat], the content shall be expressed as zero," *id.* at 770 (quoting 21 C.F.R. § 101.9(c)(2)(ii)). A second regulation, which governed "nutrient content claims" made outside the nutrition panel, mandated that claims regarding nutrient levels not be "false or misleading in any respect." *Id.* at 770–71 (quoting 21 C.F.R. 101.13(i)(3)).[10] We resolved this conflict by holding that a manufacturer was bound to follow the rounding rules for the nutrition panel, but could not make the same misleading claim elsewhere on the label. *Id.* at 771–72. In light of the federal regulation precluding misleading nutrient content claims, we held that the FDA regulations did not preempt a plaintiff's state-law claim that a statement on a product's label (and not within the nutrition panel) advertising zero grams trans fat was misleading. *Id.* at 772.

Hawkins is inapposite here. This case does not involve a nutrient content claim, conflicting regulations, or any regulation requiring a manufacturer to make a misleading

[10] A "nutrient content claim" is defined as "[a] claim that expressly or implicitly characterizes the *level* of a nutrient" of a specific type, such as calories, sodium, or fat. 21 C.F.R. § 101.13(b) (emphasis added).

claim. Rather, the regulations here detail an appropriate testing method to determine the "common or usual name" of an ingredient for purposes of the nutrition panel, 21 C.F.R. § 101.36(b)(3)(i), and raise the question whether using that "common or usual name" of the active ingredient elsewhere on the label constitutes offering the product for sale "under the name of another food," 21 U.S.C. § 343(b). Because, unlike in *Hawkins*, federal testing regulations governing the nutrition panel do not require the use of misleading information, there is no conflicting federal regulation which would prevent the use of the name determined in accordance with the federal testing requirements elsewhere on the label. Therefore, the federal rules preempt any state rules that might preclude the use of the name of an ingredient determined in accordance with federal testing requirements.[11]

Applying the summary judgment standard, there is "no genuine dispute as to any material fact" that Hollins's mislabeling claims would "permit a state to impose requirements" for labeling a dietary supplement such as Walmart's glucosamine sulfate potassium chloride product "different from those permitted under the FDCA." *Durnford*, 907 F.3d at 603. Therefore, the claims are preempted, *see* 21 U.S.C. § 343-1(a)(3), (4), and Walmart is entitled to judgment as a matter of law.[12]

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[11] The dissent's reliance on *Rigo Amavizca v. Nutra Mfg., LLC*, No. 8:20-cv-01324, 2021 WL 682113 (C.D. Cal. Jan. 27, 2021), is misplaced. Dissent at 25–26, 28–30. We are not bound by this district court case, and its reasoning is not persuasive for the reasons stated in this opinion.

[12] Prior to considering the second summary judgment motion, after Hollins completed testing, the district court granted Walmart's motion to dismiss Hollins's claims for equitable restitution, disgorgement, and

AFFIRMED.

WARDLAW, J., dissenting in part:

I write separately to clarify the applicability of the Federal Drug Administration's (FDA's) testing and sampling requirements to Hollins's state-law mislabeling claims. In my view, Hollins is not required to comply with the FDA's testing requirements with respect to her claims outside of the nutrition facts panel. Challenges to the label under 21 U.S.C. § 343(b) are distinct from those to the nutrition facts panel (the "nutrition panel") under 21 U.S.C. § 343(q), such that the 21 C.F.R. § 101.9(g) federal testing requirements do not apply to the label outside of the nutrition panel, and, therefore, these claims are not preempted by federal law.

I.

According to the National Institute of Health's website, glucosamine sulfate potassium chloride (what Hollins believed she was purchasing) and glucosamine hydrochloride with potassium sulfate (what Hollins actually purchased) are chemically and molecularly different. *See* Appendix A. "[N]ot all glucosamines are the same . . . . [G]lucosamine sulfate has demonstrated clinical effectiveness for certain [health] conditions, whereas other forms of glucosamine have not. The common perception of glucosamine sulfate is that it performs better than

unjust enrichment for failure to allege that she lacked a legal remedy, under *Sonner v. Premier Nutrition Corp.*, 971 F.3d 834, 844 (9th Cir. 2020). Because we find Hollins's claims were preempted, we need not reach the issue of whether the district court erred in dismissing these claims. We also need not address Hollins's arguments that the district court erred by assessing Spingarn's credibility on summary judgment.

glucosamine hydrochloride; consumers therefore prefer the former, and companies charge more for it." *Rigo Amavizca v. Nutra Mfg., LLC*, No. 20-01324, 2021 WL 682113, at *1 (C.D. Cal. Jan. 27, 2021).[1] While Hollins is unable to prove the distinction between the two molecules through a validated testing and sampling method as required under 21 C.F.R. § 101.9(g)(2), such testing requirements apply only to Hollins's § 343(q) nutrition panel claims, not her § 343(b) mislabeling claims. Accordingly, Hollins's state law claims regarding the label outside of the nutrition panel can proceed.

