FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

GILLIAN DAVIDSON; SAMUEL DAVIDSON, as individuals, on behalf of themselves, the general public, and those similarly situated, *Plaintiffs-Appellants*, v. SPROUT FOODS, INC., *Defendant-Appellee*.	No. 22-16656 D.C. No. 3:22-cv-01050-RS OPINION

Appeal from the United States District Court
for the Northern District of California
Richard Seeborg, Chief District Judge, Presiding

Argued and Submitted November 9, 2023
Phoenix, Arizona

Filed June 28, 2024

Before: Mary M. Schroeder, Daniel P. Collins, and Roopali H. Desai, Circuit Judges.

Opinion by Judge Schroeder;
Partial Concurrence and Partial Dissent by Judge Collins

SUMMARY*

Food Labeling

The panel affirmed the district court's dismissal of plaintiffs' fraud-based claims, and reversed the district court's dismissal of plaintiffs' California Sherman Law claim and unjust enrichment claim, in a putative class action challenging the labels on Sprout Foods, Inc.'s baby food pouches.

The Sherman Law, California's analog to the federal Food Drug and Cosmetic Act (FDCA), incorporates by reference all federal food labeling standards, including a prohibition against labeling the front of baby food containers with the product's nutrient content. Sprout produced pouches of baby food with labels on the front stating the amount of nutrients the pouches contained. Plaintiffs seek to represent a class of consumers who purchased Sprout's products.

The panel held that federal law did not preempt private enforcement of the Sherman Law's labeling requirements, and reversed the district court's dismissal of plaintiffs' Sherman Law claims. Although the FDCA provides, with limited exceptions, that the law can only be enforced by the federal government, the federal food labeling statute—the Nutrition Labeling and Education Act—permits states to enact labeling standards so long as they are identical to the federal standards. California has done that. Because plaintiffs were seeking to enforce the parallel state law that Congress intended states to enact, the district court should not have relied on authority preempting private enforcement of the

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

federal law.

The panel affirmed the district court's dismissal of plaintiffs' fraud-based claims because the claims were subject to the heightened pleading requirements of Fed. R. Civ. P. 9, and the allegations failed to allege with particularity why the products were harmful.

In light of the reversal on the Sherman Law claim, the panel held that an additional unjust enrichment claim survived, and the panel reversed the district court's dismissal of that claim.

Concurring in part and dissenting in part, Judge Collins would affirm the district court's judgment dismissing the entire action. He agreed with the majority that plaintiffs' fraud-based claims were properly dismissed as inadequately pleaded. He would further hold that plaintiffs' remaining substantive claim—which attempted to use California state law to enforce a specific federal regulation concerning the labeling of toddler food products—was impliedly preempted because the relevant federal statute barred private enforcement of its provisions. He dissented to the extent that the majority reached a contrary conclusion and allowed the claim, and the related unjust enrichment claim, to proceed.

COUNSEL

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OPINION

SCHROEDER, Circuit Judge:

INTRODUCTION

California's analog to the federal Food Drug and Cosmetic Act (FDCA) is known as the Sherman Law. It incorporates by reference all federal food labeling standards. These include a prohibition against labeling the front of baby food containers with the product's nutrient content. Sprout Foods, Inc. (Sprout), the Defendant-Appellee, nevertheless produced pouches of baby food with labels on the front of the package conspicuously stating the amount of nutrients the pouches contained. Gillian and Samuel Davidson, the plaintiff-appellants, purchased some of the pouches.

The Davidsons filed this putative class action in federal court claiming violation of California's Unfair Competition Law, and alleging the pouch labels violate the Sherman

Law.[1] The amended complaint also contained state law claims of false advertising, fraud, and deception, alleging that the nutrient content labels misled consumers into believing the products were good for babies when they were actually harmful.

The district court dismissed the complaint for failure to state a claim. It held that the Sherman Law claim was impliedly preempted because the Sherman Law is derived from the FDCA, and the federal law calls for federal government enforcement. The federal law, however, expressly permits states to enact standards identical to the federal standards and in this case, plaintiffs are attempting to enforce identical standards set forth in a state statute, the Sherman Law. The federal law does not limit the manner in which the state statute is enforced, and private enforcement of that statute does not conflict with federal enforcement of the FDCA. We therefore conclude that the federal law does not preempt private enforcement of the Sherman Law's labeling requirements, and we reverse the district court's dismissal of the Sherman Law claim.

The district court also dismissed the fraud-based claims for failure to plausibly allege the products were misleading. We affirm the district court's dismissal of these claims, because they do not meet the elevated pleading standards of Federal Rule of Civil Procedure 9(b).

[1] For consistency, because the Davidsons' Unfair Competition Law claim is premised on alleged violations of the Sherman Law, we refer to the Davidsons' claim as the "Sherman Law claim."

FACTUAL AND PROCEDURAL BACKGROUND

This case is about the relationship between the federal labeling requirements for baby food and the identical California labeling requirements. The umbrella federal statute, the FDCA, provides, with limited exceptions, that the law can be enforced only by the federal government. Nevertheless, the federal food labeling statute, the Nutrition Labeling and Education Act (NLEA), permits states to enact labeling standards so long as they are identical to the federal standards. California has done that. Plaintiffs therefore claim that Sprout has violated the California requirements.

The principal legal question in the case is whether the California requirements can be privately enforced or whether the federal limitation, effectively preventing private enforcement of the federal law, preempts private enforcement of the state standards. The regulatory background is therefore important to understanding the relationship between the federal and state labeling standards.

Food labeling has traditionally been the province of the states, and California has made the false or misleading labeling of food unlawful at least since 1939. *See* Cal. Health & Safety Code § 110660, previously codified as Cal. Health & Safety Code § 26490. In 1970, California enacted more modern and comprehensive provisions, known as the Sherman Law. *See* 1970 Cal Stat. ch. 1573.

Congress in 1990 amended the FDCA by enacting the NLEA in order to provide nationally uniform standards for nutrition labeling. The law was intended to displace disparate state standards. *See* 21 U.S.C. § 343-1. It contains an express preemption provision that allows states to enact only standards identical to federal law. *Id*. California then amended the Sherman Law to incorporate all federal

standards, thereby ensuring that California standards will be the same as the federal standards and not be preempted. Cal. Health & Safety Code § 110100(a).

The relevant federal regulation prohibits "nutrient content claims . . . on food intended for use by infants and children less than 2 years of age." 21 C.F.R. § 101.13(b)(3). California law incorporates the same prohibition. *See* Cal. Health & Safety Code § 110100(a).

In setting out its reason for the prohibition, the FDA essentially explained that what is good for adults may not be so good for babies. *See* Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. 60421, 60424 (Nov. 27, 1991). The agency pointed to a general agreement among associations of health professionals that fat and cholesterol should not be restricted in the diets of infants. *Id.* The agency also said that it lacked evidence that restricting nutrients like sodium or increasing intake of nutrients such as fiber would be beneficial for infants and toddlers. *Id.* It therefore concluded that until it had such evidence, it was prohibiting nutrient content claims on food products intended for babies under two. *Id.* The agency was clearly concerned that such labeling could lead consumers to believe that a product was good for babies when the agency had no basis for such conclusions.

Sprout sells baby and toddler food products under its label, including pouches of pureed food intended for babies under two. The front of the pouches have labels that prominently feature statements of the nutrient content of the food inside. The example alleged in the amended complaint and cited by the district court was "3g of Protein, 5g of Fiber and 300mg Omega-3 from Chia ALA." These types of claims on the labels of the Sprout pouches appear to be what

the FDA regulation and, by extension, the Sherman Law prohibit.

This is an example:

The parties agree that the federal statute does not expressly preempt private enforcement of the state standards. It expressly preempts only state standards that deviate from the federal. 21 U.S.C. § 343-1(a). Still, the Supreme Court has recognized that preemption of state law may be implied where preemption "was the clear and manifest purpose of Congress." *Altria Grp., Inc. v. Good*, 555 U.S. 70, 77 (2008) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). We have, for example, said state law is impliedly preempted when it stands in the way of fulfilling a Congressional objective. *See McClellan v. I-Flow Corp.*, 776 F.3d 1035, 1039 (9th Cir. 2015). There have been a number of cases filed in federal district courts in California where private parties sought to enforce the provisions of the California Sherman Law that parallel the federal law, but this is the first to reach this court.

