No. 24-____

IN THE

Supreme Court of the United States

SPROUT FOODS, INC.,
Petitioner,
v.
GILLIAN DAVIDSON & SAMUEL DAVIDSON,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

When enacting the Food, Drug, & Cosmetic Act of 1938 ("FDCA"), Congress expressly barred private enforcement of the act and its regulations (the provision now found at 21 U.S.C. § 337(a)). Despite amending the FDCA several times in the 86 years since enactment, Congress has never repealed the act's express prohibition on private enforcement.

After Congress passed the Nutrition Labeling and Education Act of 1990 ("NLEA"), which amended the FDCA by creating a national standard for food labeling, California amended its own food labeling law. With a mere 38 words, California's Sherman Food, Drug, and Cosmetic Law ("Sherman Law") automatically adopts all of the FDCA's current and future food labeling regulations as state law. The Ninth Circuit found that the Sherman Law has now transformed the hundreds of pages of federal food labeling regulations into independent state food labeling requirements not subject to § 337's ban on private enforcement of the FDCA. In other words, according to the Ninth Circuit, an allegation that a defendant has violated the FDCA or federal regulations promulgated thereunder is now privately enforceable—notwithstanding § 337's express bar on private enforcement—simply because, in California, *federal* laws can be cross-cited as *state* laws.

The question presented is:

1. Whether § 337's explicit bar on private enforcement of the FDCA precludes a private action seeking to enforce FDCA food labeling regulations by asserting a state statute that incorporates FDCA regulations wholesale?

PARTIES TO THE PROCEEDING

Petitioner in this Court is Sprout Foods, Inc. Respondents are Gillian and Samuel Davidson.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Supreme Court Rule 29.6, Sprout Foods, Inc. states that Neptune Growth Ventures, Inc., is a majority parent corporation of Sprout Foods, Inc. Neptune Growth Ventures, Inc., is a subsidiary of Neptune Wellness Solutions, Inc. Neptune Wellness Solutions Inc. is a publicly traded company and no publicly held company owns 10% or more of the stock of Neptune Wellness Solutions Inc. The undersigned counsel further certifies that NH Expansion Credit Fund Holdings LP, is the minority parent corporation of Sprout Foods, Inc., and no publicly held company owns 10% or more of the stock of NH Expansion Credit Fund Holdings LP.

STATEMENT OF RELATED PROCEEDINGS

U.S. Court of Appeals for the Ninth Circuit: *Gillian and Samuel Davidson et. al., v. Sprout Foods, Inc.*, No. 22-16656 (Jun. 28, 2024) (reported at 106 F.4th 842).

U.S. District Court for the Northern District of California: *Gillian and Samuel Davidson et. al., v. Sprout Foods, Inc.*, No. 3:22-cv-01050-RS (Oct. 21, 2022) (available at 2022 WL 13801090).

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PETITION FOR A WRIT OF CERTIORARI

Petitioner Sprout Foods, Inc., respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Ninth Circuit in this case.

OPINIONS BELOW

The Ninth Circuit's opinion (Pet. App. 1a – 48a) is reported at 106 F.4th 842. The Ninth Circuit's order denying Sprout's petition for rehearing/rehearing en banc (Pet. App. 49a – 50a) is not reported.

The District Court's order dismissing the Davidsons' First Amended Complaint (Pet. App. 51a – 61a) is not reported but is available at 2022 WL 13801090.

JURISDICTION

The judgment of the court of appeals was entered on June 28, 2024. Pet. App. 1a – 48a. The court of appeals denied a timely petition for rehearing or rehearing en banc on September 10, 2024. Pet. App. 49a – 50a. On November 26, 2024, this Court extended Petitioner's deadline to petition for a writ of certiorari up to and including January 8, 2025. This Court has jurisdiction under 28 U.S.C. § 1254(1).

PROVISIONS INVOLVED

21 U.S.C. § 337 provides in relevant part:

> (a) Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any

> district, may run into any other district in any proceeding under this section.

The entirety of 21 U.S.C. § 337 is reproduced at Pet. App. 63a – 64a. The relevant provision of the Nutrition Labeling and Education Act, 21 U.S.C. 343-1 (FDCA §403A) is reproduced at Pet. App. 64a – 66a. 21 C.F.R. § 101.13(b)(3), an FDA regulation promulgated under the NLEA, is reproduced at Pet. App. 67a.

Cal. Health & Safety Code § 110100(a) provides in relevant part:

> (a) All food labeling regulations and any amendments to those regulations adopted pursuant to the federal act, in effect on January 1, 1993, or adopted on or after that date shall be the food labeling regulations of this state.

Cal. Health & Safety Code § 109930 provides:

> "Federal act" means the federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. Sec. 301 et seq.).

INTRODUCTION

This case presents an important and frequently recurring question about the scope of the FDCA's prohibition on private enforcement, with significant implications for the Food and Drug Administration's ("FDA") authority over food labeling regulations. The FDCA explicitly bars private enforcement of the federal statute and regulations promulgated thereunder; instead, "***all such proceedings*** for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States," with only a limited exception for state governmental enforcement of certain provisions. *See* 21 U.S.C. § 337(a)-(b) (emphasis added). By operation

of this explicit statutory provision, *no private plaintiff* may sue to enforce the FDCA or its regulations.

Meanwhile, California's Sherman Food, Drug, and Cosmetic Law ("Sherman Law") states: "All food labeling regulations and any amendments to those regulations adopted pursuant to the federal act [FDCA], in effect on January 1, 1993, or adopted on or after that date shall be the food labeling regulations of this state." Cal. Health and Safety Code § 110100(a). Through this one sentence, the Sherman Law incorporates hundreds of pages of FDCA regulations into California law. According to the divided Ninth Circuit panel below, these 38 words turn the FDCA's detailed food labeling regulations into California "state law requirements" that are independent of the federal law from which they originated. The opinion also allows any consumer to privately enforce these "state law requirements,"—even though Congress explicitly forbids private enforcement of the same FDCA food labeling ones. Accordingly, the Ninth Circuit has opened the door for plaintiffs to privately enforce the FDCA.

The Ninth Circuit's decision conflicts with this Court's precedent, and incorrectly applies *Buckman Company v. Plaintiffs' Legal Committee* to reject implied preemption under § 337 of the FDCA. 531 U.S. 341 (2001). The Ninth Circuit conflates the FDCA's scope of express preemption with the distinct concept of implied preemption, which as outlined in *Buckman*, hinges on whether a state law claim seeks to privately enforce FDCA requirements. In *Buckman*, this Court held that state law claims that "exist solely by virtue" of FDCA "requirements" and "originate from, are governed by, and terminate according to federal law" are impliedly preempted under § 337, which bans

private enforcement of the FDCA. 531 U.S. at 347, 353. *Buckman* demands the same result here.

Additionally, the decision creates a circuit split. Before this case, the First, Second and Sixth Circuits agreed that § 337 bars a private litigant from bringing claims to enforce the FDCA under the guise of state law that parasitically copies the federal statute and regulations. *See DiCroce v. McNeil Nutritionals, LLC*, 82 F.4th 35 (1st Cir. 2023); *Loreto v. Procter & Gamble Co.*, 515 F. App'x 576 (6th Cir. 2013); *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105 (2d Cir. 1997). The Ninth Circuit's decision is a stark departure from this precedent and this Court's intervention is necessary to resolve the circuit split and clarify the scope of implied preemption under § 337.

Moreover, the Ninth Circuit's decision permitting private enforcement of a state law incorporating FDA regulations wholesale also conflicts with the NLEA—which centralizes food labeling standards and enforcement coordination within the federal government. This opinion not only threatens to disrupt the uniformity and reliability of food labeling across the nation but also risks burdening manufacturers with inconsistent "state requirements" pursued by a myriad of private consumers instead of coordinated by FDA and the federal government. It also poses a serious threat to the FDCA's ban on private enforcement, and potentially opens the door for any state to create a private right of action for other FDCA provisions, using nothing more than a few words of incorporation. Following the Ninth Circuit's decision, a state need only adopt those FDCA provisions as state law and offer a private remedy to do so. Accordingly, this decision could create significant confusion, not just for food labeling cases, but for other FDCA regulated

products, including drugs, dietary supplements, and cosmetics.

The potential to undermine federal enforcement and FDA authority is real, and the impact could extend to other provisions of the FDCA or other federal statutes prohibiting private enforcement. Given the rising proliferation of food marketing litigation and the current circuit split on this issue, this Court's intervention is essential to resolve this important legal question and ensure consistent legal standards for food labeling nationwide.

STATEMENT

A. Statutory Framework

1. Congress passed the Food, Drug, and Cosmetic Act in 1938, which, with subsequent amendments, led to the modern FDA. The FDCA grants FDA broad authority to nationally regulate pharmaceutical drugs, cosmetics, medical devices, as well as food and beverages, among other products. *See, e.g., Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996). Within its statutory charge, FDA nationally regulates and has the authority to prohibit the introduction, adulteration, or misbranding of any food product in interstate commerce. *See* 21 U.S.C. § 331(a)-(b). To protect that exclusive authority over all products falling within its regulatory purview, the FDCA provides no private right of action for consumers, a prohibition included in the original 1938 Act. *See* Federal Food, Drug, and Cosmetic Act of 1938, § 307, Pub. L. 75-717, 52 Stat. 1040, 1046 (1938) ("Sec. 307. All such proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States."). Congress has not repealed this private enforcement prohibition. Regarding FDA

regulations at issue here, Congress continues to provide that all enforcement of this Act "shall be by and in the name of the United States," and, in limited circumstances not present here, states. 21 U.S.C. § 337(a)-(b).

2. In enacting the Nutrition Labeling and Education Act of 1990, Congress amended the FDCA to provide nationally uniform standards for nutrition labeling. Pet. App. 6a. To effectuate national uniformity, the NLEA contains an express preemption provision that addresses 21 U.S.C. § 343(q) and § 343(r), the statutory basis for the food labeling regulations at issue here. *See* Pet. App. 24a. 21 U.S.C § 343-1 relevantly 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 [343(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 [section 343(r)]." Pet. App. 27a; s*ee* 21 U.S.C. § 343-1(a)(4),(5) (emphasis added).

3. FDA promulgated two federal regulations pursuant to 21 U.S.C. § 343(q) and (r) upon which the Davidsons base their state statutory claims. First, food product manufacturers are required to disclose specified nutritional information in a standardized box that is typically placed on the back of packages. Pet. App. 23a (citing 21 U.S.C. § 343(q), 21 C.F.R. § 101.9(d)). Second, for foods intended specifically for children under the age of two, manufacturers may not make any other nutritional claims on food labeling, including the front of the product, unless specifically authorized by relevant federal regulations. Pet. App. 23a – 24a

(citing 21 C.F.R § 101.13(b)(3); 58 Fed. Reg. 2302, 2303-04 (Jan. 6, 1993); 56 Fed. Reg. 60421, 60423-24 (Nov. 27, 1991)).

4. California's Health & Safety Code includes statutes governing the false or misleading labeling of food known as the Sherman Food Drug & Cosmetic Law. *See* 1970 Cal. State. Ch. 1573. After the NLEA's passage, California amended the Sherman Law to automatically incorporate all federal food-labeling regulations into California law. Cal. Health & Safety Code § 110100(a). Specifically, § 110100(a) expressly adopts, as "the food labeling regulations" of California, all "food labeling regulations" that have been adopted on or after January 1, 2003 pursuant to the FDCA. Cal. Health & Safety Code §§ 110100(a), 109930. In other words, the Sherman Law's incorporate-by-reference approach automatically adopts or repeals all FDA food labeling regulations as California law that have been either promulgated or rescinded.

