United States Court of Appeals
For the First Circuit

No. 22-1910

KRISTIN DICROCE,
individually and on behalf of all persons similarly situated,

Plaintiff, Appellant,

v.

MCNEIL NUTRITIONALS, LLC and JOHNSON & JOHNSON CONSUMER INC.,

Defendants, Appellees.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. Patti B. Saris, U.S. District Judge]

Before

Kayatta, Gelpí, and Montecalvo,
Circuit Judges.

John Peter Zavez, with whom Noah Rosmarin, Brendan M. Bridgeland, and Adkins, Kelston & Zavez, P.C. were on brief, for appellant.

Hannah Y. Chanoine, with whom Kayla N. Haran, Matthew D. Powers, and O'Melveny & Myers LLP were on brief, for appellees.

September 18, 2023

GELPÍ, Circuit Judge. Plaintiff-Appellant Kristin DiCroce ("DiCroce") challenges the district court's dismissal of her complaint against McNeil Nutritionals, LLC and Johnson & Johnson Consumer, Inc. (collectively, "Appellees") for their allegedly misleading labeling and marketing of Lactaid supplements. We agree with the dismissal outcome, albeit on different grounds. Therefore, we affirm.

I. BACKGROUND

Given that "[t]he maze of detail" in DiCroce's complaint is clearly laid out in the district court's opinion,[1] we recite only the facts needed "for purposes of th[is] appeal." Dukes Bridge LLC v. Beinhocker, 856 F.3d 186, 187 (1st Cir. 2017).

Lactose intolerance is "characterized by abdominal cramps and diarrhea after consumption of food that contains lactose," a sugar found in dairy products. Lactose Intolerance, Stedmans Medical Dictionary 452780, Westlaw (databased updated Nov. 2014). Individuals who suffer from lactose intolerance do not produce enough lactase -- an enzyme that aids in the digestion of lactose. See id. Lactaid is a tablet form of the enzyme lactase -- made and distributed by Appellees -- that claims to prevent "gas," "bloating," and "diarrhea" "associated with digesting dairy," among other things.

[1] DiCroce v. McNeil Nutritionals, LLC, 640 F. Supp. 3d 182 (D. Mass. 2022).

DiCroce lives in Massachusetts and has purchased Lactaid supplements "on multiple occasions within the past four years." DiCroce filed this putative class action in October 2021 challenging certain statements on the packaging of Lactaid products.[2] Her general argument proceeds as follows:

> (1) Lactose intolerance is a disease, per 21 C.F.R. § 101.93(g)(1)'s definition of a "disease";
>
> (2) Lactaid, although marketed as a dietary supplement, claims to treat the disease of lactose intolerance, thereby violating 21 U.S.C § 343(r)(6), and making it a drug, per § 101.93(f);
>
> (3) Because Lactaid is a drug under the relevant federal laws, it is misleading, and thus violative of state law, for Appellees to misbrand Lactaid as a dietary supplement, and to make statements on Lactaid's label disclaiming Food and Drug Administration ("FDA") approval, thereby implying that FDA approval is not required;
>
> (4) Had Lactaid's product not claimed to treat the disease of lactose intolerance, DiCroce would not have been misled into

---

[2] DiCroce's complaint claims that: (1) Appellees engaged in deceptive acts or practices in violation of Mass. Gen. Laws ch. 93A (the Massachusetts Consumer Protection Act); (2) that Appellees engaged in false advertising in violation of Mass. Gen. Laws ch. 266, § 91; and (3) that Appellees were unjustly enriched because, by buying Lactaid, DiCroce conferred an economic benefit on Appellees. The district court granted Appellees' initial motion to dismiss for lack of standing, concluding that DiCroce had failed to plausibly allege an injury in fact because her claims that Lactaid's labeling "affected her purchasing decisions" were "vague," and, thus, she had no Article III standing.