The plaintiffs in this case, Gillian and Samuel Davidson, filed this diversity action in district court seeking to represent a class of consumers who purchased Sprout's products, beginning in 2018. Plaintiffs asserted a claim that Sprout's conduct was "unlawful" under California's Unfair Competition Law (UCL) because the Sprout pouches were labeled in violation of California's Sherman Law. *See* Cal. Bus. & Prof. Code § 17200 (UCL). Plaintiffs also invoked the California False Advertising Law (FAL), the California Consumer Legal Remedies Act (CLRA), the UCL, and common law fraud to contend that the labeling was fraudulent and misleading in that the labeling led purchasers to believe the products were good for babies when they were actually harmful. *See* Cal. Bus. & Prof. Code § 17500, (FAL); Cal. Civ. Code § 1770 (CLRA).

Sprout moved to dismiss the First Amended Complaint under Rule 12(b)(6) for failure to state a claim. The district court granted the motion in its entirety. The court dismissed the Sherman Law claim as impliedly preempted by the federal statute, reasoning that because the Sherman Law depends upon and "adopts the FDCA and regulations as state law," the claim was essentially governed by the federal law that barred private enforcement.

The district court also dismissed the claims sounding in fraud. The district court accepted for purposes of surviving a motion to dismiss, that plaintiffs had plausibly alleged the nutrient content labels imply health benefits. But it ruled plaintiffs had failed to plausibly allege that this implied message was misleading because they did not sufficiently allege that the products caused harm. The court dismissed under Rule 9 with further leave to amend, but plaintiffs chose to stand on their First Amended Complaint and appeal.

In this appeal, they first argue that the district court erred in holding their Sherman Law claim was impliedly preempted. Plaintiffs contend that because they are seeking to enforce the parallel state law that Congress intended states to enact, the district court should not have relied on authority preempting private enforcement of the federal law. We agree with plaintiffs in this regard.

Plaintiffs also contend the district court erred in dismissing their fraud-based claims. Here we affirm the district court, because the claims were subject to the heightened pleading requirements of Rule 9, and the allegations failed to allege with particularity why the products were harmful.

DISCUSSION

I. Sherman Law Claim

The primary legal issue in this case is whether the FDCA provision, granting the federal government virtually exclusive authority to enforce the federal law, preempts private enforcement of California's Sherman Law, even though the FDCA does not preempt the Sherman Law itself. The plaintiffs seek such private enforcement through the state's UCL. The district court correctly recognized that the success of this claim turns on the relationship between federal and state law. It is therefore helpful to review the relevant statutory and regulatory provisions:

- 21 U.S.C. § 337(a) (FDCA § 310(a)) - This provision dictates that the FDCA shall only be enforced by the United States, except as described in § 337(b).

- 21 U.S.C. § 337(b) (FDCA § 310(b)) - This provision permits states to enforce the FDCA in limited circumstances.
- 21 U.S.C. § 343-1 (NLEA § 403A) - This is the NLEA's express preemption provision, which prevents states from enacting labeling requirements that are "not identical to" federal standards.
- 21 C.F.R. § 101.13(b)(3) - This FDA regulation promulgated under the NLEA prohibits "nutrient content claims" on "food intended specifically for use by infants and children less than 2 years of age."
- Cal. Health & Safety Code § 110100(a) - This section of California's Sherman Law incorporates by reference food labeling regulations adopted under the NLEA.

Because the Sherman Law incorporates all the federal food labeling requirements, it is "identical" to federal standards and not expressly preempted. It is expressly permitted. *See* 21 U.S.C. § 343-1 (NLEA § 403A). In preempting state laws that differ from the federal standards, and thereby permitting parallel state laws, the FDCA did not even purport to limit enforcement of such parallel state laws in any way. The express preemption provision simply states, "no State . . . may directly or indirectly establish . . . or continue in effect . . . any requirement for nutrition labeling of food that is not identical to the [NLEA] requirement[s]." 21 U.S.C. § 343-1(a)(4) (NLEA § 403A(a)(4)).

The district court nevertheless held that enforcement of the state standards under state law was impliedly preempted. It reasoned that because federal law prohibited private enforcement of the federal standards, and the substance of

the state law was the same as the federal law, Congress impliedly preempted private enforcement of the state standards as well. The district court adopted reasoning from its own prior decision finding that the FDCA impliedly preempted a similar Sherman Law claim. *See Chong v. Kind, LLC*, 585 F. Supp. 3d 1215, 1219-20 (N.D. Cal. 2022). That decision, in turn, relied upon the leading Supreme Court case holding that the FDCA impliedly preempts state law claims premised on FDCA violations. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). It is therefore important to understand what *Buckman* was and was not about.

Buckman did not involve any violation of duties owed under a state consumer protection statute. Plaintiffs there were attempting to use causes of action available under state law to claim damages for violations of duties owed under the federal FDCA. Plaintiffs had been injured by faulty medical devices that required FDA approval and attempted to sue the manufacturer under state tort law for violating duties owed to the FDA under federal law. *Id.* at 343. They claimed the defendant had misrepresented the uses of the devices to the FDA in order to receive pre-market approval. *Id.* The Supreme Court held the claims were impliedly preempted by the FDCA because the duties allegedly violated were duties owed to the federal agency, and the claim was in essence a claim of violation of federal law. *Id.* at 348, 353. The Court explained that the claims existed "solely by virtue of FDCA . . . requirements" to make disclosures to the FDA during the pre-market approval process. *Id.* at 353. The Court further explained that such claims are impliedly preempted because they "inevitably conflict" with the federal government's exclusive enforcement authority over the FDCA's

regulatory scheme for medical devices. *Id.* at 348-50 (citing 21 U.S.C. § 337(a) (FDCA § 310(a))).

Our court has reached the same conclusion where plaintiffs attempted to use state causes of action to claim violations of FDCA duties. For example, in *Perez*, this court considered a common law fraud-by-omission claim that medical device manufacturers failed to disclose that a laser system was not FDA-approved to treat farsightedness. *See Perez v. Nidek Co.*, 711 F.3d 1109, 1117 (9th Cir. 2013). This claim rested "solely [upon a] failure to disclose lack of FDA approval," a disclosure that the FDCA requires. *Id.* at 1119-20. Like the claim in *Buckman*, this claim "exist[ed] solely by virtue of the FDCA . . . requirements" rather than a state law duty. *Id.* at 1119 (quoting *Buckman*, 531 U.S. at 353). We therefore held the claim was impliedly preempted because it "amount[ed] to an attempt to privately enforce the FDCA," which is barred by the enforcement limitation in § 337 (FDCA § 310). *Id.* at 1117, 1119.

In a more recent case, we followed *Buckman* and *Perez* in concluding that a state law claim premised on violation of FDCA duties was impliedly preempted. *Nexus Pharms., Inc. v. Cent. Admixture Pharmacy Servs. Inc.*, 48 F.4th 1040, 1050-51 (9th Cir. 2022). There, the plaintiffs claimed that drug-compounding facilities violated state statutes prohibiting the sale of drugs not approved by the FDA. *Id.* at 1044. Such a claim would require litigating whether the facilities qualified for an exception to FDA approval, i.e., whether an FDCA violation had occurred. *Id.* at 1049. Because this was a task reserved for the FDA, we held that the claim was impliedly preempted under § 337 (FDCA § 310) as an attempt to privately enforce the FDCA's requirements for compounding facilities. *Id.* at 1050-51.

This case fundamentally differs from *Buckman*, *Perez*, and *Nexus*. In this case, plaintiffs are claiming violations of California law, the Sherman Law, not the federal FDCA. It is true that the Sherman Law standards are identical to the federal standards, but Congress said such standards are not preempted and hence permitted states to adopt them. *See* 21 U.S.C. § 343-1(a) (NLEA § 403A(a)). There is no reason we can perceive why Congress would permit states to enact particular legislation and then deny enforcement by their citizens.

Federal law does not support such a strange result. In cases where private plaintiffs claimed violations of state law, as opposed to federal standards, the Supreme Court and our court have held the claims are not preempted. In the leading Supreme Court case, the Court held that the FDCA did not preempt state common law claims that a medical device manufacturer had failed to warn of the known dangers of a pacemaker. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 474, 481, 495 (1996). The Court interpreted a preemption provision, similar to § 343-1 (NLEA § 403A) in this case, as permitting states to enact requirements identical to those imposed by the federal law. *Id.* at 496-97. The Court reasoned that "[n]othing . . . denied [the state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Id.* at 495. The claims were not preempted because plaintiffs claimed violations of parallel state law duties, not the violation of duties owed under federal law.