II.

A.

The majority opinion misapplies *Durnford v. MusclePharm Corp.*, 907 F.3d 595, 604 (9th Cir. 2018). The majority interprets our decision in *Durnford* narrowly, finding that it stands only for the proposition that challenges to a label's characterization of the *source* of an ingredient are exempt from the Food, Drug, and Cosmetic Act (FDCA). Maj. Op. 21. In fact, *Durnford*'s reasoning supports Hollins's position—at least in part—that some of her claims are not preempted by federal law.

[1] *See also* Lucio C. Rovalti et al., *Crystalline Glucosamine Sulfate in the Management of Knee Osteoarthritis: Efficacy, Safety, and Pharmacokinetic Properties*, 4 Therapeutic Advances in Musculoskeletal Disease 167, 167 (2012) ("As a whole, the use of glucosamine in the management of osteoarthritis is supported by the clinical trials performed with the original prescription product, that is, crystalline glucosamine sulfate. This is the stabilized form of glucosamine sulfate, while other formulations or different glucosamine salts (e.g. hydrochloride) have never been shown to be effective.").

In *Durnford*, a consumer brought claims against MusclePharm Corporation, a manufacturer of nutritional supplements, "for making false or misleading statements about the protein in one of its products." *Id.* at 597. We concluded that some, but not all, of Durnford's state-law misbranding claims were preempted by federal law. *Id.*

We made two distinctions between claims which were preempted and those which were not. First, we noted that the "FDCA and its implementing regulations concern only the calculation and disclosure of protein *amounts*." *Id.* But "[t]hey say nothing about the source or composition of protein," and "Durnford's claims are therefore not preempted to the extent they arise under that theory." *Id*.

But we made a second distinction which the majority ignores. We explained that Durnford's mislabeling theory which referred to misrepresentations on the *nutrition panel* was preempted, but that his theory which referred to misrepresentation on the *rest of the label* was not. *See id.* at 602–604. Specifically, we held that "[u]nder Durnford's theory of misbranding [related to the label outside of the nutrition panel], whether or not there was compliance with the FDA's 12-sample testing protocol [did] not matter." *Id.* at 603.

The second distinction is pertinent here. As the *Durnford* Court aptly explained in a footnote:

> We refer to the product's packaging as a whole as the "label." We refer to the federally mandated declaration of nutritional content within the label as the "nutrition panel" . . . [T]he latter is subject to a *unique set of stringent federal regulations*.

Id. at 598 n.1 (emphasis added).

The majority focuses on only one of *Durnford*'s distinctions—the amount versus the content of the protein in the supplement. But *Durnford*'s second distinction—between "[t]he label – separately from the mandatory nutrition panel"—is controlling here such that the testing requirements under 21 C.F.R. § 101.9(g)(2) do not apply to Hollins's § 343(b) misnaming claims beyond the nutrition panel, and therefore these claims are not preempted. *Id.* at 603.

Accordingly, even though Hollins cannot show that the product she purchased is mislabeled on the nutrition panel based on the 21 C.F.R. § 101.9(g)(2) testing requirements, she can still state a mislabeling claim. Under § 343(b), Hollins can show that the product was offered for sale under the name of another food because the supplement's packaging names the product "glucosamine sulfate potassium chloride," and she has presented evidence that this substance is structurally and chemically different than glucosamine hydrochloride blended with potassium sulfate—what the supplement actually contained. The fact that Hollins cannot prove the distinction between the two molecules through the federal sampling and testing requirements is irrelevant to her § 343(b) claims.

Further, even assuming there is no distinction between glucosamine sulfate potassium chloride and glucosamine hydrochloride with potassium sulfate, Hollins has an additional mislabeling claim because when the suit was filed the supplement's front label stated the product's name as "glucosamine sulfate," but the nutrition panel listed the product as "glucosamine sulfate potassium chloride," a different supplement.

B.