With leave of court, DiCroce later filed an amended complaint, adding to her original allegations that she paid an "unwarranted premium" for Lactaid products because the products' "illegal disease claims" led her to reasonably believe that they were worth more than less expensive lactase supplements. DiCroce noted that Lactaid products cost $0.20 per dosage, while alternative products, which she cited specific examples of, cost at least $0.11 less. We draw the relevant facts from her amended complaint.

> purchasing Lactaid products, which are more expensive than other lactase supplements.

The district court granted Appellees' second motion to dismiss, despite finding that DiCroce's amended complaint sufficiently alleged an injury in fact for purposes of Article III standing. DiCroce, 640 F. Supp. 3d at 185, 187-88. The district court held that DiCroce's false advertising and deceptive trade practices claims both failed because "no reasonable consumer could find Lactaid's product labels deceptive, nor has DiCroce identified a misrepresentation of fact." Id. at 188. Nor was the district court convinced by DiCroce's disclaimer argument, explaining that her "conclusory allegation d[id] not accord with the language of the disclaimers" and that no "reasonable consumer's purchasing decision" would be swayed by the fact that the product required FDA evaluation given that the label disclosed that the product is not FDA approved. Id. at 188-89.

DiCroce timely appealed.

II. DISCUSSION

Before we proceed to the merits of DiCroce's appeal, we pause to address the issue of standing. See United States v. Catala, 870 F.3d 6, 9 (1st Cir. 2017) ("Because Article III standing is a sine qua non to federal judicial involvement, a federal court must resolve any doubts about such standing before proceeding to adjudicate the merits of a given case."). Contested

by the parties is whether DiCroce has plausibly pled an injury in fact, as required for Article III and statutory standing, under chapter 93A of the Massachusetts General Laws. See Hochendoner v. Genzyme Corp., 823 F.3d 724, 731 (1st Cir. 2016) (explaining the injury requirement for standing in the Article III context); Shaulis v. Nordstrom, Inc., 865 F.3d 1, 10 (1st Cir. 2017) (discussing cognizable injuries under chapter 93A). We begin with DiCroce's Article III standing.

"[A]t the pleading stage, the plaintiff bears the burden of establishing sufficient factual matter to plausibly demonstrate h[er] standing to bring the action." Hochendoner, 823 F.3d at 731. For an injury in fact to be plausibly pled, it "must be both concrete and particularized and actual or imminent, not conjectural or hypothetical." Id. (cleaned up). Concreteness requires that the injury "actually exist[s]." Id. (alteration in original) (quoting Spokeo, Inc. v. Robins, 578 U.S. 330, 340 (2016)). And particularization demands that, in addition to alleging "injurious conduct attributable to the defendant," a plaintiff must also claim to be "among the persons injured by that conduct." Id. at 731-32.

DiCroce's second amended complaint satisfies both requirements. DiCroce claims that she personally purchased Lactaid supplements on multiple occasions during the four years preceding the complaint. She further alleges that Lactaid

supplements cost at least $0.11 more per tablet than other brands and that she was misled into purchasing overpriced lactase supplements because of Appellees' purportedly unlawful marketing statements. Put another way, DiCroce claims that she has personally suffered economic harm in the past as a result of Appellees' alleged misconduct. At the pleading stage, we find these allegations sufficient to meet the minimal plausibility standard for establishing Article III standing. See In re Evenflo Co., Inc., Mktg., Sales Pracs. & Prods. Liab. Litig., 54 F.4th 28, 35 (1st Cir. 2022) ("This court has repeatedly recognized overpayment as a cognizable form of Article III injury."); Gustavsen v. Alcon Lab'ys, Inc., 903 F.3d 1, 7-8 (1st Cir. 2018) (holding that plaintiffs sufficiently pled a concrete, actual, particularized injury for standing purposes where they claimed that they, themselves, had suffered "out-of-pocket loss of money" in the past because of defendants' conduct).

Appellees' remaining standing arguments are statutory in nature, insofar as they pertain to whether DiCroce "has a cause of action" under chapter 93A. Catala, 870 F.3d at 10. Because statutory standing is not determinative of "a court's power to adjudicate a case," we choose to forgo this inquiry, "in the interest of efficiency," given our ultimate conclusion that DiCroce's claims were properly dismissed by the district court.