Our court followed *Lohr* in *Stengel*, holding that the FDCA did not preempt a state law negligence claim for violation of duties that paralleled duties owed under federal requirements. *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013) (en banc). There, citing *Lohr* and

Buckman, we described the Supreme Court's preemption jurisprudence as establishing a rule that the FDCA "does not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty" under the FDCA. *Id.* at 1228-29. The claim at issue was that a medical device manufacturer was negligent in failing to report known risks of a medical pump to the FDA, an FDCA requirement. *Id.* at 1226. Because state law also contemplated a duty to warn a third party such as the FDA, we concluded that the claim "rest[ed] on a state-law duty that parallel[ed] a federal-law duty" and was thus not preempted by the FDCA. *Id.* at 1233.

In a recent case even more analogous to the present one, our court reaffirmed that the FDCA does not preempt claims for violations of parallel state law duties. *See Kroessler v. CVS Health Corp.*, 977 F.3d 803 (9th Cir. 2020). *Kroessler* involved dietary supplement labels, which, like food labels, are governed by the NLEA. *Id.* at 808. Accordingly, as in this case, the express preemption provision of § 343-1 (NLEA § 403A), and the federal enforcement limitations in § 337 (FDCA § 310) both applied. We interpreted those provisions to permit private enforcement of state standards so long as they were identical to the federal standards. We said that "private plaintiffs may bring only actions to enforce violations of '*state laws* imposing requirements identical to those contained in the FDCA.'" *Id.* at 808 (quoting the California Supreme Court in *Farm Raised Salmon Cases*, 175 P.3d 1170, 1177 (2008) (emphasis in the original)). The plaintiffs in *Kroessler* had brought claims under California statutes, alleging that a retailer made false and misleading representations on dietary supplement labels without meeting a substantiation standard that was identical to the one found in the FDCA. *Id.* at 809-10. Because the claims were brought under state law and the state standard was

identical to the federal, we again concluded that the claims were not preempted. *Id*. at 813-14.

The reasoning of this line of cases, involving claimed violations of parallel state law, controls our decision in this case. We therefore hold that the FDCA does not impliedly preempt plaintiffs' Sherman Law claims. Because the Sherman Law incorporates federal standards, the state requirements at issue are identical to their federal counterparts, and thus permitted by § 343-1 (NLEA § 403A). Plaintiffs' claim is that Sprout violated these parallel state requirements. Because the FDCA places no limitations on enforcement of these state parallels, plaintiffs' Sherman Law claim is not preempted.

In contending that enforcement of the Sherman Law is preempted, Sprout can do no more than point to the federal origin and content of the state's labeling standards. Sprout ignores that Congress permitted identical state laws and offers no explanation for why Congress would want states to enact laws that its citizens cannot enforce. The dissent makes the same mistakes. The anomaly of their position has been observed by the California Supreme Court. It said "[i]f Congress intended to permit states to enact identical laws on the one hand, but preclude states from providing private remedies for violations of those laws on the other hand, 'its failure even to hint at it is spectacularly odd.'" *Farm Raised Salmon*, 175 P.3d at 1178 (quoting *Lohr*, 518 U.S. at 491 (Stevens, J., concurring)).

Sprout looks to the prohibition of private enforcement in § 337(a) (FDCA § 310(a)) as evidence of Congress's intent to preempt private enforcement of the state law. Indeed, Sprout takes the position that, except for the limited enforcement powers granted to the states in § 337(b) (FDCA

§ 310(b)), the enforcement power of the United States is exclusive, and there is no entity within the states that can enforce the state law. Yet, by its terms, § 337(a) (FDCA § 310(a)) implicates only enforcement of the federal law, not enforcement of identical state requirements.

The dissent does not go so far as to suggest that only the federal government can enforce the state law. The dissent speculates that the state might vest enforcement power in a state agency. Nevertheless, like Sprout, the dissent assumes that because § 337(a) (FDCA § 310(a)) prohibits private enforcement of the federal law, Congress must have intended to prohibit the private enforcement of parallel state laws as well. Yet, we are offered no basis for such an assumption. The dissent never comes to grip with the fact that the text of § 337(a) (FDCA § 310(a)) addresses only enforcement of the federal law. Nor does the dissent explain how private enforcement of identical state standards would conflict with federal enforcement of the federal law.

Sprout also seeks support from § 337(b) (FDCA § 310(b)), which permits states to enforce certain provisions of the federal law. Sprout points out that Congress provided this limited enforcement authority to the states, not to private parties, and contends Congress must therefore have intended to prohibit any private enforcement of parallel state laws. The dissent agrees. But again, both read too much into the text of § 337(b) (FDCA § 310(b)), which relates only to the enforcement of the federal law. It does not limit enforcement of state law.

The dissent would fashion a rule found in none of the cases but that it contends follows from them: to avoid preemption, the state law's substance must be identical to the federal standards but derive from a source "independent" of

the federal law. The dissent borrows the term "independent" from *Stengel* where it was used to differentiate a claim premised on the violation of state law from a claim premised on the violation of the federal law, as in *Buckman*. *See Stengel*, 704 F.3d at 1233. The claims here seek to enforce state standards that are similarly "independent" of the federal law, as they arise from a state statute. Still, the dissent would hold that a cause of action is "independent" only if it is grounded in the common law and predates the FDCA. While *Buckman* indicated that such claims survive implied preemption, *see Buckman*, 531 U.S. at 353, neither the Supreme Court nor our court has said that these are the only claims that do so. Statutory causes of action to enforce identical state standards that Congress permitted must also survive implied preemption.

The dissent views *Kroessler* as our leading example of a case where the FDCA did not preempt state-law claims. Yet as we have seen, the claims there escaped preemption because they were based on a state standard identical to the federal. *See Kroessler*, 977 F.3d at 810, 813-14. *Kroessler* did not make that standard's enforceability depend on whether its content had an origin "independent" of the federal law. Rather, the claims were not preempted because they sought to enforce an identical state standard that the federal law expressly spared from preemption. *Id*. The same result should obtain here.

Section 343-1 (NLEA § 403A) is not unique in providing that states may only adopt provisions identical to the federal law. Other statutory schemes have similar provisions that the Supreme Court has interpreted to permit private enforcement of parallel state requirements. *See, e.g.*, 21 U.S.C. § 360k(a) (prohibiting states from establishing requirements "different from, or in addition to" any

requirements in the Medical Device Amendments (MDA) to the FDCA); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (holding that § 360k(a) does not prevent states from providing a damages remedy for claims premised on violations of the MDA's implementing regulations); *see also* 7 U.S.C. § 136v(b) (prohibiting states from imposing requirements "in addition to or different from" the requirements in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)); *Bates v. Dow Agrosciences*, 544 U.S. 431, 432 (2005) (holding that nothing in § 136v(b) prevents states from providing a damages remedy for state requirements equivalent to federal requirements). Sprout's position conflicts with all of this authority.

While this is the first case to reach our court involving the Sherman Law and food labels, the district courts in this circuit are in near unanimous agreement that the FDCA does not preempt Sherman Law food labeling claims. Most agree that § 337 (FDCA § 310) does not limit states' authority to provide private remedies for identical state laws that are expressly permitted by § 343-1 (NLEA § 403A). *See, e.g.*, *Hesano v. Iovate Health Scis., Inc.*, No. 13CV1960-WQH-JMA, 2014 WL 197719, at *7 (S.D. Cal. Jan. 15, 2014). One district court collected the cases and concluded that "[d]istrict courts have routinely rejected arguments that . . . food-labeling claims . . . under the Sherman Law are impliedly preempted under § 337(a) and *Buckman*." *Corbett v. PharmaCare U.S., Inc.*, 567 F. Supp. 3d 1172, 1193 (S.D. Cal. 2021) (quoting *Sandoval v. PharmaCare US, Inc.*, 145 F. Supp. 3d 986, 995 (S.D. Cal. 2015)).

Finally, even if we were to conclude that there is some doubt as to whether § 337 (FDCA § 310) permits private enforcement of state laws, we would still have to reverse the district court and hold the plaintiffs' claim is not preempted.

This is because of the longstanding presumption against preemption that our court recognizes. In implied preemption cases, "we start with the assumption that the historic police powers of the States are not preempted unless that was the clear and manifest purpose of Congress." *R.J. Reynolds Tobacco Co. v. County of Los Angeles*, 29 F.4th 542, 561 (9th Cir. 2022) (quoting *In re Volkswagen "Clean Diesel" Mktg., Sales Pracs., & Prod. Liab. Litig.*, 959 F.3d 1201, 1212 (9th Cir. 2020)). When we are faced with "plausible alternative reading[s]" of a statute's preemptive effect, we apply this presumption and "have a duty to accept the reading disfavoring pre-emption." *Bates*, 544 U.S. at 432. Thus, even if Sprout's interpretation of § 337 (FDCA § 310) were equally plausible, we would be bound to accept the interpretation that we ultimately adopt: the FDCA does not impliedly preempt private enforcement of the Sherman Law.