5. The Sherman Law, like the FDCA, expressly limits enforcement of the act to the government, here the California Department of Health Services. Cal. Health & Safety Code § 110045 ("The department shall administer and enforce this part."). Further, California Health and Safety Code § 111840 provides that "[t]he Attorney General, any district attorney, or any city attorney to whom the department reports any violation of this part shall begin appropriate proceedings in the proper court." Additionally, California Health and Safety Code § 111900 provides that "[t]he Attorney General or any district attorney, *on behalf of the department,* may bring an action in superior court . . ." (emphasis added).

B. Factual and Procedural Background

1. Since 2008, Sprout Foods, Inc. ("Sprout") has manufactured and sold organic plant-based baby and toddler foods, including baby food pouches, snacks, and toddler meals. Pet. App. 7a. The pouches' front panel contained statements of nutrient content such as "3g of Protein, 4g of Fiber and 300mg Omega-3 from Chia ALA," which are at issue in this case. *Id*. "This same information – along with additional nutrition information – was also included in the Nutrition Facts Panel on the back of the packaging." Pet. App. 52a. The Davidsons have never alleged that the at-issue nutrient information was quantitatively inaccurate or untruthful.

2. The Davidsons filed their diversity action in district court seeking to represent a class of consumers who purchased Sprout's products beginning in 2018. Pet. App. 8a. They contended that Sprout violated FDA's food labeling regulation on foods specifically intended for children under two years of age (21 C.F.R. § 101.13(b)(3)). That regulation, in turn, was wholesale and automatically incorporated into California's Sherman Law. Knowing that 21 U.S.C. § 337 only permits the federal government or a state qua state (under certain conditions) to enforce the NLEA, the Davidsons brought a claim under California's Unfair Competition Law ("UCL") premised on an alleged violation of the Sherman Law ("Sherman Law claim")[1]. Pet. App. 8a. The Davidsons' First Amended Complaint did not hide the federal content and nature of their Sherman Law

[1] Because California's UCL is the procedural consumer protection vehicle for several of plaintiffs' claims, this petition will call the UCL claim based on violations of § 110100 of the California Health & Safety Code as the "Sherman Law claim".

claim, repeatedly citing federal laws and regulations as the basis of liability. Pet. App. 114a (alleging that Sprout engaged in unlawful practices by failing to follow the advertising provisions of the Sherman Law, the misbranded food provisions of the Sherman Law, and "federal laws regulating the advertising and branding of food in 21 U.S.C. § 343 et seq. and FDA regulations including but not limited to 21 U.S.C. § 101.13(b), which are incorporated into the Sherman Law . . ."). Additionally, the Davidsons asserted state-law fraud claims pursuant to California's UCL, False Advertising Law, Consumer Legal Remedies Act, and California common law ("fraud-based claims") alleging that Sprout's front-label quantitative statements were fraudulent and misleading. Pet. App. 25a. The Davidsons further alleged a state law unjust enrichment claim. *Id*.

3. The district court dismissed the Davidsons' First Amended Complaint in its entirety pursuant to Federal Rule of Civil Procedure ("FRCP") 12(b)(6). Pet. App. 51a – 52a. The district court explained that the Davidsons' Sherman Law claim "is entirely dependent upon the FDCA, in that [the Sherman Law] expressly adopts the FDCA and regulations as state law." Pet. App. 60a. The district court thus found the Davidsons' Sherman Law claim impliedly preempted because it "orginate[d] from, [was] governed by and terminate[d] according to federal law." *Id*. (citing *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1230 (9th Cir. 2013) (en banc) (quoting *Buckman*, 531 U.S. at 347-48)).

The district court also dismissed the fraud-based claims, finding the Davidsons failed to allege sufficient facts under FRCP 9(b)'s heightened pleading standard. Even accepting the allegations as true, the First Amended Complaint failed to sufficiently allege why the challenged statements were misleading or false,

i.e., that the products were in fact harmful. Pet App. 55a – 58a. Finally, the Davidsons' unjust enrichment claim was dismissed for lack of an underlying basis of recovery given the other claims' dismissal. Pet. App. 60a. The Davidsons then appealed.

4. On appeal, a divided Ninth Circuit panel reversed as to the Sherman Law and unjust enrichment claims, but unanimously affirmed as to the fraud-based claims. In an opinion by Judge Schroeder, joined by Judge Desai, the panel majority held that the Davidsons' Sherman Law claim was not expressly preempted because by incorporating the federal regulations, the Sherman Law's state labeling requirements are identical to their federal counterparts and permitted under the NLEA. Pet. App. 16a – 20a. And, because the Sherman Law seeks to enforce only "parallel state requirements," this claim is not impliedly preempted by the FDCA's ban on private enforcement. *Id*.

In reversing dismissal, the panel majority stated that "plaintiffs are claiming violations of California law, the Sherman Law, not the federal FDCA." Pet. App. 13a. The panel majority recognized that § 337 bans private enforcement of the federal law, but reasoned that "[b]ecause the FDCA places no limitations on enforcement of these state parallels, plaintiffs' Sherman Law claim is not preempted." Pet. App 16a. The panel majority further stated that its conclusion was supported by the NLEA's express preemption provision, which allows only state "requirements" that are "identical" to the federal ones. According to the panel majority, there was "no reason" "why Congress would permit states to enact particular legislation and then deny enforcement by their citizens." Pet. App. 13a. In fact—even though the FDCA itself imposes substantive requirements without permitting private enforcement—the panel majority

found that if the FDCA were read to allow states to impose parallel substantive requirements but not allow private enforcement, that would be a "strange result" and "spectacularly odd." Pet. App. 13a, 16a. Finally, the panel majority reasoned that "the longstanding presumption against preemption" of "the historic police powers of the States" applies even if there were some doubts whether § 337 permitted private enforcement of state laws. Pet. App. 19a.

Turning to the fraud-based claims, the panel unanimously affirmed the district court's holding that the Davidsons failed to meet Rule 9's heightened pleading standard as to why the alleged misstatements were false. Pet. App. 20a, 22a. Because the remaining Sherman Law claim provides an underlying basis for relief, the panel majority reversed the unjust enrichment claim's dismissal. Pet. App. 22a.

Judge Collins dissented from the panel majority's revival of the Davidsons' Sherman Law claim, concluding that it was impliedly preempted by the FDCA's private enforcement prohibition. According to him, the "central legal question . . . is how to determine when private enforcement of a *non-expressly-preempted* state law that draws on the FDCA's provision is nonetheless *impliedly* preempted on the ground that it amounts to impermissible indirect private enforcement of the FDCA itself." Pet. App. 29a. According to Judge Collins, the line is simple: "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." *Id*. Because the Davidsons' Sherman Law claim falls in the latter category, Judge Collins would find it preempted. *Id*.

Subsequently, Sprout's timely petition for rehearing or rehearing en banc was denied. Pet. App. 49a – 50a. Judge Collins again noted his dissent. *Id.*

REASONS FOR GRANTING THE PETITION

The Ninth Circuit—a hotbed for food marketing litigation—has now declared that private citizens are free to enforce FDCA food labeling regulations, so long as a state has declared those regulations to be incorporated into state law. As Judge Collins expressed in his dissent, "[a]ccording to the majority, it does not matter that § 110100 parasitically incorporates the FDCA's food labeling requirements *in toto*, so that the resulting state law has an entirely 'federal origin and content.'" Pet. App. 41a. The decision below boldly states that such provisions are merely parallel state requirements. This Court need look no further than § 110100(a)'s modus operandi to see that any Sherman Law food labeling claim is entirely of federal origin and content. If FDA rescinded 21 C.F.R. § 101.13(b)(3) (or the underlying § 343(q), (r) were repealed), the Davidsons' Sherman Law claim would cease to exist because these provisions would no longer be California's food labeling requirements. Yet despite the FDCA's prohibition on private enforcement of its provisions, the Ninth Circuit has authorized such claims through a parasitic state statute.

The consequences of this decision are staggering for both food manufacturers and consumers. The Ninth Circuit's decision opens the door for private citizens to potentially enforce any FDCA provision that has been

incorporated as a "state law requirement," completely eviscerating the FDCA's prohibition on private enforcement. Neither the FDCA nor the other circuit courts addressing this issue have permitted the same result. This Court should grant review to correct the flawed decision below.

I. The Decision Below Creates a Conflict Among the Courts of Appeals.

In holding that the Davidsons' Sherman Law claim does not amount to an impermissible attempt to enforce the FDCA, the Ninth Circuit diverges from not only this Court's precedent (as explained in section II, *infra*), but also conflicts with precedent set amongst other federal circuits.

1. *Davidson* directly conflicts with a recent First Circuit decision concerning state statutory claims premised on a dietary supplement allegedly violating FDCA's food labeling requirements. *DiCroce v. McNeil Nutritionals, LLC*, 82 F.4th 35 (1st Cir. 2023), cert. denied, No. 23-919, 144 S. Ct. 1382 (2024). In *DiCroce*, the First Circuit addressed allegations that Lactaid's labels violated Massachusetts state law barring unfair or deceptive trade practices, Mass. Gen. Laws ch. 93A (the Massachusetts Consumer Protection Act), and false advertising, Mass. Gen. Laws ch. 266, § 910. *Id*. at 38 n.2. DiCroce claimed that the Lactaid labels contained impermissible statements purporting to treat the "disease of lactose intolerance," which is prohibited under FDA labeling regulations, and instead rendered the supplement a drug sold without FDA approval. *Id.* at 38. Notably, DiCroce's claims were premised on federal food labeling requirements incorporated into Massachusetts state law, including 21 C.F.R. § 101 (food labeling); and 101.14 (health claims on food/supplement labeling). Plaintiff's First

Amended Class Action Complaint and Demand for Trial by Jury at 2, 4-6, 8, *DiCroce v. McNeil Nutritionals, LLC,* No. 21-11660-PBS (D. Mass May 6, 2022), ECF No. 45; *see also* 105 C.M.R. 500.004(B)(5) (incorporating various FDA regulations including 21 C.F.R. § 101 *et seq.*). Additionally, DiCroce also alleged violations of 21 U.S.C §§ 343(r)(6) (dietary supplement labeling) and 331 (prohibited acts) to further support her claims of deceptive trade practices and false advertising. Plaintiff's First Amended Class Action Complaint and Demand for Trial by Jury, *supra*, at 2, 4.

On appeal, the First Circuit held that § 337 preempted DiCroce's state law claims, because they "hinge[d] on her assumption that Lactaid's labels violate the FDCA's food labeling requirements and are therefore misleading to consumers" under Massachusetts state law. *DiCroce*, 82 F.4th at 40. Lacking any independent basis for why the labels were misleading under Massachusetts deceptive trade practices or false advertising laws, DiCroce's state statutory claims were preempted because they were entirely premised on Lactaid allegedly violating FDCA food labeling requirements. The First Circuit was clear in its decision: "Congress tasked the FDA with addressing said violations when it enacted § 337(a), not private citizens." *Id*. at 42.

In all relevant aspects, the facts of *DiCroce* are nearly identical to those here. First, both dietary supplements and food are governed by the same federal statute for misbranded food, 21 U.S.C. § 343. In 1994, the Dietary Supplement Health and Education Act ("DSHEA") amended the FDCA adding a statutory definition for dietary supplements—and deemed them "to be a food" under the FDCA. DSHEA § 3, Pub. L. 103-417, 108 Stat. 4325, 4327 (1994) (codified at 21

U.S.C. § 321(ff)). It also authorized FDA to issue dietary supplement-specific labeling regulations. S*ee* DSHEA § 7(b), 108 Stat. at 4330 (codified at 21 U.S.C. § 343(q)(5)(F)). Both *DiCroce* and the decision below concerned the FDCA's provision for misbranded foods and related regulations. *DiCroce*, 82 F.4th at 38 (§ 343(r)(6) and 21 C.F.R. § 101.14); Pet. App. at 23a – 24a (§ 343(r) and (q) and 21 C.F.R. § 101.13). Further, both cases concerned state deceptive trade practice claims based on FDCA food labeling violations under § 343 and provisions of 21 C.F.R. § 101 as incorporated into state law. But, in contrast to the First Circuit, the decision below reached the opposite conclusion, holding that § 337 does not prohibit state statutory claims premised on violations of FDCA food labeling laws incorporated into state law. The comparison between the two cases is stark, and each circuit's outcome on the issue of federal preemption regarding food labeling requirements incorporated into state statutes is irreconcilable. The matter can only be clarified by this Court.

