FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

JACOB SCHEIBE, on behalf of all those similarly situated, *Plaintiff - Appellant*, v. PROSUPPS USA, LLC, a Texas limited liability company, *Defendant - Appellee*.	No. 23-3300 D.C. No. 3:22-cv-01784-BEN-MSB OPINION

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

Argued and Submitted November 20, 2024
Pasadena, California

Filed June 23, 2025

Before: Johnnie B. Rawlinson, Morgan B. Christen, and Anthony D. Johnstone, Circuit Judges.

Opinion by Judge Johnstone

SUMMARY**

Food, Drug, and Cosmetic Act/Preemption

The panel reversed the district court's dismissal on preemption grounds of a putative class action brought against ProSupps USA under California consumer protection laws for mislabeling a dietary supplement named Hydro BCAA.

Plaintiff alleged that Hydro BCAA was mislabeled because his preliminary testing found that the supplement contained more grams of carbohydrates and calories than was listed on the supplement's FDA-prescribed label. Plaintiff alleged he tested the supplement using the FDA's testing methods, but not the FDA's twelve-sample sampling process. The district court found that the Food, Drug, and Cosmetic Act preempted the claims because plaintiff failed to plead that he tested the supplement according to the FDA's sampling process.

The Food, Drug, and Cosmetic Act preempts state laws imposing labeling requirements that are not identical to those of the Act. Consumers can bring claims under state law alleging that foods are mislabeled, but those claims cannot impose liability beyond what the Act requires. If a product's label complies with the Act, then the Act preempts any state-law claim that the product is mislabeled.

The panel held that plaintiff's complaint allowed a court to draw a reasonable inference that ProSupps misbranded the

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supplement under the Act. Although plaintiff did not allege that he complied with the FDA's twelve-sample sampling process, his preliminary testing of one sample, by an independent laboratory using the FDA-prescribed process, found that the supplement contained more carbohydrates and calories than ProSupps listed on the supplement's label. It was plausible that additional samples would show similar results. A court could therefore draw a reasonable inference that testing a composite sample according to FDA regulations would show that the supplement was misbranded under the Act. Accordingly, plaintiff's complaint survived preemption on a motion to dismiss.

COUNSEL

Charles C. Weller (argued), Charles C. Weller APC, San Diego, California, for Plaintiff-Appellant.

Jaikaran Singh (argued), Foley & Lardner LLP, San Diego, California; Jessica N. Walker, Foley & Lardner LLP, Los Angeles, California; for Defendant-Appellee.

OPINION

JOHNSTONE, Circuit Judge:

Under the Food, Drug, and Cosmetic Act, a food's label must display certain nutritional information, including the amounts of carbohydrates and calories in the food. This information appears in what consumers know as the "Nutrition Facts" panel. The Food and Drug Administration ("FDA") specifies testing methods for determining the amount of carbohydrates and calories in a food. The FDA also mandates a sampling process for those tests. That process requires applying one of the specified testing methods to a composite of twelve randomly chosen samples. Generally, a food, including a dietary supplement, is "misbranded" in violation of the Act if its label differs by a specified margin from the results of these tests. The FDA also allows foods containing up to 0.5 grams of carbohydrates to be labeled as zero-carbohydrate, and foods containing up to 5 calories to be labeled as zero-calorie. The Act preempts state laws imposing labeling requirements that are not identical to those of the Act. So consumers can bring claims under state law alleging that foods are mislabeled, but those claims cannot impose liability beyond what the Act requires.

ProSupps USA LLC ("ProSupps") sells a dietary supplement named Hydro BCAA. The supplement's FDA-prescribed label states that each 13.8-gram serving contains 10 grams of amino acids but zero grams of carbohydrates and zero calories. Based on this label, Jacob Scheibe bought the supplement to help him lose weight and gain muscle mass. Now he alleges that the supplement's zero-carbohydrate and zero-calorie claims were too good to be

true. His preliminary testing found that the supplement contained 5.68 grams of carbohydrates and 51 calories per serving, far exceeding the FDA's allowable margins for zero-carbohydrate and zero-calorie labeling. Scheibe sued ProSupps under California consumer protection laws for mislabeling the supplement. He alleges that he tested the supplement using the FDA's testing methods, but not that he used the FDA's sampling process. Based on the results of these tests, he claims that the supplement is mislabeled.