We also recognized the distinction between claims on the nutrition panel and those "made elsewhere on the [label]" in *Hawkins v. Kroger Co.*, 906 F.3d 763, 770 (9th Cir. 2018). In *Hawkins*, we were tasked with determining "whether [ ] FDA trans fat regulations governing the content of the Nutrition Facts Panel preempt" state mislabeling claims "elsewhere on a food product's label." *Id.* at 767. We held that the "rules[] contained in 21 C.F.R. § 101.9[] govern[] what must be stated within the Nutrition Facts Panel," and "[c]ritically, the rules that govern claims made within the Nutrition Facts Panel and the rules that govern nutrition content claims elsewhere on the label are different." *Id.* at 770.

To be sure, the nutrition panel versus packaging label distinction in *Hawkins* focused on nutrient content claims, which are not at issue here. But our holding that "the FDA regulations did not preempt a plaintiff's state-law claim that a statement on a product's label (and not within the nutrition panel) . . . was misleading," Maj. Op. 22, highlights the distinction between the nutrition panel and the rest of the product's label and further lends support to the conclusion that only Hollins's § 343(q) claims related to the nutrition panel are subject to the federal testing and sampling requirements.

C.

The majority opinion is also inconsistent with a related district court case, *Amavizca*. *Amavizca* dealt with nearly identical facts to the case before us. There, plaintiffs brought state law mislabeling claims against a supplement manufacturer arguing that the supplement they purchased was labeled as glucosamine sulfate, when in fact the

substance was actually glucosamine hydrochloride and sodium sulfate. 2021 WL 682113 at *2. The *Amavizca* defendants argued, as Walmart does here, that the plaintiff consumers' claims were preempted. *Id.* at *4.

Although not binding on us, *Amavizca*'s analysis is persuasive. Relying on the FDA preemption framework we laid out in *Durnford*, the *Amavizca* court concluded that the consumer plaintiffs were not required to comply with the federal testing requirements for their label-related claims, but were required to comply if they sought to prove their nutrition panel-related claims. *Id.* at *5. The *Amavizca* court explained:

> Plaintiff's allegations thus implicate different provisions of the FDCA and FDA regulations. Plaintiff's allegation that the "Supplement Facts" panels on Defendants' products contain misrepresentations implicates 21 U.S.C. § 343(q) and 21 C.F.R. § 101.36, which govern the nutrition labeling of dietary supplements. Plaintiff's allegation that Defendants' Products have the words "Glucosamine Sulfate" displayed prominently on the label, however, implicates 21 U.S.C. § 343(b), under which a food is deemed misbranded "[i]f it is offered for sale under the name of another food." 21 U.S.C. § 343(b).

Id. at *4.

Further, the *Amavizca* court emphasizes that the requirements of 21 C.F.R. §§ 101.36 and 101.9(g) govern "the nutrition labeling of dietary supplements," and "FDA

regulations define 'nutrition labeling' as synonymous with 'Supplement Facts' panels." *Id*. Accordingly, here, as in *Amavizca*, Hollins's claims that are not premised on the "'nutrition labeling' or 'Supplement Facts' panels . . . do not implicate the testing method set forth in 21 C.F.R. § 101.9(g)(2)." *Id*. at *5.

The district court in *Amavizca* properly relied on our decision in *Durnford* in holding that the distinction between the overall label and the nutrition panel applies not only to nutrient content claims, but also to other mislabeling claims. By contrast, the majority opinion disregards our circuit precedent by failing to follow the distinction required by *Durnford* and applied in *Amavizca*.

III.

Finally, the majority opinion runs counter to the presumption against preemption. *Hawkins*, 90 F.3d at 769 ("[I]n all pre-emption cases, and particularly in those in which Congress has 'legislated . . . in a field which the States have traditionally occupied,' . . . we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'") (alterations in original) (quoting *Wyeth v. Levine*, 555 U.S. 555, 565 (2009)).

Even assuming the majority is correct that this is an express preemption case, only when "the statute's language is plain," should the language of the preemption clause itself end our inquiry. *Puerto Rico v. Franklin Cal. Tax-Free Tr.*, 579 U.S. 115, 125 (2016) (quoting *United States v. Ron Pair Enter., Inc.,* 489 U.S. 235, 241 (1989)). Here, contrary to the majority's assertion, the applicable FDCA preemption provision is unclear.