2. Two additional circuits have also held that private citizens may not bring claims under state consumer protection laws predicated on violations of the FDCA and associated regulations for drug or dietary supplement food labeling.

In *Loreto v. Procter & Gamble Co.*, the plaintiffs alleged that Procter & Gamble violated a New Jersey consumer protection law by selling a cold medicine that was "illegal" because the label did not comply with FDCA requirements. 515 F. App'x 576, 579 (6th Cir. 2013). The Sixth Circuit held that the claim was prohibited under § 337 and *Buckman* because plaintiff's theory of liability was entirely dependent upon the subject label's failure to comply

with the FDCA labeling requirements and lacked any other independent basis (such as the drugs' failure to perform as promoted) for the claim. *Id.*

Likewise, in *PDK Labs, Inc. v. Friedlander*, the plaintiff alleged that a weight loss dietary supplement violated Georgia law for deceptive trade practices because the supplement was sold without FDA approval. The Second Circuit held that the claim was prohibited by § 337. 103 F.3d 1105, 1113 (2d Cir. 1997). The plaintiff claimed that the weight loss supplements violated the Georgia Uniform Deceptive Trade Practices Act and False Advertising Law because either the supplements amounted to a "new drug" for which FDA approval was required, or the supplements' labels violated FDCA regulations by making disease claims. *Id.* at 1112 n.6. The Second Circuit affirmed the dismissal, noting that the "true goal [was] to privately enforce alleged violations of the FDCA. However, no such private right of action exists." *Id.* at 1113.

These prior appellate rulings reveal the disparity that the Ninth Circuit's holding in this matter creates with regard to the other federal circuit court's interpretation and application of § 337's prohibition on private enforcement of state statutes applying federal labeling requirements. Further review by this Court is thus warranted.

II. The Decision Below is Incorrect.

1. The Ninth Circuit incorrectly applied *Buckman* and conflated the scope of the FDCA's express preemption with the scope of its implied preemption. Pet. App. 15a – 16a. (holding that because the Sherman Law is "permitted by § 343-1 . . . plaintiffs' claims are not preempted."). As Judge Collins explained, "[a]ccording 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 state law." Pet. App. 42a. But this holding is contrary to *Buckman*, which found the plaintiff's claims impliedly preempted without regard as to whether the FDCA expressly preempted the alleged state-law duty on which the claims rested. *See* 531 U.S. at 348 n.2 ("In light of this conclusion [implied preemption], we express no view on whether these claims are subject to express pre-emption."). By declining to determine whether the *Buckman* plaintiff's claims were expressly preempted under 21 U.S.C. § 360k, this Court effectively held that the scope of express preemption under that statute and implied preemption for § 337 is not identical. Therefore, the fact the FDCA does not expressly preempt a private state law cause of action is not preclusive of a finding that the claim is impliedly preempted under § 337's private enforcement ban. In other words, it is not enough that the Davidsons' Sherman Law claim is not expressly preempted under § 343-1 and thus "permitted." *Buckman* requires a determination on whether the Davidsons' attempt to privately enforce a state law that incorporates FDCA regulations amounts to implied conflict preemption. The Ninth Circuit sidestepped this entire analysis.

2. The dispositive reliance the Ninth Circuit placed on § 343-1's express preemption provision is belied by and directly contrary to NLEA's statutory construction rules. While NLEA's § 6(a) added 21 U.S.C. § 343-1 to the FDCA, § 6(c) outlined statutory construction rules for this express preemption provision. NLEA, Pub. L. No. 101-535, 104 Stat. 2353, 2362 (1990). Section 6(c)(1) states that the NLEA—and thus § 343-1—"shall not be construed to preempt any provision of State law, unless

such provision is expressly preempted under [§ 343-1] . . . ." *Id.* § 6(c)(1), 104 Stat. at 2364. However, the NLEA § 6(c)(3) provides 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 . . . any provision of [the FDCA] not amended by subsection (a)." *Id.* § 6(c)(3), 104 Stat. at 2364 (emphasis added). Section 6(a) did not amend 21 U.S.C. § 337. *See* 104 Stat. at 2362-63. Accordingly, § 6(c)(3) explicitly precludes § 343-1's express preemption provision from nullifying § 337's implied preemptive effect. The Ninth Circuit's reasoning is at odds with this statutory construction requirement.

3. The Ninth Circuit's rhetorical question—why would Congress "want states to enact laws that its citizens cannot enforce?"—is not only flawed but also ignores the simple statutory answer. Initially, the Ninth Circuit cited no authority to support its assertion that state laws must have a private right of action (as explained below, the Sherman Law does not). Further, the Ninth Circuit failed to accept the answer the statutory language provides. The FDCA authorizes states to pass "identical" state laws to be enforced by the appropriate state authorities. The NLEA amended § 337 by adding subsection (b), which provides an enforcement provision for the state qua state regarding food labeling. *See* Pub. L. 101-535, 104 Stat. 2362, § 4 (amending 21 U.S.C. § 337 by adding the current language of subsection b). Noticeably absent from this amendment is a private enforcement provision for these same labeling requirements. Section 337(b) allows a state to bring an action to enforce food labeling requirements under § 341 and several subsections of § 343 if the state first petitions or gives notice to the Secretary of Health and Human Services ("HHS"). 21 U.S.C. § 337(b)(2); § 321(d) (defining "Secretary" as

"the Secretary of Health and Human Services"). If Congress wanted both states and their residents to enforce these food labeling provisions through either a state agency or private action, it could have easily and clearly done so when enacting the NLEA. Rather, it carved out only a state's right to enforce a few of the FDCA food labeling statutes as a state. The NLEA's failure to enlarge enforcement beyond that demonstrates Congress's intent to maintain § 337(a)'s private enforcement prohibition. The Ninth Circuit bypassed this intent and held that a single sentence in the Sherman Law that automatically incorporates all of the FDCA as state law was enough to add the private enforcement remedy that Congress deliberately withheld when amending § 337 with the NLEA.

Further undermining the rhetorical question, the Sherman Law appears to be what the Ninth Circuit mused as a "strange result" and "spectacularly odd" because it rests enforcement almost exclusively with the State of California.[2] The Sherman Law states that "[t]he [California Department of Public Health] shall administer and enforce this part," Cal. Health & Safety Code § 110045, and provides enforcement remedies unique to public agency enforcement, i.e.,

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[2] The Sherman Law contains a single exception to the rule that private causes of action are prohibited—organic food products. Section 111910 specifies "any person may bring an action in the superior court" for an injunction to enforce violations of the Sherman Law as it relates to organic products. *See* Cal. Health & Safety Code § 111910. If private causes of action were generally permissible under the Sherman Law, there would be no reason to specifically enumerate an exception to a non-existent rule. *See Andrus v. Glover Const. Co.*, 446 U.S. 608, 616-17 (1980) ("Where Congress explicitly enumerates certain exceptions to a general prohibition, additional exceptions are not to be implied, in the absence of evidence of a contrary legislative intent.").

providing written notice or warnings of minor violations, reporting violations to prosecuting officers, and inspecting establishments in which food, drugs, devices, or cosmetics are manufactured, packed, or held. *See* Cal. Health & Safety Code §§ 111840, 111845, and 110140. It is entirely logical for a state to limit who can enforce state statutes, especially one mirroring (and specifically here, automatically incorporating *in toto*) federal law.

4. The Ninth Circuit's reliance on the presumption against preemption was misplaced and ignored the realities of the FDCA. This presumption is not a dispositive bar, as this Court in *Buckman* and *Riegel v. Medtronic, Inc.,* found state law claims preempted in an area traditionally left to the states. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001); *Riegel*, 552 U.S. 312, 330 (2008). Moreover, in furthering the FDCA's broad, national regulatory authority over drugs, medical devices, food, tobacco products and cosmetics, Congress has from time to time "swept back some state obligations and imposed a regime of detailed federal oversight." *Riegel*, 552 U.S. at 315-16 (explaining how the Medical Device Amendments of 1976 provided FDA with extensive oversight over medical devices that until then "was left largely for the States to supervise as they saw fit."). In 1990, Congress "swept back" and "imposed" a federal regime by enacting the NLEA and giving FDA enhanced control over national food labeling. The Ninth Circuit's recitation of the presumption ignored the reality that the products the FDCA now regulates were historically subject to the states' police powers. Finally, in the case of food labeling, the NLEA and this Court's caselaw have adequately preserved these powers through state agency action under § 337(b) or private causes of action that rest on state tort law with

independent substantive content that parallels federal law to the extent such powers require preservation. Pet. App. 46a – 47a; *see also Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996) (finding Lohr's state-law negligent manufacturing and failure-to-warn claims rested on "violations of common-law duties" that "parallel federal requirements," and thus were not preempted).

5. The Ninth Circuit wrongly decided that while § 343-1 does not expressly preempt the Sherman Law, the Davidsons' claim was not barred by § 337's ban on private causes of action. The Sherman Law wholly incorporates the FDCA's labeling requirements and in substance seeks to enforce those requirements. As demonstrated by their First Amended Complaint, the Davidsons' claim relies on the incorporation of 21 U.S.C. § 343(a) into the Sherman Law, FDA regulations for nutrient content claims, 21 C.F.R. § 101.13(b)-(c), the FDCA's definition of the term misleading, FDA regulatory decisions, 56 Fed. Reg. 60421, 60426 (Nov. 27, 1991); 58 Fed. Reg. 33731, 33733 (June 18, 1993); 58 Fed. Reg. 2302, 2305, 2206, 2201 (Jan. 6, 1993); 60 Fed. Reg. 67184, 67191 (Dec. 28, 1995), and FDA regulation for nutrition labeling of food, 21 C.F.R. § 101.9(c)(8)(4). Pet. App. 87a – 93a at ¶¶ 21, 22, 23, 27, 41, 42, 43, 44, 45, 46. Accordingly, the Davidsons' Sherman Law claim "exist[s] solely by virtue" of the FDCA "requirements" and "originate[s] from, [is] governed by, and terminate[s] according to federal law." *Buckman*, 531 U.S. at 347, 353. This Court should grant the petition and reverse the Ninth Circuit's decision to shield the Davidsons' Sherman Law claim based wholly on federal food labeling requirements from § 337's private enforcement prohibition.

III. Question Presented is Recurring, Important, and Squarely Presented.

1. The question presented in this case is exceptionally important. Litigation against food and drink manufacturers has proliferated, with class action lawsuits increasing more than a thousand percent since 2008. *See* Sarah McCammon, *Meet the Lawyer Who Is Driving the Lawsuits Against Food and Beverage Companies,* NPR (Nov. 12, 2021), https://www.npr.org/2021/11/12/1055030251/meet-the-lawyer-who-is-driving-the-lawsuits-against-food-and-beverage-companies [https://perma.cc/R6SP-BQ7F]. Historically, California accounted for the majority of food marketing litigation, with the Northern District of California earning the moniker of the "Food Court." U.S. Chamber Institute for Legal Reform, The New Lawsuit Ecosystem, pg. 92 (Oct. 2013), https://instituteforlegalreform.com/wp-content/uploads/media/The_New_Lawsuit_Ecosystem_pages_web.pdf [https://perma.cc/2MHL-V3BT] (citing Paul M. Barrett, *California's Food Court: Where Lawyers Never Go Hungry*, *Bloomberg* Businessweek, Aug. 22, 2013)). However, in recent years, this trend has spread across the country, with other jurisdictions, such as New York, the District of Columbia, Illinois, and Missouri emerging as food marketing litigation hotbeds. *See,* U.S. Chamber Institute for Legal Reform, The Food Court: Developments in Litigation Targeting Food and Beverage Marketing, U.S. Chamber Institute for Legal Reform, pg. 3 (Aug. 2021), https://instituteforlegalreform.com/wp-content/uploads/2021/07/Food-Litigation-Update_web.pdf [https://perma.cc/5FXF-46L5] ("At the current pace, the number of food class action lawsuits filed in New York alone in 2021 is likely to approach or exceed the total filed across the entire country just a few years ago."). In August 2021, there were more class actions alleging deceptive business

practices targeting food and beverage labeling than all other products and services combined in New York. *Id.*

The Ninth Circuit's "direct reversal of Congress's intent that the food-labeling provisions 'be enforced exclusively by the Federal Government' and state authorities" will ultimately undermine food nutrition labeling and unduly burden food manufacturers with inconsistent labeling regulations across jurisdictions. Pet. App. 45a (citing *Buckman*, 531 U.S. at 352). Permitting private litigants to pick apart these labels through piecemeal litigation will create inconsistencies frustrating the NLEA's purpose of a national uniform labeling regime. And, at the manufacturing level, the Ninth Circuit's decision will force manufacturers to return to a time pre-NLEA, when products required different labels based on the jurisdiction in which they were sold. Permitting such litigation could have a chilling effect on manufacturers' ability to label food effectively and could disproportionally affect small, independently owned businesses that lack the resources of larger corporations.