See id. Having "resolve[d] any doubts" about DiCroce's Article III standing, we proceed to the merits. Id. at 9.

We review de novo the district court's order granting a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6). Sullivan v. etectRx, Inc., 67 F.4th 487, 491 (1st Cir. 2023). Accordingly, "we ask whether the well-pleaded factual allegations, viewed in the light most favorable to the plaintiff, . . . 'plausibly narrate a claim for relief.'" Id. (quoting Germanowski v. Harris, 854 F.3d 68, 71 (1st Cir. 2017)). In reaching a conclusion, we are not tied to the district court's reasoning "but may affirm the order of dismissal on any ground made manifest by the record." González v. Vélez, 864 F.3d 45, 50 (1st Cir. 2017) (quoting Katz v. Pershing, LLC, 672 F.3d 64, 71 (1st Cir. 2012)).

Before us, DiCroce argues that the district court's ruling was incorrect and continues to press her claim that Lactaid's label is misleading because it fails to comply with federal labeling requirements. DiCroce further contends that the district court should have allowed the matter of whether lactose intolerance is a disease to go beyond the pleading stage. Such arguments lack merit. DiCroce's claims are impliedly preempted by the FDA's statutory enforcement authority.

We begin with the relevant regulatory background. The Food, Drug, and Cosmetic Act ("FDCA") was enacted to protect

consumers from "harmful products." In re Zofran (Ondansetron) Prods. Liab. Litig., 57 F.4th 327, 330 (1st Cir. 2023) (quoting Wyeth v. Levine, 555 U.S. 555, 574 (2009)). The FDA regulates dietary supplements through the FDCA, as amended by the Dietary Supplement Health and Education Act of 1994 ("DSHEA") and FDA regulations.[3] Ferrari v. Vitamin Shoppe Indus. LLC, 70 F.4th 64, 67–68 (1st Cir. 2023) (citing Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325, 4325–26 (1994)). In Ferrari, we examined the legislative history related to DSHEA before concluding that "Congress intended dietary supplements to escape the regulatory gauntlet that drugs must go through." Id. at 73-74 ("It enacted the DSHEA to 'ensur[e] that the Federal Government erects no barriers that impede the ability of consumers to improve their nutrition through the free choice of safe dietary supplements' and 'to clarify that dietary supplements are not drugs . . . [and] should not be regulated as drugs.'" (alterations in original) (quoting S. Rep. No. 103-410 (1994), 1994 WL 562259, at *2)).[4] Unlike dietary supplements, drugs, which

[3] DSHEA defines a dietary supplement as a product that is "intended to supplement the diet" and that contains certain "dietary ingredients." 21 U.S.C. § 321(ff).

[4] Under the FDCA and DSHEA, manufacturers are allowed to make "structure/function claims" about dietary supplements. Kaufman v. CVS Caremark Corp., 836 F.3d 88, 92 (1st Cir. 2016). DiCroce does not allege that Lactaid does not perform as advertised in the label. Therefore, we need not delve into whether Appellees possess substantiation for Lactaid's label claims.

are also regulated under the FDCA, require prior FDA approval before they can be sold or marketed to consumers. In re Zofran, 57 F.4th at 330 (explaining that the FDA reviews a drug's efficacy and proposed label).

Importantly, only the FDA may enforce the FDCA, meaning that the FDCA provides no private right of action. 21 U.S.C. § 337(a); see Plourde v. Sorin Grp. USA, Inc., 23 F.4th 29, 33 (1st Cir. 2022) (explaining that § 337(a)'s "language shows 'that Congress intended that the [FDCA] be enforced exclusively by the Federal Government.'" (quoting Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 352 (2001))).

DiCroce's legal action hinges on her assumption that Lactaid's labels violate the FDCA's labeling requirements and are therefore misleading to consumers. But we have made it clear that "§ 337(a) preempts any state-law claim that exists 'solely by virtue' of an FDCA infraction." Plourde, 23 F.4th at 33.