The district court dismissed Scheibe's complaint, holding that the Act preempted his claims because he did not plead that he tested the supplement according to the FDA's sampling process. We reverse because, even without these sampling allegations, Scheibe's complaint still allows a court to draw a reasonable inference that ProSupps misbranded the supplement under the Act. Scheibe has not pleaded his state-law claims into preemption.

I. Scheibe alleges that the supplement is mislabeled.

On a motion to dismiss, we accept the allegations of the complaint as true. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). ProSupps Hydro BCAA powder is a dietary supplement containing an amino-acid blend. Consumers use the supplement to increase the efficiency of workouts, increase muscle mass, support weight loss, and aid in muscle repair. According to the label, although a serving of the supplement contains 10 grams of amino acids, it has zero grams of carbohydrates and zero calories. Scheibe counts his carbohydrates and calories to meet his weight-loss and muscle-building goals. In August 2022, after reviewing the supplement's label, Scheibe bought the supplement in the watermelon flavor.

Scheibe appears to take his food labels seriously. He asked an independent laboratory to verify the supplement's claim of zero carbohydrates and calories. The laboratory tested a single 100-gram sample of the supplement using FDA-approved testing methods. Nutrition labeling of dietary supplements, 21 C.F.R. § 101.36(b)(2)(i) (2024) (incorporating Nutrition labeling of food, 21 C.F.R.§ 101.9(c)(1)(i), (c)(6) (2024)); *id.* § 101.36(f)(1) (incorporating *id.* § 101.9(g)(2)). The test found 41.2 grams of carbohydrates in the sample, or 5.68 grams of carbohydrates per serving. And it found 372 calories in the sample, or 51 calories per serving.

Based on these test results, Scheibe claims that the supplement's label is false and so violates California law. Scheibe filed a putative class action in federal district court under the Class Action Fairness Act, 28 U.S.C. § 1332(d), against ProSupps for: (1) violations of California's Consumer Legal Remedies Act, Cal. Civ. Code § 1750, *et seq*.; (2) violations of California's Unfair Competition Law, Cal. Bus. & Prof. Code § 17200, *et seq.*; (3) violations of California's False Advertising Law, Cal. Bus. & Prof. Code § 17500, *et seq.*; and (4) unjust enrichment. ProSupps moved to dismiss Scheibe's amended complaint under Federal Rule of Civil Procedure 12(b)(6), arguing that Scheibe's state-law claims are preempted because they hold ProSupps to a different standard for carbohydrate and calorie labeling than the Act. *See* 21 U.S.C. § 343-1(a)(4). The district court agreed and dismissed Scheibe's complaint.

In its order, the district court noted a divide between district courts in the Ninth Circuit. Some courts hold that to avoid preemption of state-law mislabeling claim, plaintiffs must plead that they followed the FDA's testing methods and sampling processes. *See, e.g.*, *Salazar v. Honest Tea,*

Inc., 74 F. Supp. 3d 1304, 1313 (E.D. Cal. 2014). Other courts hold that plaintiffs need only allege facts that allow a court reasonably to infer that a product would be misbranded if it were tested using the FDA's testing methods and sampling processes. *See, e.g.*, *Murphy v. Olly Pub. Benefit Corp.*, 651 F. Supp. 3d 1111, 1124 (N.D. Cal. 2023).

We have jurisdiction under the Class Action Fairness Act, 28 U.S.C. § 1332(d), and review de novo the grant of a Rule 12(b)(6) motion to dismiss for failure to state a claim, *Bain v. Cal. Tchrs. Ass'n*, 891 F.3d 1206, 1211 (9th Cir. 2018).

II. Scheibe did not plead his claims into preemption under the Act.

To promote "[n]ational uniform nutrition labeling," the Food, Drug, and Cosmetic Act preempts state laws that "directly or indirectly establish . . . any requirement for nutrition labeling of food that is not identical" to the Act's nutrition labeling requirements. 21 U.S.C. § 343-1(a)(4). Thus, "private plaintiffs may bring only actions to enforce violations of '*state laws* imposing requirements identical to those contained in the [Act].'" *Kroessler v. CVS Health Corp.*, 977 F.3d 803, 808 (9th Cir. 2020) (emphasis in original) (quoting *Farm Raised Salmon Cases*, 175 P.3d 1170, 1177 (Cal. 2008)). So if a product's label complies with the Act, then the Act preempts any state-law claim that the product is mislabeled. *See Hollins v. Walmart Inc.,* 67 F.4th 1011, 1016 (9th Cir. 2023). And because compliance with the Act can be determined only by the FDA's testing methods and sampling processes, the Act necessarily preempts mislabeling claims proven only through testing methods and sampling processes "not validated or accepted by the FDA for use in th[at] context." *Id.* at 1019.