In the circuits following the majority approach, the Davidsons' claim would have been preempted. Sprout and other food manufacturers should not be subject to the enforcement of the FDCA through private action. This Court should address whether a plaintiff may seek to privately enforce FDA food labeling regulations through state statutory claims that are based entirely on these incorporated federal requirements. The time is ripe for the Court to resolve this important question. Given that the decision below splits with the majority of circuits to address the question presented, this Court's prompt intervention is warranted to ensure that outcomes in food-marketing litigation do not depend on where a plaintiff is able to file suit.

2. By permitting private parties to enforce FDCA regulations, the Ninth Circuit's decision threatens to undermine FDA's authority, leading to a patchwork of private causes of actions that interfere with the uniformity and consistency the federal food labeling laws seek to achieve. Upholding FDA as the principal authority for FDCA enforcement ensures that the agency's expertise informs and directs complex factual and legal determinations, such as identifying applicable requirements and assessing FDCA violations. This centralization also guarantees that discretionary decisions—such as whether to pursue enforcement actions, and if so, which remedies are appropriate—are made by policymakers rather than private litigants, thereby promoting uniformity and consistency. In contrast, private enforcement remedies in these cases are typically limited to the crude cudgel of compensatory damages. Congress deliberately centralized the decision-making authority within FDA, and preserving this implied preemption framework will maximize the effectiveness of FDCA enforcement.

Congress's express direction that the federal government be the exclusive enforcer of food nutrition labeling and thus provide a uniform and consistent approach is evident in 21 U.S.C. § 337(b). While permitting a state to "bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of [certain provisions of the NLEA]," § 337(b) provides a specific procedural mechanism for such actions guaranteeing federal oversight. A state cannot initiate an action to enforce certain nutrition labeling requirements without first notifying the Secretary of HHS of its intent to do so. 21 U.S.C. § 337(b)(2). And, if after receiving such notice, the federal government chooses to commence "an informal or formal enforcement action pertaining to the food

which would be the subject of such proceeding," the State must wait ninety days before initiating its own enforcement action. *Id.* at § 337(b)(2)(B). The purpose of these procedural mechanisms is to maintain federal control over the FDCA enforcement while allowing for state involvement under specific conditions. The provision ensures that state enforcement actions are aligned with the priorities of HHS and by delegation FDA and that there is no duplication or conflict in enforcement efforts. It helps prevent states from independently taking actions that could interfere with the comprehensive federal regulatory framework. Permitting private enforcement negates the purpose of § 337(b) and invites various interpretations and applications of the FDCA and associated regulations, which undercuts the purpose of the NLEA.

3. The Ninth Circuit's decision impermissibly opens courts to private enforcement of federal laws under the guise of state statutes where Congress has prohibited such enforcement. At a minimum, consumers can now evade Congress's direction that only the federal government (and, in specific situations, a state) can enforce FDCA's food labeling requirements. However, the Ninth Circuit has now provided states a road map to bestow a private right of action on its citizens (or any individual who seeks to file suit in that state) for other provisions of the FDCA by endorsing California's statutory scheme related to food labeling. With just a single sentence, a state can adopt all sections of the FDCA, and these state statutes are potentially neither expressly nor impliedly preempted. Several sections of the FDCA contain similar express preemption language like the NLEA. Per this decision, implied preemption would cease to exist within this statutory framework, which simply cannot be the correct result.

4. This case presents a clean vehicle to review the question presented. This case is disparate from other cases concerning the use of state statutes, primarily consumer protection laws, to enforce FDCA regulations. Here, the rationale for the Davidsons' claim is that because the Sherman Law wholesale incorporates the FDCA food labeling regulations, the Davidsons are not seeking to enforce the FDCA itself, but instead, California law. This case places the application of § 337(a) squarely at issue in the context of a state statute incorporating and transforming federal law into state law for enforcement purposes. Indeed, it was this exact issue on which the Ninth Circuit reversed the District Court's order dismissing the Davidsons' amended complaint, finding that § 337(a) "implicates only enforcement of the federal law, not enforcement of identical state requirements." Pet. App. 16a. And, with the dismissal of the Davidsons' fraud claims affirmed by the Ninth Circuit, the Court's input on the application of § 337 has the potential to be case dispositive for Sprout.

Absent this Court's review, the Ninth Circuit's outlier decision in this case will lead to inconsistent application of the FDCA, further open the floodgates for private citizens to use the Ninth Circuit to litigate FDCA violations, and potentially invite a similar workaround for other federal statutes which prohibit private rights of action. The Court should grant the petition to resolve the disagreement among the circuit courts and to correct the Ninth Circuit's erroneous decision.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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January 8, 2025

APPENDIX

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APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 22-16656
D.C. No. 3:22-cv-01050-RS

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.

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

OPINION

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 federal law.

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

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

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[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."

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).

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, pre-

empts 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 differ-

ent 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-WQHJMA, 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 long-standing 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 "consump-

tion 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.

[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/COMPS973.pdf.

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 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

[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.

(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 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

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[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."

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. § 3431(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 preempted," 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 preemption 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*. 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 enact-

ments 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 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

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

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 Fed-

eral 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 pre-emption 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-enforcementonly 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 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.

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

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 pre-

sumption 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] 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.

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[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.

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.

APPENDIX B

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

[Filed Sept. 10, 2024]

No. 22-16656

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.

D.C. No. 3:22-cv-01050-RS
Northern District of California, San Francisco

ORDER

Before: SCHROEDER, COLLINS, and DESAI, Circuit Judges.

Judges Schroeder and Desai have voted to deny the petition for rehearing, and Judge Collins has voted to grant it. Judge Desai has voted to deny the petition for rehearing en banc, Judge Schroeder has so recommended, and Judge Collins has voted to grant the petition for rehearing en banc.

The full court has been advised of the petition for rehearing en banc and no judge has requested a vote

on whether to rehear the matter en banc. Fed. R. App. P. 35.

The petition for panel rehearing and rehearing en banc, Docket No. 48, are **DENIED.**

APPENDIX C

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

Case No. 22-cv-01050-RS

GILLIAN DAVIDSON, ET AL.,

Plaintiffs,

v.

SPROUT FOODS INC.,

Defendant.

ORDER GRANTING MOTION TO DISMISS

I. INTRODUCTION

Plaintiffs Gillian and Samuel Davidson bring this putative class action against Defendant Sprout Foods Inc. ("Sprout"), which sells baby and toddler food products. The First Amended Complaint ("FAC") avers violations of California law based on statements made on various Sprout products that tout the nutrients included in them, such as "3g of Protein" or "4g of Fiber." Defendant moves under Rule 12(b)(6) to dismiss the FAC in its entirety.

For the reasons stated below, the motion is granted. Plaintiffs have still not plausibly claimed that Defendant's labeling is misleading, and thus their claims under the California False Advertising Act ("FAL"), the California Consumer Legal Remedies Act ("CLRA"), common law fraud, and the "fraudulent" prong of the California Unfair Competition Law ("UCL") are dismissed, though with leave

to amend. Further, Plaintiffs' claim under the "unlawful" prong of the UCL is preempted by federal law and must be dismissed. Without any other viable claims, Plaintiffs' unjust enrichment claim must also be dismissed.

II. BACKGROUND[1]

Sprout sells branded baby and toddler food products, including (but not limited to) pouches of puréed baby food. Plaintiffs purchased three types of these pouches for their child: "Pumpkin, Apple, Red Lentil, and Cinnamon; Strawberry with Banana & Butternut Squash; and Sweet Potato, White Beans, and Cinnamon." Dkt. 29 ("FAC") ¶¶ 11, 69, 75; *see id*. Exs. B, C.[2] These pouches, along with a number of other Sprout products addressed in the FAC (collectively, "the Products"), contained statements about nutrition content in the front panel of the packaging, such as "3g of Protein, 4g of Fiber and 300mg Omega-3 from Chia ALA." *Id*. ¶ 18. This same information – along with additional nutrition information – was also included in the Nutrition Facts Panel on the back of the packaging. Plaintiffs argue that these statements constitute "nutrient content claims" and thus violate Food and Drug Administration ("FDA") regulations that prohibit manufacturers from including such claims on "food intended specifically for use by infants and children less than 2 years

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[1] Unless noted otherwise, all facts recited are from the FAC and must be taken as true for the purposes of a Rule 12(b)(6) motion to dismiss. *See Knievel v. ESPN*, 393 F.3d 1068, 1072 (9th Cir. 2005).

[2] The FAC states that Plaintiffs purchased all three types of pouches, but their declarations do not state that either purchased the Strawberry with Banana & Butternut Squash pouch. *See* FAC, Exs. B, C.

of age." 21 C.F.R. § 101.13(b)(3). They further allege that these statements "deceive and mislead reasonable consumers into believing that the Products provide physical health benefits for their child when in fact, the Products are harmful for children under two both nutritionally and developmentally." FAC ¶ 20.

Defendant moved to dismiss Plaintiffs' original Complaint, and that motion was granted with respect to the fraud-based claims and otherwise denied. *See* Dkt. 23. Plaintiffs filed an amended complaint that presents five claims for relief: (1) violation of the CLRA; (2) violation of the FAL; (3) common law fraud; (4) violation of the "unlawful" and "fraudulent" prongs of the UCL; and (5) unjust enrichment. Defendant now moves to dismiss the FAC in its entirety.

III. LEGAL STANDARD

A. Rule 12(b)(6) Standard

Federal Rule of Civil Procedure 12(b)(6) governs motions to dismiss for failure to state a claim. A complaint must contain a short and plain statement of the claim showing the pleader is entitled to relief. Fed. R. Civ. P. 8(a). While "detailed factual allegations" are not required, a complaint must have sufficient factual allegations to "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic v. Twombly*, 550 U.S. 544, 570 (2007)). However, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id*. Dismissal under Rule 12(b)(6) may be based on either the "lack of a cognizable legal theory" or on "the absence of sufficient facts alleged" under a

cognizable legal theory. *UMG Recordings, Inc. v. Shelter Capital Partners LLC*, 718 F.3d 1006, 1014 (9th Cir. 2013) (internal quotation marks and citation omitted). When evaluating such a motion, courts "accept all factual allegations in the complaint as true and construe the pleadings in the light most favorable to the nonmoving party." *Knievel v. ESPN*, 393 F.3d 1068, 1072 (9th Cir. 2005).

When a claim is "grounded in fraud," the pleading as a whole "must satisfy the particularity requirement of Rule 9(b)." *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1125 (9th Cir. 2009). "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). "Averments of fraud must be accompanied by 'the who, what, when, where, and how' of the misconduct charged." *Kearns*, 567 F.3d at 1124 (quoting *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097 (9th Cir. 2003)).