II. Fraud Claims

The essence of plaintiffs' fraud-based claims is that Sprout's labels misled consumers into believing the products provided health benefits to children under two when the products were in fact nutritionally and developmentally harmful. In the First Amended Complaint, plaintiffs pleaded these claims as common law fraud and as violating California's FAL, CLRA, and UCL.

Because all these claims are grounded in fraud, plaintiffs' First Amended Complaint needed to satisfy not only Rule 12(b)(6)'s plausibility pleading standard but also the heightened pleading requirements of Rule 9(b). *See Davidson v. Kimberly-Clark Corp.*, 889 F.3d 956, 964 (9th Cir. 2018). Rule 9(b) requires that a party plead fraud with particularity. This means the complaint must "identify the who, what, when, where, and how of the misconduct

charged, as well as what is false or misleading about the purportedly fraudulent statement, and why it is false." *Id.* (quoting *Cafasso*, *U.S. ex rel. v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1055 (9th Cir. 2011)).

The district court held that plaintiffs failed to do this. The court first noted that plaintiffs had sufficiently alleged what the misstatement was, i.e., that the nutrient content claims imply that the products provide health benefits for babies. But the court ultimately found that plaintiffs had failed to sufficiently allege why this implied message was false, i.e., that the products were in fact harmful. Because this was a core component of their theory of fraud, the district court held that plaintiffs failed to plausibly allege the claims sounding in fraud.

In support of their contention that Sprout's products are harmful, plaintiffs offer two sets of allegations in the First Amended Complaint. The first allegation is that Sprout's products contain high amounts of sugar and that sugars in pureed, pouch-based foods can lead to health issues such as tooth decay. Second, the complaint cites to several articles and reports suggesting that pouch-based foods may lead to long-term health risks and hinder babies' development.

Plaintiffs' allegations regarding harm are largely unspecific to Sprout's products. The exception is their allegation that the products "contain high amounts of free sugars" accompanied by a list of the grams of sugar in some of the products. But as the district court rightly noted, this allegation lacks context. Plaintiffs do not explain at what level sugars become harmful or why the levels of sugar in these products, in particular, could cause harm.

The rest of plaintiffs' harm-related allegations offer explanations for how pouch-based foods in general may be

unhealthy for children, nutritionally and developmentally. These allegations are largely speculative. For example, plaintiffs allege that "consumption of pouches may lead to long term health risks"; that if babies are "overly dependent on pouches," there are "noted delays in [their] motor development"; and that pouches "can be a gateway to bad long-term snacking habits and routine overeating." The district court correctly observed that each of these allegations of harm relies on hypotheticals and contingencies outside the scope of this case. Moreover, plaintiffs never actually alleged that Sprout's products cause any of these harms.

The district court identified the deficiencies before dismissing plaintiffs' fraud claims and gave plaintiffs a second opportunity to amend. But plaintiffs chose to stand on their First Amended Complaint. We agree with the district court that this complaint failed to allege fraud with particularity as required by Rule 9(b).

III. Unjust Enrichment

The district court dismissed the unjust enrichment claim because, after dismissing all other claims, there was no underlying basis for recovery. In light of our reversal on the Sherman Law claim, an additional claim survives. We thus reverse the district court's dismissal of the unjust enrichment claim.

CONCLUSION

Because the FDCA does not preempt private enforcement of the Sherman Law, we reverse the district court's dismissal of plaintiffs' Sherman Law claim and remand for further proceedings consistent with this opinion. We also reverse the district court's dismissal of the unjust

enrichment claim. We affirm the district court's dismissal of plaintiffs' fraud-based claims.

AFFIRMED IN PART, REVERSED IN PART, AND REMANDED.

COLLINS, Circuit Judge, concurring in part and dissenting in part:

I would affirm the district court's judgment dismissing this action, in which Plaintiffs challenge the lawfulness of the nutrition claims made by the defendant on certain food pouches that it markets for toddlers. As the majority explains, Plaintiffs' fraud-based claims were properly dismissed as inadequately pleaded. In my view, Plaintiffs' remaining substantive claim—which attempts to use state law to enforce a specific federal regulation concerning the labeling of toddler food products—is impliedly preempted because the relevant federal statute bars private enforcement of its provisions. To the extent that the majority reaches a contrary conclusion and allows this claim (and a related unjust enrichment claim) to proceed, I respectfully dissent.

I

Federal regulations issued by the Food and Drug Administration ("FDA") under § 403(q) of the Federal Food, Drug, and Cosmetic Act ("FDCA") require manufacturers of food products to disclose specified nutritional information in the familiar standardized box that is typically placed on the back of the package. *See* 21 U.S.C. § 343(q); 21 C.F.R.

§ 101.9(d).[1] A separate federal regulation, adopted under § 403(r) of the FDCA, imposes an additional special rule on foods that are intended specifically for children under the age of two. 21 C.F.R. § 101.13(b)(3); *see also* 58 Fed. Reg. 2302, 2303–04 (Jan. 6, 1993); 56 Fed. Reg. 60421, 60423–24 (Nov. 27, 1991). Under that rule, manufacturers may not make any *other* nutritional claims on the package, including on the front, unless specifically authorized by the relevant federal regulations. 21 C.F.R. § 101.13(b)(3). Contending that Defendant Sprout Foods, Inc. ("Sprout") violated this regulation in the packaging of a variety of its baby and toddler food products, Plaintiffs Gillian and Samuel Davidson filed this putative class action seeking equitable relief for those violations.[2]

In seeking such relief, however, Plaintiffs did not and could not rely directly on § 101.13(b)(3) itself. That is because, under FDCA § 310, FDA regulations, including § 101.13(b)(3), can only be enforced in suits brought by the federal Government or by a State, and not by a private party. *See* 21 U.S.C. § 337(a) (providing that suits to enforce the FDCA generally must be brought "by and in the name of the United States"); *id*. § 337(b) (allowing a "State" to "bring in its own name" a suit to enforce specified provisions of the FDCA, including § 403(q) and § 403(r)). Instead, Plaintiffs

[1] The FDCA has been classified as chapter 9 of the unenacted title 21 of the U.S. Code. Its current text can be found at the website of the Government Publishing Office at https://www.govinfo.gov/content/pkg/COMPS-973/pdf/COMPS-973.pdf.

[2] As this suit comes to us, the parties have assumed that Sprout's conduct violated § 101.13(b)(3) and that the prohibition contained in that regulation is valid. I therefore take those points as true, without expressing any view as to their correctness.

rested this aspect of their suit on a California statute that automatically incorporates all federal food-labeling regulations into California law, including § 101.13(b)(3). Specifically, § 110100(a) of the California Health and Safety Code expressly adopts, as "the food labeling regulations" of California, all "food labeling regulations" that have been "adopted pursuant to the federal act," *i.e.*, the FDCA. *See* CAL. HEALTH & SAFETY CODE § 110100(a); *id*. § 109930 (defining the "federal act" as the FDCA).[3] Plaintiffs sought enforcement of that state statute under the private right of action conferred by California's Unfair Competition Law ("UCL"). *See* CAL. BUS. & PROF. CODE § 17204 (authorizing a private right of action for equitable relief by those who have "lost money or property as a result of . . . unfair competition"); *id*. § 17200 (defining "unfair competition" to include, *inter alia*, any practice that is "unlawful" under other law).

Plaintiffs also asserted additional state-law claims alleging that Sprout's front-label nutritional claims were misleading in violation of the UCL, *see* CAL. BUS. & PROF. CODE § 17200 (defining "unfair competition" to also include any practice that is "fraudulent"); California's False Advertising Law ("FAL"), *see id*. § 17500 (generally prohibiting "untrue or misleading" advertising); the California Consumer Legal Remedies Act ("CLRA"), *see* CAL. CIV. CODE § 1770(a) (prohibiting a variety of specified "deceptive acts or practices"); and the California common law of fraud. For these claims, Plaintiffs sought

[3] Section 110100 is contained in Part 5 of Division 104 of the Health and Safety Code, and that Part, which encompasses §§ 109875–111929.4, is "known as the Sherman Food, Drug, and Cosmetic Law." *See* CAL. HEALTH & SAFETY CODE § 109875. I will refer to that Part by its more colloquial name of the "Sherman Law."

compensatory, statutory, treble, and punitive damages. Finally, Plaintiffs also asserted an unjust enrichment claim that was predicated on the unlawful nature of Sprout's conduct as alleged in the other claims.