The FDCA limits preemption to "any requirement for *nutrition labeling* of food that is not identical to the requirements of section 343(q)." 21 U.S.C. § 343-1(a)(4) (emphasis added). Although the "any requirement" language is broad, the "nutrition labeling" requirement creates some ambiguity. As the *Hawkins* court points out, "[s]omewhat confusingly, the FDA regulations refer to the ubiquitous box that contains nutritional facts as 'nutrition labeling,' 21 C.F.R. § 101.9, while also referring to the rest of the product's exterior as labeling." *Hawkins*, 906 F.3d at 766 n.1. Accordingly, the plain language of the statute supports the contention that the clause applies only to the nutrition panel, or at a minimum, creates ambiguity as to whether all labeling claims, or only those in the nutrition panel, are subject to § 343(q)'s regulations for preemption purposes.

Because the statutory language is ambiguous, and we are instructed to construe ambiguous federal statutes not to preempt state law whenever possible, the presumption against preemption applies here. *See, e.g.*, *Altria Grp., Inc v. Good*, 555 U.S. 70, 77 (2008) ("[W]hen the text of a pre-emption clause is susceptible of more than one plausible reading, courts ordinarily 'accept the reading that disfavors pre-emption.'") (quoting *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005)).

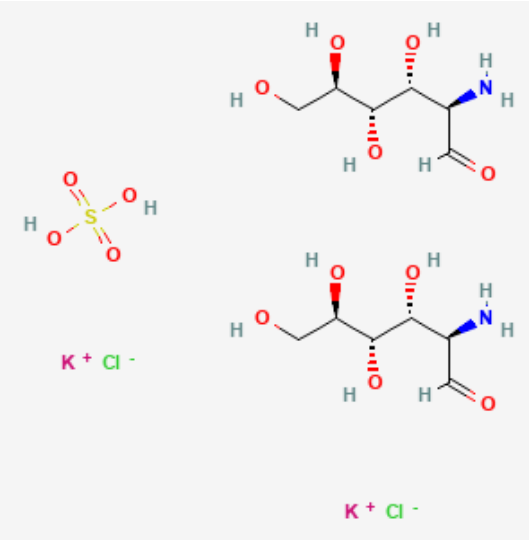
IV.

In sum, I respectfully disagree with the majority's holding to the extent it finds that the federal testing and sampling requirements apply to Hollins's state-law mislabeling claims targeting the label outside of the nutrition panel. Accordingly, I would hold that such claims are not preempted by the FDCA and allow them to proceed.

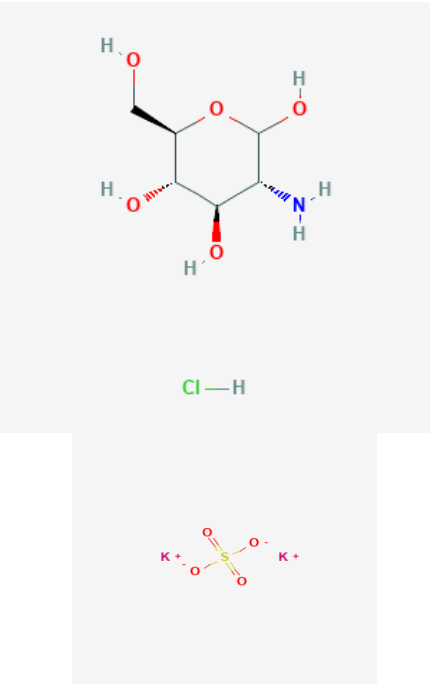
APPENDIX A

Depictions of the different molecular structures of the molecules:

Glucosamine Sulfate Potassium Chloride



Glucosamine Hydrochloride with Potassium Sulfate



See PubChem Compound Summary for CID 76965765, Glucosamine Sulfate Potassium Chloride, Nat'l Ctr. for Biotechnology Info., https://pubchem.ncbi.nlm.nih.gov/compound/Glucosamine-sulfate-potassium-chloride (last visited Feb. 7, 2023); *PubChem Compound Summary for CID 2723635,*

Glucosamine hydrochloride, Nat'l Ctr. for Biotechnology Info., https://pubchem.ncbi.nlm.nih.gov/compound/Glucosamine-hydrochloride (last visited Feb. 7, 2023); *PubChem Compound Summary for CID 24507, Potassium Sulfate*, Nat'l Ctr. for Biotechnology Info., https://pubchem.ncbi.nlm.nih.gov/compound/Potassium-Sulfate (last visited Feb. 7, 2023).