B. California Statutes

Plaintiffs aver violations of the UCL, FAL, and CLRA. The UCL "bars 'unfair competition' and defines the term as a 'business act or practice' that is (1) 'fraudulent,' (2) 'unlawful,' or (3) 'unfair.'" *Shaeffer v. Califia Farms, LLC*, 44 Cal. App. 5th 1125, 1135 (2020). "Each is its own independent ground for liability under the unfair competition law, but their unifying and underlying purpose is to protect both consumers and competitors by promoting fair competition in commercial markets for goods and services." *Id.* (internal quotation marks and citations omitted).

The FAL "bars 'any advertising device . . . which is untrue or misleading.'" *Id.* (quoting Cal. Bus. & Prof.

Code § 17500). "[T]his law and the fraudulent prong of the unfair competition law substantively overlap," and thus "plaintiff's burden under these provisions is the same." *Id.* at 1136. "[T]o state a claim under either the UCL or the [FAL], based on false advertising or promotional practices, it is necessary only to show that members of the public are likely to be deceived." *Kasky v. Nike, Inc.*, 27 Cal. 4th 939, 951 (2002) (internal quotation marks omitted).

The CLRA defines various "unfair methods of competition and unfair or deceptive acts or practices." Cal. Civ. Code § 1770. Some of these unfair methods or acts include representing that goods have characteristics or benefits they do not have, and representing that goods are "of a particular standard, quality, or grade" when they actually are not. *Id.* The UCL, FAL, and CLRA, along with common law fraud, all utilize the reasonable consumer standard, "which requires a plaintiff to show potential deception of consumers acting reasonably in the circumstances – not just any consumers." *Hill v. Roll Int'l Corp.*, 195 Cal. App. 4th 1295, 1304 (2011); *see Ham v. Hain Celestial Group, Inc.*, 70 F. Supp. 3d 1188, 1193 (N.D. Cal. 2014).

IV. DISCUSSION

A. Fraud Claims

In their original Complaint, Plaintiffs argued that Defendant had "misle[d] reasonable consumers into believing that the Products will provide more benefits than its competitors and induce[d] parents to purchase the Products despite a lack of evidence that an increased intake for the nutrients advertised are appropriate or recommended for [children]." Complaint, Dkt. 1 ¶ 13. Their fraud claims (also brought

under the FAL, CLRA, UCL "fraudulent" prong, and common law fraud) were dismissed because "no reasonable consumer would be misled by the inclusion of truthful statements about nutrient contents on the front of the challenged labels." Dkt. 23, at 8.

Plaintiffs' new argument, as presented in the FAC, is still too mushy. They claim to make two showings: first, that the labels communicate a message that the Products provide physical health benefits for children; and second, that the Products are "harmful both nutritionally and developmentally." FAC ¶ 20. As to the first showing, Plaintiffs do not argue that the Products explicitly claim to provide physical health benefits, either by using words like "healthy," *see Hadley v. Kellogg Sales Co.*, 273 F. Supp. 3d 1052, 1094 (N.D. Cal. 2017), or more general phrases tying the nutrients to a healthy lifestyle, *see Coe v. General Mills, Inc.*, 2016 WL 4208287, at *1 (N.D. Cal. 2016) (label on cereal box claimed to provide "a great start to your day"). Plaintiffs thus argue that the labels implicitly tout the Products' health benefits. This theory has at least some limited support. *See Marek v. Molson Coors Beverage Co.*, 580 F. Supp. 3d 848, 853, 861–62 (N.D. Cal. 2022) (plaintiffs adequately pleaded that hard seltzer with label touting it contained "antioxidant Vitamin C" could mislead reasonable consumers into believing product was "healthy or healthier than other hard seltzers"); *Howard v. Hain Celestial Group, Inc.*, No. 22-cv-00527-VC (N.D. Cal. Oct. 19, 2022). For the purposes of surviving a motion to dismiss, Plaintiffs plausibly aver the Products' nutrient content claims imply they provide physical health benefits.

The second required showing, however, is harder to swallow. Plaintiffs suggest that the Products are

harmful for children because they contain "high amounts of free sugars," FAC ¶ 50,[3] but they do not place this averment in context by describing at what point "high" sugar content crosses into harmful levels (or even why, in particular, these sugar levels are harmful). *Cf. Krommenhock v. Post Foods, LLC*, 255 F. Supp. 3d 938, 945 (N.D. Cal. 2017) (noting plaintiffs cited studies tying excess sugar intake to numerous adverse health conditions). Plaintiffs also argue that pouch-based foods may be unhealthy for developing children, *id.* ¶¶ 49–58, but they rely for support on speculative research conclusions and hypothetical scenarios to argue these products are harmful – for instance, that pouches "*may* lead to long term health risks," *id.* ¶ 51 (emphasis added), or may be harmful *if* overly relied on by parents, *see id.* ¶ 55–57, or "*can* be a gateway to bad long-term snacking habits and routine overeating," *id.* ¶ 58 (emphasis added) (quotation marks omitted).[4] It is unclear from these averments why the Products are *per se* harmful, rather than harmful only after a series of contingencies outside the scope of this case. Finally, Plaintiffs do little to explain why, even if these averred harms exist, they outweigh any potential benefits of the Products – such as protein or fiber intake – such that the Products no longer provide any physical health benefits. *Cf. Williams v. Gerber Prods. Co.*, 552 F.3d 934, 939 n.3

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[3] As the FAC describes, puréeing food creates "free sugars" by breaking down the cell walls within fruits and vegetables, thus "liberating" the "intrinsic sugar" in those foods. FAC ¶ 49.

[4] Defendant also notes that some of the Products do not contain "free sugars," are not pouches, or both. *See* Dkt. 38, at 5–6.

("[N]utritiousness can be difficult to measure concretely.").

The California Court of Appeal has cautioned against permitting food labeling claims that rely on inferential leaps and which could ultimately "place almost any advertisement truthfully touting a product's attributes at issue for litigation." Dkt. 23, at 9 (citing *Califia*, 44 Cal. App. 5th at 1139). Rule 9(b)'s heightened pleading standard, noted above, further requires plaintiffs to explain adequately why challenged statements are misleading. *See, e.g.*, *Clorox Co. v. Reckitt Benckiser Group PLC*, 398 F. Supp. 3d 623, 636 (N.D. Cal. 2019). These background principles, as well as a review of the face of the FAC, all lead to the conclusion that Plaintiffs have not provided enough to state plausibly that the Product labels are misleading. Therefore, the FAL claim, CLRA claim, UCL "fraudulent" prong claim, and common law fraud claim are dismissed, with leave to amend.

B. Preemption of UCL "Unlawful" Prong Claim

Defendant argues that Plaintiffs' claim under the "unlawful" prong of the UCL is preempted by federal law and must therefore be dismissed. Plaintiffs counter that this argument is both procedurally erroneous and substantively incorrect. On the former point, they point out that Federal Rule of Civil Procedure 12(g)(2) prohibits parties from raising, in a second Rule 12(b) motion, an argument that could have been raised in the first motion. Because preemption could have been raised in Defendant's first motion to dismiss, Plaintiffs argue that Defendant has waived its right to raise preemption now.

Plaintiffs are technically correct. Ninth Circuit courts have interpreted Rule 12(g)(2) to bar successive arguments that could have been raised in an initial motion to dismiss, even where plaintiffs file an amended complaint. *E.g.*, *Gardner v. Starkist Co.*, 2020 WL 1531346, at *3 (N.D. Cal. Mar. 31, 2020) ("Because the allegations are not substantively different in the [second amended complaint], Starkist's argument could have been raised in its first motion to dismiss and its motion violates Rule 12(g)(2)'s ban on successive Rule 12(b) motions."); *see also Fed. Agr. Mortg. Corp. v. It's A Jungle Out There, Inc.*, 2005 WL 3325051, at *5 (N.D. Cal. Dec. 7, 2005) (discussing legal commentary and the practices of other federal circuits). However, "courts faced with a successive motion often exercise their discretion to consider the new arguments in the interests of judicial economy." *Banko v. Apple, Inc.*, 2013 WL 6623913, at *2 (N.D. Cal. Dec. 16, 2013). Here, Defendant notes that it will simply reraise preemption in a Rule 12(c) motion for judgment on the pleadings if it is barred from raising the issue here. The interests of judicial economy weigh in favor of deciding the preemption question now, and therefore Defendant's motion to dismiss the UCL "unlawful" claim should be reached.

Substantively, Defendant argues that Plaintiffs' UCL "unlawful" claim is preempted because it is premised on a violation California's Sherman Food, Drug, and Cosmetic Law ("Sherman Law"), Cal. Health & Safety Code § 110100(a), which "expressly adopted the Federal Food, Drug, and Cosmetic Act ('FDCA') regulations" that Plaintiffs aver have been violated by the Products' labeling. Dkt. 33, at 8. Defendant argues that because a violation of the Sherman Law requires a finding that the FDCA has been violated, and the FDCA, in turn, can be enforced

only by the United States, Plaintiffs' claim is preempted. This is the same argument that was confronted in *Chong v. Kind LLC*, 2022 WL 464149 (N.D. Cal. Feb. 15, 2022), which concluded a plaintiff could not bring suit under the Sherman Law because it "post-dates and is entirely dependent upon the FDCA, in that it expressly adopts the FDCA and regulations as state law." *Id.* at *4. Thus, the claims were impliedly preempted by the FDCA insofar as they "originate[d] from, [were] governed by, and terminate[d] according to federal law." *Id.* (quoting *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1230 (9th Cir. 2013)).

Plaintiffs present valid arguments for why their claim should not be preempted, but they do not explain adequately why *Chong* should not be controlling here. Notwithstanding the contrary conclusions reached by others on this Court, without controlling guidance from the Ninth Circuit or the Supreme Court on the nature of preemption under the FDCA, there is no reason to depart from *Chong*'s earlier holding. The motion is therefore granted as to Plaintiffs' UCL "unlawful" prong claim. Because the defect is one of legal theory, not factual insufficiency, Plaintiffs are not granted leave to amend this claim.

C. Unjust Enrichment

Defendant argues that Plaintiffs' claim for unjust enrichment must fail as a matter of law because there is no underlying basis for recovery. *See* Dkt. 33, at 12. Given that the first four claims have now been dismissed, there is no longer an underlying basis for recovery. Defendant is thus correct, and Plaintiffs' claim for unjust enrichment is dismissed as well, with leave to amend.

V. CONCLUSION

For the foregoing reasons, the motion is granted, and the FAC is dismissed in its entirety. Plaintiffs are granted leave to amend with respect to their UCL "fraudulent" prong claim, FAL claim, CLRA claim, and common law fraud claim, as additional facts could render their claims plausible. Claim 5 is also dismissed with leave to amend. Claim 4 is dismissed without leave to amend. Any amended complaint must be filed within 21 days of the filing of this Order.

IT IS SO ORDERED.

Dated: October 21, 2022

/s/ Richard Seeborg
Richard Seeborg
Chief United States District Judge

APPENDIX D

UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF CALIFORNIA

Case No. 22-cv-01050-RS

GILLIAN DAVIDSON and SAMUEL DAVIDSON,
as individuals, on behalf of themselves,
the general public, and those similarly situated,

Plaintiffs,

v.

SPROUT FOODS, INC.,

Defendant.

JUDGMENT

Pursuant to the October 21, 2022 order granting Defendant Sprout Foods, Inc.'s motion to dismiss, and the December 19, 2022 stipulation of the parties to enter judgment, judgment is hereby entered against plaintiffs and in favor of defendant.

IT IS SO ORDERED.

Dated: 12/19/2022

/s/ Richard Seeborg
Honorable Richard Seeborg

APPENDIX E

Title 21. Food and Drugs (Refs & Annos)
Chapter 9. Federal Food, Drug, and Cosmetic Act
Subchapter III. Prohibited Acts and Penalties

21 U.S.C. § 337. Proceedings in name of United States; provision as to subpoenas

(a) Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

(b)(1) A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 341, 343(b), 343(c), 343(d), 343(e), 343(f), 343(g), 343(h), 343(i), 343(k), 343(q), or 343(r) of this title if the food that is the subject of the proceedings is located in the State.