Because preemption is an affirmative defense ProSupps bears the burden of showing that Scheibe's claims are preempted. *See Durnford v. MusclePharm Corp.*, 907 F.3d 595, 603 n.8 (9th Cir. 2018) (citing *Lusnak v. Bank of Am., N.A.*, 883 F.3d 1185, 1194 n.6 (9th Cir. 2018)). Under Rule 12(b)(6), "[o]nly when the plaintiff pleads itself out of court," by admitting all the elements of an affirmative defense, may a complaint that otherwise states a claim be dismissed. *Id.* (quoting *Xechem, Inc. v. Bristol-Myers Squibb Co.*, 372 F.3d 899, 901 (7th Cir. 2004)). To state a claim, a pleading need only contain "a short and plain statement . . . showing that the pleader is entitled to relief[.]" Fed. R. Civ. P. 8(a)(2). This rule means that Scheibe's complaint merely has to nudge his claim "from conceivable to plausible." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Thus, to state a "plausible" mislabeling claim that is not preempted, Scheibe must plead facts that "allow[] the court to draw the reasonable inference that the defendant is liable." *Iqbal*, 556 U.S. at 678.

Here, for ProSupps to be liable, Scheibe's state-law claims must survive federal preemption. In other words, the complaint must allege that the supplement was mislabeled "within the meaning of the federal regulations." *Nacarino v. Kashi Co.*, 77 F.4th 1201, 1212 (9th Cir. 2023). This requires Scheibe to plead facts that allow a court reasonably to infer that the supplement is not only mislabeled under state law, but also misbranded under the Act. To establish its affirmative defense of preemption on a motion to dismiss, ProSupps must show that Scheibe's complaint fails to support that inference.

To start, the Act requires labels on foods that list the total amount of carbohydrates and calories contained in each serving. 21 U.S.C. § 343(q)(1)(C)–(D); *see also id.* § 321(ff)

("a dietary supplement shall be deemed to be a food"). Congress delegated authority, through the Secretary of Health and Human Services, to the FDA to enforce the Act through regulations. *See* 21 U.S.C. § 371(a); *Hollins*, 67 F.4th at 1014. Separate regulations control the nutrition labeling of dietary supplements and foods, *see* 21 C.F.R. § 101.36; *cf. id.* § 101.9, but the regulations controlling dietary supplement labels incorporate many of the regulations controlling food labels. *See, e.g.*, *id.* § 101.36(f)(1) (providing that "[c]ompliance with this section will be determined in accordance with § 101.9(g)(1) through (g)(8), (g)(10), and (g)(11)," with exceptions). The FDA requires manufacturers to determine a nutritional supplement's content by testing a sample consisting 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). For carbohydrates, the FDA requires testing each sample according to a method prescribed by the Association of Official Analytical Collaboration ("AOAC") International. *Id.* (incorporating *id.* § 101.9(g)(2)); *id.* § 101.36(b)(2)(i) (incorporating *id.* § 101.9(c)(6)). For calories, the FDA requires the use of any of the six approved methods for testing each sample, one of which is bomb calorimetry testing. *Id.* § 101.36(b)(2)(i) (incorporating *id.* § 101.9(c)(1)(i)(E)).

ProSupps fails to show that Scheibe's nutritional content claims are preempted because Scheibe plausibly pleads that the supplement is mislabeled in a way that also violates the Act. Scheibe alleges that his testing methods complied with FDA regulations: he used the AOAC method for carbohydrates and bomb calorimetry for calories. But he does not allege that he complied with the FDA's sampling

process. Instead, Scheibe simply alleges that one sample of the supplement, tested by an independent laboratory, contained more carbohydrates and calories than ProSupps listed on the supplement's label. Still, his preliminary testing of that one sample is enough to avoid preemption on the pleadings because it allows a court to draw a reasonable inference that testing a composite sample according to FDA regulations would show that the supplement is misbranded under the Act. Scheibe's single sample contained several times more carbohydrates and calories than the FDA allows to be listed as zero on the label. It is plausible that additional samples would contain similar amounts of nutrients. And even if those samples contained far fewer carbohydrates and calories than Scheibe's original sample, they still could lead to a result that exceeds the margins for zero-carbohydrate or zero-calorie labels and thereby establish misbranding under the Act.