On October 21, 2022, the district court dismissed without leave to amend the Sherman-Law-based UCL claim on the ground that it was impliedly preempted by the FDCA's prohibition on private enforcement of its provisions. As to the fraud-based claims under the UCL, the FAL, the CLRA, and the common law, the court held that Plaintiffs had failed to allege sufficient facts, in accordance with the heightened pleading standards of Federal Rule of Civil Procedure 9(b), to plausibly infer that the challenged statements were misleading. Because all predicate causes of action had thus been dismissed, the district court also dismissed Plaintiffs' derivative claim for unjust enrichment. The district court, however, granted leave to amend as to the fraud-based claims and as to the unjust enrichment claim.

Rather than amend their complaint, Plaintiffs filed a notice of appeal four days later. Because the district court subsequently entered a final judgment dismissing the action, Plaintiffs' premature notice of appeal is effective to invoke our appellate jurisdiction. *See Weston Family P'ship LLLP v. Twitter, Inc.*, 29 F.4th 611, 618–19 (9th Cir. 2022) (holding that, although "orders dismissing claims with leave to amend are considered not final and thus not appealable as of right," a district court "effectively cure[s] [a] premature notice of appeal when it later issue[s] a final order").

II

In addressing whether Plaintiffs' UCL claim based on § 110100 is impliedly preempted, I begin by setting forth the basic statutory and legal framework concerning the FDCA's

preemptive scope. I will then explain why I think that Plaintiffs' claim is impliedly preempted and then discuss why the majority's reasons for its contrary conclusion are flawed.

A

Under the Constitution's Supremacy Clause, all "Laws of the United States which shall be made in Pursuance" of the Constitution "shall be the supreme Law of the Land." U.S. CONST. art. VI, cl. 2. The resulting "pre-emption" of state law by federal statutes "may be either expressed or implied, and 'is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose.'" *Gade v. National Solid Waste Mgmt. Ass'n*, 505 U.S. 88, 98 (1992) (citation omitted). Here, the relevant provisions of the FDCA implicate both express and implied preemption.

Section 403A of the FDCA contains an express preemption provision that addresses FDCA § 403(q) and § 403(r), which are the two key provisions concerning food labeling that provide the asserted statutory basis for the regulation at issue here, 21 C.F.R. § 101.13(b)(3). *See* 56 Fed. Reg. at 60423–24. Section 403A generally provides that "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[,]" either (1) "any requirement for nutritional labeling of food that is *not identical* to the requirement" of section 403(q); or (2) "any requirement respecting" any "nutrient" content claim that is "made in the label or labeling of food that is *not identical* to the requirement" of § 403(r). 21 U.S.C. § 343-1(a)(4), (5) (emphasis added). Because, as explained earlier, the California statute here expressly adopts, as "the food

labeling regulations" of California, all "food labeling regulations" that have been "adopted pursuant to" the FDCA, *see* CAL. HEALTH & SAFETY CODE § 110100(a), the relevant substantive prohibition set forth in 21 C.F.R. § 101.13(b)(3) is incorporated by reference into California law as a "food labeling regulation" under California law. And because that incorporated-by-reference regulation was adopted under § 403(q) and § 403(r) of the FDCA, the resulting California-law obligation derived from § 101.13(b)(3) is "identical" to the requirements of § 403(q) and § 403(r). It therefore is not expressly preempted by § 403A(a)(4) or § 403A(a)(5). The parties do not contest these points for purposes of this appeal.

The Supreme Court has held, however, that a statute with an express preemption provision also may have an additional *implied* preemptive effect. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001); *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287–89 (1995). Implied preemption occurs when "the scope of a statute indicates that Congress intended federal law to occupy a field exclusively . . . or when state law is in actual conflict with federal law." *Freightliner*, 514 U.S. at 287 (citation omitted). Here, Sprout relies only on "conflict" preemption, not "field" preemption. Specifically, Sprout notes that § 310 of the FDCA generally provides that "all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a). The only exception is that certain suits—including specifically suits to enforce § 403(q) and § 403(r)—may also be brought by a State "in its own name and within its jurisdiction . . . if the food that is the subject of the proceedings is located in the State." *Id*. § 337(b)(1). Sprout contends that allowing Plaintiffs to indirectly enforce

§ 101.13(b)(3) through a UCL action based on § 110100 would undermine the FDCA's exclusive reservation of enforcement jurisdiction to the federal Government and the State of California. In other words, Sprout asserts that to the extent the UCL provides a private right of action to indirectly enforce § 101.13(b)(3), it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" as expressed in § 310. *Freightliner*, 514 U.S. at 287 (citation omitted).

B

Against this backdrop, the central legal question presented in this case is how to determine when private enforcement of a *non-expressly-preempted* state law that draws on the FDCA's provisions is nonetheless *impliedly* preempted on the ground that it amounts to impermissible indirect private enforcement of the FDCA itself. Fortunately, we are not writing on a clean slate, and our caselaw provides what I ultimately believe is a relatively clear line. Expressed in general terms, the rule that emerges from our precedent is that a private cause of action based on state law with *independent* substantive content that *parallels* the FDCA's applicable requirements in a given case (such as, for example, a negligence claim predicated on a duty to warn that matches the FDCA's requirements) is not impliedly preempted, but a private claim based on state law that has no substantive content other than a parasitic copying of the FDCA's requirements is impliedly preempted. Here, Plaintiffs' § 110100-based UCL claim falls on the latter, preempted side of the line.

1

The seminal Supreme Court decision addressing implied preemption in light of FDCA § 310's prohibition of private

enforcement is *Buckman Co.*, 531 U.S. 341. Accordingly, a careful review of that decision is critical to any assessment of implied preemption in this area.

In *Buckman*, the defendant, Buckman Co., was a "consulting company that assisted" AcroMed Corporation, a manufacturer of "orthopedic bone screws," "in navigating the federal regulatory process" for those devices. 531 U.S. at 343. Under FDCA § 515(b), "Class III" devices (such as AcroMed's bone screws) are exempt from the FDCA's otherwise-applicable pre-market approval if they are "shown to be 'substantially equivalent'" to a device on the market at the time the pre-market approval provisions of the FDCA were enacted in 1976. *Id*. at 345 (quoting 21 U.S.C. § 360e(b)(1)(B)); *see also id*. at 344–46. "Demonstrating that a device qualifies for this exception is known as the '§ 510(k) process,'" which refers to the section of the FDCA under which such an exception request is submitted. *Id*. at 345. The plaintiffs alleged that Buckman Co. "made fraudulent representations to the FDA" in successfully applying for a § 510(k) exemption for AcroMed's bone screws. *Id*. at 347. The plaintiffs, "who claim[ed] injuries resulting from the use" of the bone screws, alleged that these fraudulent statements violated state-law duties against fraud and that Buckman was therefore liable in damages "under state tort law." *Id*. at 343. The Third Circuit held that these state-law "fraud claims were neither expressly nor impliedly pre-empted," but the Supreme Court reversed. *Id*. at 347.

The *Buckman* Court explicitly declined to address the question of express preemption, and its decision therefore necessarily proceeded on the assumption that the state-law fraud claims might not be expressly preempted by FDCA § 521, which is the FDCA's express preemption provision applicable to medical devices. 531 U.S. at 348 & n.2; *see* 21

U.S.C. § 360k. The Court first held that, because "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied,'" there was no "warrant" for applying "a presumption against finding federal pre-emption of a state-law cause of action." *Buckman*, 531 U.S. at 347. "Given this analytical framework," the Court held that the plaintiffs' state-law fraud claims "conflict[ed]" with the FDCA and were therefore "impliedly pre-empted." *Id*. at 348. The Court held that allowing the state common law of fraud to regulate the quality of the required disclosures made in connection with the § 510(k) application process would interfere both with the FDA's exercise of its "statutorily required judgment as to whether the device qualifies" for an exception and with the FDA's "flexibility" in developing a "measured response to suspected fraud" on the FDA. *Id*. at 348–51. Citing FDCA § 310, the Court emphasized that the FDCA provided "clear evidence that Congress intended" that the statute's medical-device provisions "be enforced exclusively by the Federal Government." *Id*. at 352.