(2) No proceeding may be commenced by a State under paragraph (1)--

(A) before 30 days after the State has given notice to the Secretary that the State intends to bring such proceeding,

(B) before 90 days after the State has given notice to the Secretary of such intent if the Secretary has, within such 30 days, commenced an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding, or

(C) if the Secretary is diligently prosecuting a proceeding in court pertaining to such food, has settled

such proceeding, or has settled the informal or formal enforcement action pertaining to such food.

In any court proceeding described in subparagraph (C), a State may intervene as a matter of right.

Title 21. Food and Drugs)
Chapter 9. Federal Food, Drug, and Cosmetic Act
Subchapter IV. Food

21 U.S.C. § 343-1. National uniform nutrition labeling

(a) Except as provided in subsection (b), 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--

(1) any requirement for a food which is the subject of a standard of identity established under section 341 of this title that is not identical to such standard of identity or that is not identical to the requirement of section 343(g) of this title, except that this paragraph does not apply to a standard of identity of a State or political subdivision of a State for maple syrup that is of the type required by sections 341 and 343(g) of this title,

(2) any requirement for the labeling of food of the type required by section 343(c), 343(e), 343(i)(2), 343(w), or 343(x) of this title that is not identical to the requirement of such section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 343(c) of this title and that is applicable to maple syrup,

(3) any requirement for the labeling of food of the type required by section 343(b), 343(d), 343(f), 343(h),

343(i)(1), or 343(k) of this title that is not identical to the requirement of such section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 343(h)(1) of this title and that is applicable to maple syrup,

(4) any requirement for nutrition labeling of food that is not identical to the requirement of section 343(q) of this title, except that this paragraph does not apply to food that is offered for sale in a restaurant or similar retail food establishment that is not part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership of the locations) and offering for sale substantially the same menu items unless such restaurant or similar retail food establishment complies with the voluntary provision of nutrition information requirements under section 343(q)(5)(H)(ix) of this title, or

(5) any requirement respecting any claim of the type described in section 343(r)(1) of this title made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title, except a requirement respecting a claim made in the label or labeling of food which is exempt under section 343(r)(5)(B) of this title.

Paragraph (3) shall take effect in accordance with section 6(b) of the Nutrition Labeling and Education Act of 1990.

(a) Upon petition of a State or a political subdivision of a State, the Secretary may exempt from subsection (a), under such conditions as may be prescribed by regulation, any State or local requirement that--

(1) would not cause any food to be in violation of any applicable requirement under Federal law,

(2) would not unduly burden interstate commerce, and

(3) is designed to address a particular need for information which need is not met by the requirements of the sections referred to in subsection (a).

Title 21. Food and Drugs
Chapter I. Food and Drug Administration, Department of Health and Human Services
Subchapter B. Food for Human Consumption
Part 101. Food Labeling
Subpart A. General Provisions

21 C.F.R. § 101.13. Nutrient content claims—general principles.

(a) This section and the regulations in subpart D of this part apply to foods that are intended for human consumption and that are offered for sale, including conventional foods and dietary supplements.

(b) A claim that expressly or implicitly characterizes the level of a nutrient of the type required to be in nutrition labeling under § 101.9 or under § 101.36 (that is, a nutrient content claim) may not be made on the label or in labeling of foods unless the claim is made in accordance with this regulation and with the applicable regulations in subpart D of this part or in part 105 or part 107 of this chapter.

(1) An expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the food, e.g., "low sodium" or "contains 100 calories."

(2) An implied nutrient content claim is any claim that:

(i) Describes the food or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount (e.g., "high in oat bran"); or

(ii) Suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., "healthy, contains 3 grams (g) of fat").

(3) Except for claims regarding vitamins and minerals described in paragraph (q)(3) of this section, no nutrient content claims may be made on food intended specifically for use by infants and children less than 2 years of age unless the claim is specifically provided for in parts 101, 105, or 107 of this chapter.

(4) Reasonable variations in the spelling of the terms defined in part 101 and their synonyms are permitted provided these variations are not misleading (e.g., "hi" or "lo").

(5) For dietary supplements, claims for calories, fat, saturated fat, and cholesterol may not be made on products that meet the criteria in § 101.60(b)(1) or (b)(2) for "calorie free" or "low calorie" claims, except, in the case of calorie claims, when an equivalent amount of a similar dietary supplement (e.g., another protein supplement) that the labeled food resembles and for which it substitutes, normally exceeds the definition for "low calorie" in § 101.60(b)(2).

(c) Information that is required or permitted by § 101.9 or § 101.36, as applicable, to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim and is not subject to the requirements of this section. If such information is declared elsewhere on the label or in

labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.

(d) A "substitute" food is one that may be used interchangeably with another food that it resembles, i.e., that it is organoleptically, physically, and functionally (including shelf life) similar to, and that it is not nutritionally inferior to unless it is labeled as an "imitation."

(1) If there is a difference in performance characteristics that materially limits the use of the food, the food may still be considered a substitute if the label includes a disclaimer adjacent to the most prominent claim as defined in paragraph (j) (2)(iii) of this section, informing the consumer of such difference (e.g., "not recommended for frying").

(2) This disclaimer shall be in easily legible print or type and in a size no less than that required by § 101.7(i) for the net quantity of contents statement, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer shall be no less than one-half the size of the claim but no smaller than one-sixteenth of an inch, unless the package complies with § 101.2(c)(5), in which case the disclaimer may be in type of not less than one thirty-second of an inch.

(e)(1) Because the use of a "free" or "low" claim before the name of a food implies that the food differs from other foods of the same type by virtue of its having a lower amount of the nutrient, only foods that have been specially processed, altered, formulated, or reformulated so as to lower the amount of the nutrient in the food, remove the nutrient from the food, or not

include the nutrient in the food, may bear such a claim (e.g., "low sodium potato chips").

(2) Any claim for the absence of a nutrient in a food, or that a food is low in a nutrient when the food has not been specially processed, altered, formulated, or reformulated to qualify for that claim shall indicate that the food inherently meets the criteria and shall clearly refer to all foods of that type and not merely to the particular brand to which the labeling attaches (e.g., "corn oil, a sodium-free food").

(f) A nutrient content claim shall be in type size no larger than two times the statement of identity and shall not be unduly prominent in type style compared to the statement of identity.

(g) [Reserved]

(h)(1) If a food, except a meal product as defined in § 101.13(l), a main dish product as defined in § 101.13(m), or food intended specifically for use by infants and children less than 2 years of age, contains more than 13.0 g of fat, 4.0 g of saturated fat, 60 milligrams (mg) of cholesterol, or 480 mg of sodium per reference amount customarily consumed, per labeled serving, or, for a food with a reference amount customarily consumed of 30 g or less or 2 tablespoons or less, per 50 g (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 101.9(f)(1), of all nutrients per reference amount customarily consumed, the per 50 g criterion refers to the "as prepared" form), then that food must bear a statement disclosing that the nutrient exceeding the specified level is present in the food as follows: "See nutrition information for content" with the blank filled in with the identity of the nutrient

exceeding the specified level, e.g., "See nutrition information for fat content."

(2) If a food is a meal product as defined in § 101.13(l), and contains more than 26 g of fat, 8.0 g of saturated fat, 120 mg of cholesterol, or 960 mg of sodium per labeled serving, then that food must disclose, in accordance with the requirements as provided in paragraph (h)(1) of this section, that the nutrient exceeding the specified level is present in the food.

(3) If a food is a main dish product as defined in § 101.13(m), and contains more than 19.5 g of fat, 6.0 g of saturated fat, 90 mg of cholesterol, or 720 mg of sodium per labeled serving, then that food must disclose, in accordance with the requirements as provided in paragraph (h)(1) of this section, that the nutrient exceeding the specified level is present in the food.

(4)(i) The disclosure statement "See nutrition information for content" shall be in easily legible boldface print or type, in distinct contrast to other printed or graphic matter, and in a size no less than that required by § 101.7(i) for the net quantity of contents statement, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclosure statement shall be no less than one-half the size of the claim but no smaller than one-sixteenth of an inch, unless the package complies with § 101.2(c)(2), in which case the disclosure statement may be in type of not less than one thirty-second of an inch.

(ii) The disclosure statement shall be immediately adjacent to the nutrient content claim and may

have no intervening material other than, if applicable, other information in the statement of identity or any other information that is required to be presented with the claim under this section (e.g., see paragraph (j)(2) of this section) or under a regulation in subpart D of this part (e.g., see §§ 101.54 and 101.62). If the nutrient content claim appears on more than one panel of the label, the disclosure statement shall be adjacent to the claim on each panel except for the panel that bears the nutrition information where it may be omitted.

(iii) If a single panel of a food label or labeling contains multiple nutrient content claims or a single claim repeated several times, a single disclosure statement may be made. The statement shall be adjacent to the claim that is printed in the largest type on that panel.

(i) Except as provided in § 101.9 or § 101.36, as applicable, or in paragraph (q)(3) of this section, the label or labeling of a product may contain a statement about the amount or percentage of a nutrient if:

(1) The use of the statement on the food implicitly characterizes the level of the nutrient in the food and is consistent with a definition for a claim, as provided in subpart D of this part, for the nutrient that the label addresses. Such a claim might be, "less than 3 g of fat per serving;"

(2) The use of the statement on the food implicitly characterizes the level of the nutrient in the food and is not consistent with such a definition, but the label carries a disclaimer adjacent to the statement that the food is not "low" in or a "good source" of the nutrient, such as "only 200 mg sodium per serving, not a low sodium food." The disclaimer must be in easily legible

print or type and in a size no less than that required by § 101.7(i) for the net quantity of contents statement except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer shall be no less than one-half the size of the claim but no smaller than one-sixteenth of an inch unless the package complies with § 101.2(c)(5), in which case the disclaimer may be in type of not less less than one thirty-second of an inch, or

(3) The statement does not in any way implicitly characterize the level of the nutrient in the food and it is not false or misleading in any respect (e.g., "100 calories" or "5 grams of fat"), in which case no disclaimer is required.

(4) "Percent fat free" claims are not authorized by this paragraph. Such claims shall comply with § 101.62(b)(6).

(j) A food may bear a statement that compares the level of a nutrient in the food with the level of a nutrient in a reference food. These statements shall be known as "relative claims" and include "light," "reduced," "less" (or "fewer"), and "more" claims.

(1) To bear a relative claim about the level of a nutrient, the amount of that nutrient in the food must be compared to an amount of nutrient in an appropriate reference food as specified below.

(i)(A) For "less" (or "fewer") and "more" claims, the reference food may be a dissimilar food within a product category that can generally be substituted for one another in the diet (e.g., potato chips as reference for pretzels, orange juice as a reference for vitamin C tablets) or a similar food (e.g., potato chips as reference

for potato chips, one brand of multivitamin as reference for another brand of multivitamin).

(B) For "light," "reduced," "added," "extra," "plus," "fortified," and "enriched" claims, the reference food shall be a similar food (e.g., potato chips as a reference for potato chips, one brand of multivitamin for another brand of multivitamin), and

(ii)(A) For "light" claims, the reference food shall be representative of the type of food that includes the product that bears the claim. The nutrient value for the reference food shall be representative of a broad base of foods of that type; e.g., a value in a representative, valid data base; an average value determined from the top three national (or regional) brands, a market basket norm; or, where its nutrient value is representative of the food type, a market leader. Firms using such a reference nutrient value as a basis for a claim, are required to provide specific information upon which the nutrient value was derived, on request, to consumers and appropriate regulatory officials.