In Buckman, plaintiffs claimed injuries related to the placement of "orthopedic bone screws" in their spines. 531 U.S. at 343. Specifically, they alleged that a consulting company made fraudulent representations to the FDA during the screws' approval process, resulting in the FDA's subsequent approval of the devices. Id. The Court concluded that plaintiffs' "state-law fraud-on-the FDA" claims were impliedly preempted because "[p]olicing fraud against federal agencies is hardly 'a field which the States have

traditionally occupied'" and said claims conflicted with the federal statutory scheme, which "amply empowers the FDA to punish and deter fraud against the Administration." Id. at 347-48 (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)).

More recently, we had the opportunity to consider Buckman's holding in the food-labeling context, in Dumont v. Reily Foods Company. 934 F.3d 35, 41-43 (1st Cir. 2019). There, we applied, without formally adopting, the Eighth and Ninth Circuits' test for deciding whether a state-law claim avoids preemption: "The plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by [the FDCA's medical device preemption provision, 21 U.S.C. § 360k], but the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under Buckman))." Dumont, 934 F.3d at 42 (alteration in original) (quoting In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig., 623 F.3d 1200, 1204 (8th Cir. 2010)) (citing Perez v. Nidek Co., 711 F.3d 1109, 1120 (9th Cir. 2013)). We explained that, based on this test, a "complaint is preempted unless the conduct it pleads: (1) violates FDCA labeling requirements and (2) would also violate chapter 93A even if the FDCA did not exist."[5] Id. at 42. We approvingly referred

[5] States are prohibited from imposing food labeling requirements beyond what the FDCA requires. Kaufman, 836 F.3d at

to this test again in Plourde, where we were confronted with state-law negligence and failure-to-warn claims related to a medical device. 23 F.4th at 33-34.

Returning to DiCroce's complaint, we hold that her state law claims -- for unfair or deceptive trade practices, false advertising, and unjust enrichment[6] -- "exist[] 'solely by virtue' of an FDCA infraction" and thus are impliedly preempted. Id. at 33. DiCroce, like the plaintiffs in Buckman, is alleging fraud under the FDCA, given that her claim that Lactaid's label is misleading is premised entirely on her belief that said label violates the FDCA.[7] See id. And DiCroce provides no other grounds on which her claims could survive. She does not contend that Lactaid did not perform as promised, nor does she provide any basis, independent of federal labeling laws, from which we could conclude that a consumer would be misled by Lactaid's label. In fact, DiCroce's complaint acknowledges that Lactaid's disclaimer

91 (citing 21 U.S.C. § 343-1(a)(5)). Thus, if a manufacturer complies with the FDCA's labeling requirements, a plaintiff has no cause of action under state law for labeling claims. Id. at 92.

[6] An unjust enrichment claim that "rests on the same improper conduct alleged in another claim . . . will stand or fall with the related claim." Kaufman, 836 F.3d at 96 (quoting Cleary v. Philip Morris, Inc., 656 F.3d 511, 517 (7th Cir. 2011)).

[7] While "state-law claim[s] based on 'traditional state tort law' that happen[] to 'parallel' the FDCA" are not necessarily preempted, Plourde, 23 F.4th at 33 (quoting Buckman, 531 U.S. at 353), DiCroce does not plead such a claim here.

statements are "literally true" before arguing that they are nevertheless misleading because they violate the FDCA.

If Lactaid's label conflicts with the FDCA's labeling requirements -- an issue we decline to take a position on -- Congress tasked the FDA with addressing said violations when it enacted § 337(a), not private citizens. See Blackman, 531 U.S. at 348; Plourde, 23 F.4th at 33.

III. CONCLUSION

Because we conclude that violation of the FDCA "is a critical element in [DiCroce's] case," we hold that her claims are impliedly preempted. Blackman, 531 U.S. at 353 (emphasis added). Thus, the district court's dismissal of DiCroce's amended complaint is

Affirmed.