In reaching these conclusions, the Court specifically rejected the plaintiffs' argument that the Court's decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), had already broadly held that state-law tort claims could be based on "violations of FDCA requirements" and still escape preemption. *Buckman*, 531 U.S. at 352. Because *Buckman*'s distinguishing of *Medtronic* is critical to the issue before us, I will first briefly summarize the relevant portions of *Medtronic* before returning to *Buckman*'s discussion of that case.

In *Medtronic*, the plaintiff, Lohr, was injured by the failure of her Medtronic pacemaker, which had been exempted from pre-market approval pursuant to the § 510(k)

exemption process. 518 U.S. at 480–81. As relevant here, Lohr asserted state common law claims for negligent manufacture and negligent failure to warn. *Id*. at 481–84. The Court held that these claims were not expressly preempted by FDCA § 521, which preempts any state-law requirement that is "different from, or in addition to, any requirement" of the FDCA that is "applicable . . . to the device" and that "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under" the FDCA. *Id*. at 481–82 (quoting 21 U.S.C. § 360k(a)); *id*. at 503. The *Medtronic* Court noted that Lohr's state-law negligent manufacturing and failure-to-warn claims included "claims that Medtronic ha[d], to the extent that they exist[ed], violated FDA regulations" concerning those matters. *Id*. at 495. The Court held that, because these claims rested on "violations of common-law duties" that "parallel federal requirements," they were not expressly preempted by § 521. *Id*.

In reaching this conclusion, the Court acknowledged that the applicable state law would require Lohr to prove the additional elements of her common law claims, including that the regulatory violations "were the result of negligent conduct" or that the pacemaker "created an unreasonable hazard for users of the product." *Medtronic*, 518 U.S. at 495. Although these further elements were arguably literally "different from, or in addition to," the FDCA's requirements, the Court held that these additional elements made the "state requirements narrower, not broader, than the federal requirement[s]." *Id*. In effect, the Court held that the state requirements thereby reached a *subset* of the situations that the federal requirements did and that, within that overlapping subset, the relevant requirements were identical. The Court further held that "[t]he presence of a damages

remedy does not amount to the additional or different 'requirement'" that gives rise to preemption under § 521; rather, the *Medtronic* Court explained, "it merely provides another reason for manufacturers to comply with identical existing 'requirements' under federal law." *Id*.

In *Buckman*, the plaintiffs argued that, because *Medtronic* had held that a common law negligence claim based on an alleged violation of the FDCA was not preempted, a common law fraud claim "arising from violations of FDCA requirements" was likewise not expressly or impliedly preempted. *Buckman*, 531 U.S. at 352. The *Buckman* Court rejected the plaintiffs' contention that *Medtronic* stood for "the proposition that any violation of the FDCA will support a state-law claim." *Id*. at 353. While noting that "*Medtronic* did not squarely address the question of implied preemption," the Court appeared to accept the *Buckman* plaintiffs' assertion that the claims at issue in *Medtronic* were neither expressly nor impliedly preempted. *Id*. Nonetheless, the Court held that the claims in *Buckman* were distinguishable in a way that made a difference to the implied-preemption inquiry. "[I]t is clear," the Court stated, "that the *Medtronic* claims arose from the manufacturer's alleged failure *to use reasonable care* in the production of the product, not solely from the violation of FDCA requirements." *Id*. (emphasis added). By contrast, the *Buckman* plaintiffs' "fraud claims exist[ed] solely by virtue of the FDCA disclosure requirements" connected to the § 510(k) exemption process. *Id*. at 352–53. Thus, "although *Medtronic* can be read to allow certain state-law causes of action that *parallel* federal safety requirements," the *Buckman* plaintiffs' fraud claims did not "rely[] on traditional state tort law which had predated the federal enactments in question[]." *Id*. at 353 (emphasis added).

The line that follows from *Buckman* is that a state-law cause of action that aligns with the content of the FDCA's requirements, and thus escapes express preemption, will also escape implied preemption if the state-law rule has *independent* content—such as the preexisting "reasonable care" standard—that supports a *parallel* result. The negligence claims in *Medtronic* met that standard, because the deficiencies in the pacemaker could be independently established under the reasonable-care standard in a way that paralleled the applicable requirements of the FDCA. By contrast, the duties imposed by the state-law fraud claims in *Buckman* vis-à-vis communications with the FDA simply could not be defined independently of the very specific "disclosure requirements" applicable to the § 510(k) process under the FDCA. 531 U.S. at 353. Those fraud claims thus "exist[ed] *solely* by virtue of the FDCA disclosure requirements." *Id*. (emphasis added).

2

Our caselaw construing *Buckman* similarly confirms that, to escape implied preemption under § 310, a state-law cause of action must rest on a duty that has sufficient independent existence apart from the FDCA.

Our decision in *Kroessler v. CVS Health Corp.*, 977 F.3d 803 (9th Cir. 2020), provides a paradigmatic case of a state-law claim that falls on the non-preempted side of the line drawn in *Buckman*. The plaintiff in *Kroessler* asserted claims under California's UCL and CLRA, as well as a common law claim for breach of express warranty. *Id*. at 806. As relevant here, the gravamen of these claims was that CVS's "glucosamine-based supplements" were advertised as supporting "joint health," but that the supplements "did not provide the advertised benefits." *Id*. As we explained,

"Kroessler allege[d] that CVS's glucosamine claims [were] false because scientific studies directly refute[d] them." *Id*. at 812. We held that Kroessler's claim that he could affirmatively refute CVS's representations rested on the same "'substantiation' standard" as applicable under the FDCA and its regulations. *Id*. at 813. Specifically, § 403(r) of the FDCA contains a provision governing dietary supplements, and it states that, with respect to claims that a dietary supplement "acts to maintain [a] structure or function" "in humans," the manufacturer must "ha[ve] substantiation that such statement is truthful and not misleading." 21 U.S.C. § 343(r)(6)(A), (B); *see Kroessler*, 977 F.3d at 809. Because the obligation on which Kroessler's California-law claims were based thus involved an obligation that was "identical" to one imposed under FDCA § 403(r), it was not expressly preempted under § 403A(a)(5). *See Kroessler*, 977 F.3d at 808. Moreover, because the substantiation standard invoked by Kroessler under California law obviously had sufficient content that existed independent of the FDCA, it could not be said to "exist solely by virtue of the FDCA." *Buckman*, 531 U.S. at 353. Kroessler's claim therefore rested on a "parallel" duty that was not impliedly preempted. *Kroessler*, 977 F.3d at 814.

Similarly, in *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013) (en banc), we held that the Arizona "state-law failure-to-warn claim" asserted by the plaintiffs was neither expressly nor impliedly preempted, because it had sufficient independent content that paralleled FDCA requirements. *See id.* at 1233. One of the plaintiffs, Richard Stengel, had been rendered paraplegic by Medtronic's device, which had been given pre-market approval by the FDA. *Id*. at 1227. The plaintiffs alleged that Medtronic was

liable under Arizona tort law requiring that warnings be provided to third parties "if, given the nature of the warning and the relationship of the third party, there is 'reasonable assurance that the information will reach those whose safety depends on their having it.'" *Id*. at 1233 (citation omitted). Specifically, the plaintiffs invoked this Arizona duty to warn third parties in alleging that Medtronic had a duty "to warn the FDA" of any product risks of which Medtronic later became aware and that Medtronic had breached that duty to Stengel's detriment. *Id*. at 1232. This state-law duty paralleled Medtronic's obligation, under the FDCA's regulations, not to "conceal[] known risks." *Id*. at 1227. We held that this state-law claim was "*independent* of the FDA's pre-market approval process that was at issue in *Buckman*," and that the claim "rest[ed] on a state-law duty that *parallels* a federal-law duty under the [FDCA], as in [*Medtronic v.*] *Lohr*." *Id*. at 1233 (emphasis added). As such, it was "not preempted, either expressly or impliedly." *Id*.; *see also id*. at 1235 (Watford, J., concurring) ("It is sufficient here that, in contrast to *Buckman*, [the plaintiffs'] claim is grounded in a traditional category of state law failure-to-warn claims that predated the federal enactments in question, and that the claim therefore does not exist solely by virtue of those enactments.").[4]

By contrast, we have repeatedly held that FDCA § 310 impliedly preempts state-law causes of action that have no independent substance apart from an explicit parasitic reliance on the FDCA's provisions. For example, in *Perez v. Nidek Co., Ltd.*, 711 F.3d 1109 (9th Cir. 2013), we addressed a state common law fraud claim in which the plaintiffs