(B) For relative claims other than "light," including "less" and "more" claims, the reference food may be the same as that provided for "light" in paragraph (j)(1)(ii)(A) of this section, or it may be the manufacturer's regular product, or that of another manufacturer, that has been offered for sale to the public on a regular basis for a substantial period of time in the same geographic area by the same business entity or by one entitled to use its trade name. The nutrient values used to determine the claim when comparing a single manufacturer's product to the labeled product shall be either the values declared in nutrition labeling or the actual nutrient values, provided that the resulting label is

internally consistent to (i.e., that the values stated in the nutrition information, the nutrient values in the accompanying information and the declaration of the percentage of nutrient by which the food has been modified are consistent and will not cause consumer confusion when compared), and that the actual modification is at least equal to the percentage specified in the definition of the claim.

(2) For foods bearing relative claims:

(i) The label or labeling must state the identity of the reference food and the percentage (or fraction) of the amount of the nutrient in the reference food by which the nutrient in the labeled food differs (e.g., "50 percent less fat than (reference food)" or "⅓ fewer calories than (reference food)"),

(ii) This information shall be immediately adjacent to the most prominent claim. The type size shall be in accordance with paragraph (h)(4)(i) of this section.

(iii) The determination of which use of the claim is in the most prominent location on the label or labeling will be made based on the following factors, considered in order:

(A) A claim on the principal display panel adjacent to the statement of identity;

(B) A claim elsewhere on the principal display panel;

(C) A claim on the information panel; or

(D) A claim elsewhere on the label or labeling.

(iv) The label or labeling must also bear:

(A) Clear and concise quantitative information comparing the amount of the subject nutrient

in the product per labeled serving with that in the reference food; and

(B) This statement shall appear adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2.

(3) A relative claim for decreased levels of a nutrient may not be made on the label or in labeling of a food if the nutrient content of the reference food meets the requirement for a "low" claim for that nutrient (e.g., 3 g fat or less).

(k) The term "modified" may be used in the statement of identity of a food that bears a relative claim that complies with the requirements of this part, followed immediately by the name of the nutrient whose content has been altered (e.g., "Modified fat cheesecake"). This statement of identity must be immediately followed by the comparative statement such as "Contains 35 percent less fat than" The label or labeling must also bear the information required by paragraph (j)(2) of this section in the manner prescribed.

(l) For purposes of making a claim, a "meal product shall be defined as a food that:

(1) Makes a major contribution to the total diet by:

(i) Weighing at least 10 ounces (oz) per labeled serving; and

(ii) Containing not less than three 40–g portions of food, or combinations of foods, from two or more of the following four food groups, except as noted in paragraph (l)(1)(ii)(E) of this section.

(A) Bread, cereal, rice, and pasta group;

(B) Fruits and vegetables group;

(C) Milk, yogurt, and cheese group;

(D) Meat, poultry, fish, dry beans, eggs, and nuts group; except that;

(E) These foods shall not be sauces (except for foods in the above four food groups that are in the sauces), gravies, condiments, relishes, pickles, olives, jams, jellies, syrups, breadings or garnishes; and

(2) Is represented as, or is in a form commonly understood to be, a breakfast, lunch, dinner, or meal. Such representations may be made either by statements, photographs, or vignettes.

(m) For purposes of making a claim, a "main dish product" shall be defined as a food that:

(1) Makes a major contribution to a meal by

(i) Weighing at least 6 oz per labeled serving; and

(ii) Containing not less than 40 g of food, or combinations of foods, from each of at least two of the following four food groups, except as noted in paragraph (m)(1)(ii)(E) of this section.

(A) Bread, cereal, rice, and pasta group;

(B) Fruits and vegetables group;

(C) Milk, yogurt, and cheese group;

(D) Meat, poultry, fish, dry beans, eggs, and nuts groups; except that:

(E) These foods shall not be sauces (except for foods in the above four food groups that are in the sauces) gravies, condiments, relishes, pickles, olives, jams, jellies, syrups, breadings, or garnishes; and

(2) Is represented as, or is in a form commonly understood to be, a main dish (e.g, not a beverage or a dessert). Such representations may be made either by statements, photographs, or vignettes.

(n) Nutrition labeling in accordance with § 101.9, § 101.10, or § 101.36, as applicable, shall be provided for any food for which a nutrient content claim is made.

(o) Except as provided in § 101.10, compliance with requirements for nutrient content claims in this section and in the regulations in subpart D of this part, will be determined using the analytical methodology prescribed for determining compliance with nutrition labeling in § 101.9.

(p)(1) Unless otherwise specified, the reference amount customarily consumed set forth in § 101.12(b) through (f) shall be used in determining whether a product meets the criteria for a nutrient content claim. If the serving size declared on the product label differs from the reference amount customarily consumed, and the amount of the nutrient contained in the labeled serving does not meet the maximum or minimum amount criterion in the definition for the descriptor for that nutrient, the claim shall be followed by the criteria for the claim as required by § 101.12(g) (e.g., "very low sodium, 35 mg or less per 240 milliliters (8 fl oz.)").

(2) The criteria for the claim shall be immediately adjacent to the most prominent claim in easily legible print or type and in a size in accordance with paragraph (h)(4)(i) of this section.

(q) The following exemptions apply:

(1) Nutrient content claims that have not been defined by regulation and that are contained in the brand name of a specific food product that was the brand name in use on such food before October 25, 1989, may continue to be used as part of that brand name for such product, provided that they are not false or misleading under section 403(a) of the Federal Food, Drug, and Cosmetic Act (the act). However, foods bearing such claims must comply with section 403(f), (g), and (h) of the act;

(2) A soft drink that used the term diet as part of its brand name before October 25, 1989, and whose use of that term was in compliance with § 105.66 of this chapter as that regulation appeared in the Code of Federal Regulations on that date, may continue to use that term as part of its brand name, provided that its use of the term is not false or misleading under section 403(a) of the act. Such claims are exempt from the requirements of section 403(r)(2) of the act (e.g., the disclosure statement also required by § 101.13(h)). Soft drinks marketed after October 25, 1989, may use the term "diet" provided they are in compliance with the current § 105.66 of this chapter and the requirements of § 101.13.

(3)(i) A statement that describes the percentage of a vitamin or mineral in the food, including foods intended specifically for use by infants and children less than 2 years of age, in relation to a Reference Daily Intake (RDI) as defined in § 101.9 may be made on the label or in labeling of a food without a regulation authorizing such a claim for a specific vitamin or mineral unless such claim is expressly prohibited by regulation under section 403(r)(2)(A)(vi) of the act.

(ii) Percentage claims for dietary supplements. Under section 403(r)(2)(F) of the act, a statement that characterizes the percentage level of a dietary ingredient for which a reference daily intake (RDI) or daily reference value (DRV) has not been established may be made on the label or in labeling of dietary supplements without a regulation that specifically defines such a statement. All such claims shall be accompanied by any disclosure statement required under paragraph (h) of this section.

(A) Simple percentage claims. Whenever a statement is made that characterizes the percentage level of a dietary ingredient for which there is no RDI or DRV, the statement of the actual amount of the dietary ingredient per serving shall be declared next to the percentage statement (e.g., "40 percent omega–3 fatty acids, 10 mg per capsule").

(B) Comparative percentage claims. Whenever a statement is made that characterizes the percentage level of a dietary ingredient for which there is no RDI or DRV and the statement draws a comparison to the amount of the dietary ingredient in a reference food, the reference food shall be clearly identified, the amount of that food shall be identified, and the information on the actual amount of the dietary ingredient in both foods shall be declared in accordance with paragraph (j)(2)(iv) of this section (e.g., "twice the omega–3 fatty acids per capsule (80 mg) as in 100 mg of menhaden oil (40 mg)").

(4) The requirements of this section do not apply to:

(i) Infant formulas subject to section 412(h) of the act; and

(ii) Medical foods defined by section 5(b) of the Orphan Drug Act.

(5) A nutrient content claim used on food that is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments shall comply with the requirements of this section and the appropriate definition in subpart D of this part, except that:

(i) Such claim is exempt from the requirements for disclosure statements in paragraph (h) of this section and §§ 101.54(d), 101.62(c), (d)(1)(ii)(D), (d)(2)(iii)(C), (d)(3), (d)(4)(ii)(C), and (d)(5)(ii)(C); and

(ii) In lieu of analytical testing, compliance may be determined using a reasonable basis for concluding that the food that bears the claim meets the definition for the claim. This reasonable basis may derive from recognized data bases for raw and processed foods, recipes, and other means to compute nutrient levels in the foods or meals and may be used provided reasonable steps are taken to ensure that the method of preparation adheres to the factors on which the reasonable basis was determined (e.g., types and amounts of ingredients, cooking temperatures, etc.). Firms making claims on foods based on this reasonable basis criterion are required to provide to appropriate regulatory officials on request the specific information on which their determination is based and reasonable assurance of operational adherence to the preparation methods or other basis for the claim; and

(iii) A term or symbol that may in some contexts constitute a claim under this section may be used, provided that the use of the term or symbol does not characterize the level of a nutrient, and a

statement that clearly explains the basis for the use of the term or symbol is prominently displayed and does not characterize the level of a nutrient. For example, a term such as "lite fare" followed by an asterisk referring to a note that makes clear that in this restaurant "lite fare" means smaller portion sizes than normal; or an item bearing a symbol referring to a note that makes clear that this item meets the criteria for the dietary guidance established by a recognized dietary authority would not be considered a nutrient content claim under § 101.13.

(6) Nutrient content claims that were part of the common or usual names of foods that were subject to a standard of identity on November 8, 1990, are not subject to the requirements of paragraphs (b) and (h) of this section or to definitions in subpart D of this part.

(7) Implied nutrient content claims may be used as part of a brand name, provided that the use of the claim has been authorized by the Food and Drug Administration. Petitions requesting approval of such a claim may be submitted under § 101.69(o).

(8) The term fluoridated, fluoride added or with added fluoride may be used on the label or in labeling of bottled water that contains added fluoride.

APPENDIX F

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

Case No.: 22-CV-01050-RS

GILLIAN DAVIDSON and SAMUEL DAVISON, on behalf of themselves and those similarly situated,

Plaintiffs,

v.

SPROUT FOODS INC., D/B/A SPROUT,

Defendant.

FIRST AMENDED CLASS ACTION COMPLAINT FOR VIOLATION OF THE CALIFORNIA UNFAIR COMPETITION LAW; FAL; COMMON LAW FRAUD; CONSUMERS LEGAL REMEDIES ACT; AND UNJUST ENRICHMENT

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JURY TRIAL DEMANDED

I. INTRODUCTION

1. Plaintiffs Gillian Davidson and Samuel Davidson, by and through their counsel, bring this class action against Defendant Sprout Foods Inc. d/b/a Sprout ("Defendant") to seek redress for Defendant's deceptive and unlawful practices in labeling and marketing the Sprout brand baby and toddler food products.

2. Parents are increasingly aware of the need to provide healthy food for their children that promotes physical development, especially at the critical age of less than two years old.

3. Intending to profit from parents' increasing desire to purchase food for their young children that provides physical health benefits, Defendant misbrands its baby and toddler food products by making nutrient content claims on the product packages that are strictly prohibited by the Food and Drug Administration ("FDA"). Moreover, the nutrient content claims on Defendant's products mislead purchasers into believing that the products provide physical health benefits for children under two years of age in order to induce parents into purchasing Defendant's products. In fact, the Products are harmful both nutritionally and developmentally for children under two.

4. Defendant's misbranding caused Plaintiffs and members of the class to pay a price premium for the products.

II. PARTIES

5. Gillian Davidson is, and at all times alleged in this Class Action Complaint was, an individual and a resident of Oakland, California. Gillian Davidson

intends to remain in Oakland and makes her permanent home in Oakland, California.

6. Samuel Davidson is, and at all times alleged in this Class Action Complaint was, an individual and a resident of Oakland, California. Samuel Davidson intends to remain in Oakland and makes his permanent home in Oakland, California. Samuel Davidson and Gillian Davidson are spouses.