Maybe Scheibe's first and only test result is an outlier. Perhaps additional tests in discovery will confirm that the supplement really does contain zero carbohydrates and zero calories within the margins set by the FDA. But the Federal Rules of Civil Procedure do not cast judges as skeptics of pleadings. To the contrary, while "[f]actual allegations must be enough to raise a right to relief above the speculative level," a court must "assum[e] that all the allegations in the complaint are true (even if doubtful in fact)[.]" *Twombly*, 550 U.S. at 555. A plaintiff's allegations need not defeat every alternative explanation. Instead, "[p]laintiff's complaint may be dismissed only when defendant's plausible alternative explanation is so convincing that plaintiff's explanation is *implausible*." *Eclectic Props. E., LLC v. Marcus & Millichap Co.*, 751 F.3d 990, 996 (9th Cir. 2014) (emphasis in original) (quoting *Starr v. Baca*, 652

F.3d 1202, 1216 (9th Cir. 2011)). ProSupps speculates that "it may also be that this testing based on a single sample was inaccurate" or that "the averaging across 12 samples could provide results consistent with the labeling[.]" These lingering possibilities do not make Scheibe's mislabeling allegations implausible. Because Scheibe's test of a single sample allows a court reasonably to infer that the supplement would be misbranded if it were tested using the FDA's twelve-sample process, Scheibe's state-law claims are not preempted.

ProSupps fails to show otherwise. Beyond offering speculative alternatives, it contends that, because Scheibe tested only one sample, he admits that he did not comply with the FDA's sampling process. The FDA, ProSupps argues, "does not require that every single product strictly comply with the labeling regulations by having the exact same amount of nutrients as stated in the supplement facts panel." But Scheibe does not argue that every serving of the supplement must have the same amount of nutrients. Rather, he argues that the amounts of carbohydrates and calories he found in one sample of the supplement allows a court to draw a reasonable inference that the FDA's twelve-sample process would find similar amounts. "Pleading that one has conducted independent, non-FDA compliant testing that suggests [misbranding] does *not* suggest that one *could not* support allegations of [misbranding] with FDA-compliant testing." *Murphy*, 651 F. Supp. 3d at 1124 (emphasis in original). To the contrary, the results of Scheibe's single-sample test suggest that he could support the complaint's allegations of misbranding under the Act and therefore avoid preemption.

Further, we decline to adopt a rule that would, in effect, require plaintiffs to perform the FDA's sampling process at

the pleading stage to avoid preemption. As Scheibe argues, it may be impracticable for a plaintiff to test 12 different samples "randomly selected to be representative of the lot" before discovery opens. 21 C.F.R. § 101.36(f)(1). And the fact that defendants may have exclusive control and possession of critical facts—like their own product inventory—cannot categorically prevent plaintiffs from stating a plausible claim. *See Soo Park v. Thompson*, 851 F.3d 910, 928–29 (9th Cir. 2017). FDA preemption is no exception to the rule that "plaintiffs are generally not expected to provide evidence in support of their claims at the pleading stage." *Durnford*, 907 F.3d at 603 n.8. ProSupps does not argue otherwise. Instead, it argues only that Scheibe should have "alleged sufficient facts to support a plausible inference that his laboratory testing demonstrates false labeling if the FDA-mandated 12-sample methodology was applied." Yet this is what Scheibe has done.

We hold that a plaintiff's failure to plead nutrition testing according to the FDA's sampling process does not preclude a court from drawing a reasonable inference that a food's label violates the Act. Scheibe's allegations that he tested the supplement using FDA testing methods are sufficient to avoid preemption, and we need not address whether they are also necessary to do so. Because Scheibe alleged facts that allow a reasonable inference that the supplement is misbranded under the Act, his complaint survives preemption on a motion to dismiss. ProSupps may establish preemption if it later proves that the supplement's labeling complies with the Act. But at this stage of the case Scheibe has stated a plausible claim that is not preempted.

REVERSED.