[4] Judge Watford's concurrence was joined by six other members of the en banc panel.

alleged that the defendant, a manufacturer of a laser that had received FDA pre-market approval for "treating nearsightedness," had "fail[ed] to disclose" to patients "that the Laser was not FDA approved" for "correct[ing] farsightedness." *Id*. at 1112, 1117. We held that this claim was impliedly preempted by § 310 under *Buckman*. We explained that, "[l]ike the fraud-on-the-FDA claims in *Buckman*, [the plaintiffs'] fraud by omission claim exists solely by virtue of the FDCA requirements with respect to approved use of the Laser" and "the existence of these federal enactments is a critical element in their case." *Id*. at 1119 (simplified). We reasoned that, although other fraud claims might not be barred, the FDCA impliedly preempted "a claim that rests solely on the non-disclosure to patients of facts tied to the scope" of pre-market approval. *Id*. We concluded by stating that the Eighth Circuit had "aptly described the 'narrow gap' through which a state-law claim must fit to escape preemption by the FDCA: 'The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a) [FDCA § 521(a)]), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*).'" *Id*. at 1120 (quoting *Bryant v. Medtronic, Inc.* (*In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*), 623 F.3d 1200, 1204 (8th Cir. 2010)).

In *Nexus Pharmaceuticals, Inc. v. Central Admixture Pharmacy Services, Inc*, 48 F.4th 1040 (9th Cir. 2022), we applied similar reasoning in holding that state statutory causes of action that parasitically borrowed from the FDCA were impliedly preempted by § 310. The plaintiff was a drug manufacturer who alleged that the defendants' compounded drug was "essentially a copy" of plaintiff's drug and was therefore required under FDCA § 503B to be approved by

the FDA pursuant to the approval process for new drugs under FDCA § 505. *Nexus*, 48 F.4th at 1043–44; *see also* 21 U.S.C. §§ 353b(a)(5), 355. The plaintiff alleged that, because the defendants' products lacked the required FDA approval, their sale was unlawful under the statutes of five States that specifically "prohibit[ed] the sale of drugs not approved by the FDA." *Id*. at 1044. One of those statutes was a provision of California's Sherman Law that prohibited the sale of any "new drug" unless "a new drug application has been approved for it and that approval has not been withdrawn, terminated, or suspended under Section 505 of the federal act." CAL. HEALTH & SAFETY CODE § 111550(a)(1) (citing 21 U.S.C. § 355).

In evaluating whether these claims were impliedly preempted, we exhaustively reviewed many of the same precedents I have summarized above, and we held that "a clear distinction reveals itself when one reads them all together." *Nexus*, 48 F.4th at 1050. That distinction, we explained, was between "a traditional common law tort action" alleging "harm to a patient," which "might" provide a private cause of action that "escape[s] preemption," and a claim that a plaintiff "is harmed economically because the defendant violated the FDCA." *Id*. We stated that the *Nexus* plaintiffs' claims fell on the preempted side of that line because the "purported state law violation is of a law that says in substance 'comply with the FDCA,' not a traditional common law tort." *Id*. We therefore held that the plaintiffs' claims, which "relie[d] on a state statute which itself relies on the federal statute, not traditional tort law theory," were impliedly preempted by § 310's prohibition on private enforcement of the FDCA. *Id*. at 1046, 1050–51; *see also id*. at 1047 (noting that the plaintiffs' claims were "based on

state laws that incorporate federal law, rather than on traditional tort law").

Notably, *Nexus* explicitly rejected the Federal Circuit's contrary conclusion in *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350 (Fed. Cir. 2013). Relying on the presumption against preemption, and the "the historic primacy of state regulation of matters of health and safety," the Federal Circuit held in *Allergan* that the very same California statute at issue in *Nexus* was *not* impliedly preempted. *Id*. at 1353–56. *Buckman* was distinguishable, the Federal Circuit concluded, because the Court there had held that the subject involved (fraud on a federal agency) was "hardly a field which the States have traditionally occupied." *Id*. at 1356 (citing *Buckman*, 531 U.S. at 347). The Federal Circuit held that implied preemption was unwarranted, despite the California statute's reliance on the content of the FDCA, because the statute still "implicate[s] an historic state power" of a sort "that may be vindicated under state law tort principles." *Id*. at 1355. We held in *Nexus* that, in reaching this conclusion, the Federal Circuit failed adequately to consider "the FDCA's prohibition of private enforcement." 48 F.4th at 1050. Taking that prohibition into account, we held, "required a contrary result" from *Allergan*. *Id*. As we explained, the private cause of action allowed in *Allergan* was impliedly preempted by § 310's ban on private enforcement of the FDCA, because the "California law merely incorporated FDCA requirements." *Id*. at 1049.

3

Under this caselaw, the answer in this case is clear: Plaintiffs' UCL claim based on § 110100 is impliedly preempted.

Here, as in *Nexus*, the California statute at issue "merely incorporate[s] FDCA requirements" and "says in substance 'comply with the FDCA." 48 F.4th at 1049–50. And, like the common law claims in *Buckman* and in *Perez*, the statutory claim here is ultimately parasitic of the FDCA and "exist[s] *solely* by virtue of the FDCA . . . requirements" that it borrows. *Perez*, 711 F.3d at 1119 (quoting *Buckman*, 531 U.S. at 353 (emphasis added)). Because the substance of the asserted violation of § 110100 is defined *entirely* by a federal regulation adopted under the FDCA, the "existence of [that] federal enactment[] is a critical element in [Plaintiffs'] case." *Id*. (citation omitted). As a result, and in contrast to the statutory and common law claims at issue in *Kroessler* and the common law claim in *Stengel*, the private state statutory cause of action here has *no independent substance* that "parallel[s]" the requirements of the FDCA. *Kroessler*, 977 F.3d at 814; *Stengel*, 704 F.3d at 1233. Accordingly, the district court correctly held that Plaintiffs' § 110100-based UCL private cause of action is impliedly preempted.

C

In reaching a contrary conclusion, the majority relies on several arguments, all of which are legally erroneous.

1

The majority's primary rationale for its no-preemption holding rests on a broad and seemingly simple syllogism that is, on closer inspection, clearly wrong.

The majority emphasizes that, "by its terms," FDCA § 310's prohibition of private enforcement "implicates only enforcement of the *federal* law." *See* Opin. at 17 (emphasis added). According to the majority, it does not matter that § 110100 parasitically incorporates the FCDA's food-

labeling requirements *in toto*, so that the resulting state law has an entirely "federal origin and content." *See* Opin. at 16. The FDCA's relevant express preemption provision, the majority concludes, clearly "permitted states to adopt" identical food-labeling requirements, and "[t]here is no reason we can perceive why Congress would permit states to enact particular legislation and then deny enforcement by their citizens." *See* Opin. at 14. In the majority's view, it would be "strange," and an "anomaly" to conclude that "Congress would want states to enact laws that [their] citizens cannot enforce." *See* Opin. at 14, 16. The majority therefore broadly concludes that "the FDCA does not preempt [private] claims for violations of parallel state law duties." *See* Opin. at 15. For multiple reasons, the majority's reasoning is deeply flawed.

First, the majority's reasoning wrongly equates the scope of the FDCA's express preemption with the scope of its implied preemption. According to the majority, because § 110100(a)'s wholesale incorporation of the FDCA's food-labeling regulations is not expressly preempted—and California is thus "permitted" to adopt such a law—there are *no* implied limitations on the enforcement of that state law. *See* Opin. at 11, 14, 16, 18–19. This holding is flatly contrary to *Buckman*. As I have explained, the Court there explicitly held that the plaintiffs' fraud-on-the-FDA claims were impliedly preempted *without regard* to whether the alleged state-law duty on which they rested was *expressly* preempted by the FDCA. *See* 531 U.S. at 348 n.2 (stating that, having concluded that the claims were impliedly preempted, the Court "express[ed] no view on whether [they were] subject to *express* pre-emption under [FDCA § 521]" (emphasis added)). By stating that it was irrelevant whether the fraud claims there were expressly preempted, the Court

effectively assumed that they might not be. *Buckman* thus holds that the mere fact that a state law is not expressly preempted—and is thus "permitted" by the express preemption provision—does *not* preclude a finding that private enforcement of that law conflicts with § 310, thereby leading to implied conflict preemption.

Likewise, in *Nexus*, we found that a private state statutory cause of action that "relie[d] on a state statute which itself relies on the [FDCA]" was impliedly preempted by § 310 even though "no applicable express preemption clause applied" at all. 48 F.4th at 1046. Like the provision at issue here, the state statute in *Nexus* "merely incorporated FDCA requirements." *Id*. at 1049. Specifically, the state statute in *Nexus*, which was another provision of the Sherman Law, prohibited "the sale of drugs not approved by the FDA." *Id*. at 1044. We held that the private cause of action was impliedly preempted because the "purported state law violation is of a law that says in substance 'comply with the FDCA,' not a traditional common law tort," and the law's features impermissibly invaded the federal Government's exclusive authority to enforce the FDCA. *Id*. at 1050. Under *Buckman* and *Nexus*, it is thus *not* enough that a state statute is not expressly preempted and is in that sense "permitted." The crucial question remains whether private enforcement of the non-expressly-preempted state statute is impliedly preempted due to the fact that the state cause of action, as in *Buckman* and *Nexus*, parasitically relies on the FDCA. By wrongly equating express preemption and implied preemption here, the majority's opinion simply begs that critical question and thus provides no answer to it.

Second, the majority's rhetorical question—why would Congress "permit states to enact particular legislation and then deny enforcement by their citizens[?]"—has an obvious

answer. *See* Opin. at 14. By mirroring the FDCA itself—which expressly permits state enforcement of § 403(q) and § 403(r)—the "identical" state law could likewise provide for enforcement by *state* authorities and could perhaps allow those authorities, in such a public suit in state court, to obtain additional remedies (monetary or otherwise) that are not afforded by the FDCA. *Cf. Medtronic*, 518 U.S. at 495. It can hardly be thought to be "strange" to limit States to using, for the "permitted" identical state laws, only the same public enforcement mechanisms that are permitted by the very federal law they are copying. If that public-enforcement-only policy is sensible for the FDCA, it cannot be dismissed as strange and anomalous for state laws whose substantive provisions must be identical to the FDCA. The unstated (and untenable) premise of the majority's opinion is that the FDCA's prohibition on private enforcement is itself "strange" and "anomal[ous]." *See* Opin. at 14, 16.

Third, the dispositive weight that the majority attaches to the express preemption provision in FDCA § 403A(a) is directly contrary to the statutory rule of construction that applies to § 403A(a). Section 403A was added to the FDCA by § 6(a) of the Nutritional Labeling and Education Act ("NLEA"), Pub. L. No. 101-535, 104 Stat. 2353, 2362 (1990). Section 6(c) of the NLEA contains certain rules of construction for this new preemption provision in § 403A, which was added to the FDCA at the same time as § 403(q) and § 403(r). Section 6(c)(1) generally states that the NLEA—as opposed to the entire FDCA—"shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under section 403A of the Federal Food, Drug, and Cosmetic Act." *Id.* § 6(c)(1), 104 Stat. at 2364 (reproduced as a note to 21 U.S.C. § 343-1). That general rule, if applicable here, would perhaps have

supported the majority's complete equation of express and implied preemption. But § 6(c)(3) goes on to state that § 6(a) "shall not be construed to affect preemption, *express or implied*, of any such requirement of a State or political subdivision, which may arise under," *inter alia*, "any provision of the Federal Food, Drug, and Cosmetic Act not amended by subsection (a)." *Id*. § 6(c)(3), 104 Stat. at 2364. Section 310 of the FDCA is a "provision of the Federal, Food, Drug, and Cosmetic Act not amended by subsection (a)" of § 6 of the NLEA, inasmuch as § 6(a) *only* adds § 403A to the FDCA. *See* 104 Stat. at 2362–63. Accordingly, § 6(c)(3) of the NLEA explicitly states that the enactment of the express preemption provision in § 403A does *not* detract from the implied preemptive force of § 310 of the FDCA. The majority's rationale is directly contrary to this statutory command.

Fourth, the majority's reasoning is difficult to square with the fact that, in adding the relevant regulatory provisions (§ 403(q) and § 403(r)) and the relevant express preemption provision (§ 403A) to the FDCA, the NLEA simultaneously amended § 310 of the FDCA (which was then called § 307)[5] by adding the provision allowing state authorities to enforce § 403(q) and § 403(r). *See* NLEA § 4, 104 Stat. at 2362. Had it wanted to do so, Congress could have added private enforcement authority to the new food-labeling provisions, but it did not. However, under the majority's reading, simply by enacting a single sentence that indiscriminately incorporates into state law *all* of the food-labeling regulations adopted under the NLEA's amendments to the FDCA, California has succeeded in adding precisely

[5] Section 307 was renumbered as § 310 in 1992. *See* Pub. L. No. 102-282, § 2, 106 Stat. 149, 150 (1992).

the private enforcement remedy that Congress deliberately withheld when it enacted the NLEA. This direct reversal of Congress's intent that the food-labeling provisions "be enforced exclusively by the Federal Government" and state authorities confirms that the private right of action the majority allows is impliedly preempted. *Buckman*, 531 U.S. at 352.

The majority is thus wrong in broadly concluding that, merely because the FDCA does not expressly preempt § 110100, a private cause of action enforcing an FDA regulation incorporated into § 110100 is not impliedly preempted.

2

The majority's additional arguments in support of its holding fare no better.

The majority's effort to distinguish *Buckman*, *Perez*, and *Nexus* on their specific facts is unavailing. According to the majority, the instant case "fundamentally differs" from those three cases in that, here, "plaintiffs are claiming violations of California law, the Sherman Law, not the federal FDCA." *See* Opin. at 14. This assertion is simply false. Indeed, the plaintiff in *Nexus*—who invoked a different provision of the Sherman Law that incorporated different provisions of the FDCA—quite literally "claim[ed] violations of California law, the Sherman Law, not the federal FDCA." The plaintiffs in *Buckman* and *Perez* likewise relied on state common law causes of action whose *state-law* content lacked relevant independent substance apart from the borrowing of FDCA requirements. The majority attempts to distinguish *Buckman* on the basis that it "did not involve any violation of duties owed under a state consumer protection statute," but this is a distinction without a difference. *See*

Opin. at 12. The claim in *Buckman* rested on the "*state-law*" tort duty against "fraudulent representations," with the substance of that duty being defined "solely" by reference to the relevant "FDCA disclosure requirements." *Buckman*, 531 U.S. at 346–47, 352–53. Because *Buckman*, *Perez*, and *Nexus* all similarly involved a borrowing of FDCA standards into the substance of state law, the majority's effort to distinguish those cases on that basis fails.

Finally, the majority relies on the presumption against preemption as justifying its holding here. *See* Opin. at 19–20. But this invocation of the presumption cannot be squared with *Nexus*. There, we expressly rejected the Federal Circuit's decision in *Allergan*, which had extensively relied on the presumption against preemption in holding that another provision of the Sherman Law that similarly borrowed from the FDCA was not impliedly preempted. *See Allergan*, 738 F.3d at 1355–56. In rejecting *Allergan*, we held that what mattered was that, because the "California law merely incorporated FDCA requirements," it ran afoul of "the FDCA's prohibition of private enforcement." *Nexus*, 48 F.4th at 1049–50. Moreover, the States's historic police powers are amply preserved by the line drawn in our caselaw, which allows private causes of action that rest on traditional state-law causes of action with independent substantive content that parallels federal law.[6]

[6] This case itself illustrates the point—Plaintiffs here have asserted fraud-based claims alleging that, by singling out particular nutrients, Sprout's front-label claims falsely suggest that increased intake of those nutrients is beneficial for toddlers. Those claims fail here because they are inadequately pleaded, but they clearly fall on the non-preempted side of the line: they rest on traditional state common law with independent substantive content that, on the facts of this case, matches the applicable provisions of the FDCA and its pertinent regulations.

By contrast, parasitically copying publicly enforced federal statutes and attaching new privately enforceable remedies to them can hardly be thought of as a traditional state power that is protected by the presumption against preemption.

For the foregoing reasons, I would hold that Plaintiffs' UCL cause of action based on § 110100 is impliedly preempted.

III

I concur in Section II of the majority opinion, which affirms the dismissal of Plaintiffs' fraud-based claims for failure to comply with the heightened pleading standards of Federal Rule of Civil Procedure 9(b). Because, in my view, no predicate claim thus remained that could support an unjust enrichment claim, that cause of action was properly dismissed as well.

* * *

For the foregoing reasons, I would affirm the district court's judgment dismissing all of Plaintiffs' claims with prejudice. To the extent that the majority does otherwise, I respectfully dissent.