7. Defendant Sprout Foods Inc. d/b/a Sprout, is a corporation existing under the laws of the State of Delaware, having its principal place of business in the State of New Jersey.

III. JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1332(d)(2). The aggregate amount in controversy exceeds $5,000,000, exclusive of interest and costs; and Plaintiffs and at least one Defendant are citizens of different states.

9. The injuries, damages and/or harm upon which this action is based, occurred, or arose out of activities engaged in by Defendant within, affecting, and emanating from, the State of California. Defendant regularly conduct and/or solicit business in, engage in other persistent courses of conduct in, and/or derive substantial revenue from products provided to persons in the State of California. Defendant has engaged, and continue to engage, in substantial and continuous business practices in the State of California.

10. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to the claims occurred in the state of California, including within this District.

11. In accordance with California Civil Code Section 1780(d), Plaintiffs concurrently file herewith a declaration establishing that, at various times throughout the class period, they purchased the following Sprout Products: Pumpkin, Apple, Red Lentil, and Cinnamon; Strawberry with Banana & Butternut Squash; and Sweet Potato, White Beans, and Cinnamon pouches in Oakland, California. (Plaintiffs' declarations are attached hereto as Exhibits B and C.)

12. Plaintiffs accordingly allege that jurisdiction and venue are proper in this Court.

IV. SUBSTANTIVE ALLEGATIONS

13. Defendant manufactures, distributes, markets, advertises, and sells a variety of baby and toddler food products under the brand name "Sprout." Many of these products have packaging that predominately, uniformly, and consistently make nutrient content claims on the principal display panel of the product labels (the "Products"). A non-exhaustive list of the Products and the nutrient content claims made on the product packages is attached hereto as Exhibit A.

14. The Products are intended for children under the age of two. The Products are labeled with the intended age for each Product on the front label. For example, the Butternut Carrot & Apple pouch is labeled as being for ages "6 months & Up." The Power Pak plant-based Strawberry with Superblend pouch is labeled as being for ages "12 months & Up." Some Products also include the word "baby" in the product name, such as the "Baby Burrito Bowl" which is also labeled as being for ages "12 months & Up." *See also* Exhibit A, listing intended ages for each Product.

15. Many of the Products are baby food "pouches." These pouches that contain pureed baby food were

introduced to the market over a decade ago, and as of 2018, accounted for 25 percent of baby food sales in the United States.

16. FDA regulations explicitly prohibit certain nutrient content claims on foods intended for children under the age of two. 21 C.F.R. § 101.13(b)(3).

17. An ever-growing industry, there is seemingly no limit to the combination of foods that can go into baby food pouches, as evidenced by the wide array of flavors of the Products. Looking for a way to differentiate itself in the growing market, Defendant has turned to making nutrient content claims on the front of the Product labels.

18. For example, Defendant has a line of "Power Pak" baby food pouches called that states on the front label, "3g of Protein, 5g of Fiber and 300mg Omega-3 from Chia ALA" and "12 Months & Up." An exemplar is shown below:

19. Another line of pouches advertises "plant protein power" and states on the front label "2 grams of Plant Protein Power" and "6 Months & Up." An exemplar is shown below.

20. As described in detail below, Defendant's advertising and labeling of the Products with nutrient content claims is unlawful, misleading, deceptive, and intended to induce consumers to purchase the Products at a premium price. These claims deceive and mislead reasonable consumers into believing that the Products provide physical health benefits for their child when in fact, the Products are harmful for children under two both nutritionally and developmentally.

Federal and State Regulations Governing Food Labeling

21. The Food and Drug Administration regulates nutrition content labeling. According to these regulations, "no nutrient content claims may be made on food intended specifically for use by infants and children

less than 2 years of age," subject to certain exceptions not applicable here. 21 C.F.R. § 101.13(b)(3).

22. According to the regulations, nutrient content claims can be expressed or implied. 21 C.F.R. § 101.13(b)(1), 21 C.F.R. § 101.13(b)(2).

23. An express nutrient content claim is "any direct statement about the level (or range) of a nutrient in the food." 21 C.F.R. § 101.13(b)(1). Further, where information that is required or permitted to be "declared in nutrition labeling, and that appears as part of the nutrition label . . . is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims." 21 C.F.R. § 101.13(c).

24. Identical federal and California laws regulate the content of labels on packaged food and require truthful, accurate information on the labels of packaged foods. The requirements of the federal Food, Drug & Cosmetic Act ("FDCA"), and its labeling regulations, including those set forth in 21 C.F.R. § 101, were adopted by the California legislature in the Sherman Food Drug & Cosmetic Law (the "Sherman Law"). California Health & Safety Code § 110100 ("All food labeling regulations and any amendments to those regulations adopted pursuant to the federal act, in effect on January 1, 1993, or adopted on or after that date shall be the food labeling regulations of this state."). The federal laws and regulations discussed herein are applicable nationwide to all sales of packaged food products. Additionally, no state imposes different requirements on labeling of packaged food for sale in the United States.

25. California's adoption of food regulations that are identical to the federal regulations stems from the

state's "historic police powers" to regulate food labeling, which long-predates the enactment of the FDCA. *See Plumley v. Massachusetts*, 155 U.S. 461, 472 (1894) ("If there be any subject over which it would seem the states ought to have plenary control, and the power to legislate in respect to which . . . it is the protection of the people against fraud and deception in the sale of food products."); *see also See Florida Lime & Avocado Growers v. Paul*, 373 U.S. 132, 144 (1963) ("States have always possessed a legitimate interest in 'the protection of (their) people against fraud and deception in the sale of food products' at retail markets within their borders.") (citation omitted).

26. Although California amended its food labeling laws in 1995 in response to the federal implementation of the 1993 Nutrition Labeling and Education Act, California's regulations of food labels predate the enactment of the Sherman Law. For example, the current Cal. Health & Safety Code § 110660 invoked herein states "[a]ny food is misbranded if its labeling is false or misleading in any particular." California originally enacted this regulation in 1939, previously found at Cal. Health & Safety Code § 26490. *See People v. 748 Cases of Life Saver Candy Drops*, 94 Cal. App. 2d 599, 607 (1949) (applying section 26490 prohibition on "labeling is false or misleading in any particular" in food labeling claim in 1949).

27. Under the FDCA the term "misleading" covers labels that are technically true, but are likely to deceive consumers. Under the FDCA, if any single representation on the labeling is misleading, the entire food is misbranded, and no other statement in the labeling can cure a misleading statement.

28. Further in addition to its blanket adoption of federal labeling requirements, California has also

enacted a number of laws and regulations that adopt and incorporate specific numerated federal food laws and regulations. *See* California Health & Safety Code § 110660 (misbranded if label is misleading).

29. Under California law, a food product that is "misbranded" cannot legally be manufactured, advertised, distributed, sold, or possessed. Misbranded products have no economic value and are legally worthless.

30. Representing that the Products will provide benefits by making unlawful nutrient content claims as Defendant's labels do is prohibited by the aforementioned misbranding laws and regulations.

31. The regulations relating to nutrient content claims discussed herein are intended to ensure that consumers are not misled as to the actual or relative nutritional value of food products.

Defendant's Marketing and Labeling of the Products Violates State and Federal Food Labeling Laws

32. The Products are unlawful, misbranded, and violate the Sherman Law, California Health & Safety Code § 110660, *et seq.*, because the Products are intended for children less than 2 years of age and the Products' labels contain nutrient content claims.

33. As described above, the Products at issue in this case are intended for children 6 months and up as evidenced on the front labels and in the Product titles.

34. Beyond the Product labels, the Products are also sold in the "Baby Food" grocery store aisles, alongside similar puree pouch products. On information and belief, Defendant directs retailers to sell the Products in the baby food aisle.

35. Defendant misbrands the Products by making nutrient content claims that are strictly prohibited by the FDA, and by misleading purchasers into believing that its Products provide physical health benefits in order to induce parents into purchasing the Products.

36. All the Product labels contain nutrient content claims that are unlawful. As shown in Exhibit A, the Product labels prominently state nutrient content claims on the front label such as "3g of Protein, 4g of Fiber and 300mg Omega-3 from Chia ALA." The grams of protein and fiber appear in the nutrition facts panel and are therefore nutrient content claims when stated elsewhere on the label. 21 C.F.R. § 101.13(c). The statement of the presence of other nutrients are also express nutrient content claims because it is a direct statement about the level of a nutrient in the product. *See* 21 C.F.R. § 101.13(b)(1).

37. Foods intended for children less than two are prohibited from making such nutrient content claims. 21 C.F.R. § 101.13(b)(3). Therefore, the Products are accordingly misbranded.

38. In addition to being unlawful, the nutrient content claims on the Products are also misleading.

39. Reasonable consumers rely on the label claims to decide to purchase the Products for children well under two years old. Reasonable consumers shopping in the baby food aisle of a grocery or online retailer see the Products alongside products intended for children as young as six months and purchase the Products for their baby or toddler under the age of two.

40. The nutrient content claims on the Products mislead reasonable consumers into believing the Products will provide physical health benefits for their children, when in fact the Products are harmful.

41. The FDA has long warned that nutrient content claims could be misleading. For example, in the context of express claims such as "4g PROTEIN," in published guidance the FDA has stated that "since many consumers have a limited knowledge and understanding of the amounts of nutrients that are recommended for daily consumption, a statement declaring that the product contained a specified amount of a nutrient could be misleading." 56 Fed. Reg. 60421, 60426. This is especially true in the context of children under two because there are different recommended daily intakes for nutrients for children 0-12 months; 1-3 years; and 4 years and above.

42. FDA has also explained that "[b]y its very presence, such a [quantitative] statement could give consumers who were unfamiliar with the dietary recommendations the false impression that the product would assist them in maintaining healthy dietary practices relative to the amount of the nutrient consumed when it, in fact, would not." *Id*.

43. The FDA described the purpose of nutrient content claim regulations to be "promoting sound nutrition for the nation's consumers." 56 Fed. Reg. 60421. The FDA relies on the USDA's development of Dietary Guidelines as the basis for encouraging and discouraging the "selection of foods containing low or high levels of certain nutrients as part of an overall diet." *Id.*

44. The FDA forbids nutrient content claims on products intended for children under two because "the agency lacks evidence that a more restrictive dietary pattern for other nutrients such as sodium or an increased intake for nutrients such as fiber are appropriate and recommended for infants and toddlers." 56 Fed. Reg. 60421; *see also* 58 Fed. Reg.

33731, 33733. Although it has been nearly thirty years, not much has changed regarding the evidence as explained below.

45. At the time the regulation was implemented, there were Recommended Daily Intakes ("RDI") and Daily Recommended Values ("DRV") for most nutrients for children under two. *See* 58 Fed. Reg. 2302, 2305 (stating there are RDIs for children under two); 58 FR 2206, 2211 (providing the RDIs). Despite knowing the target daily intake of nutrients for these ages, the FDA concluded that it would not be appropriate to promote nutrients on labels for this young group because "relatively little attention has been given" to the dietary patterns of children under two. 56 Fed. Reg. 60421; *see also* 60 Fed. Reg. 67184, 67191.

46. The same is true today. For example, there are still RDIs and DRVs for most nutrients for children under two. Just as in 1991, the RDIs and DRVs of nutrients is different for different ages, with a different set of values for children 0-12 months, 1-3 years old, and 4 and above. 21 C.F.R. § 101.9(c)(8)(4). And just as in 1991, in 2020 a USDA working group concluded "[d]eveloping recommended food patterns for infants and toddlers ages 6 to 24 months is challenging. . . in part because the scientific evidence for many questions is relatively scant." Dietary Guidelines Advisory Committee. 2020. *Scientific Report of the 2020 Dietary Guidelines Advisory Committee: Advisory Report to the Secretary of Agriculture and the Secretary of Health and Human Services* (hereinafter "2020 Scientific Report").[1]

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[1] U.S. Department of Agriculture, Agricultural Research Service, Washington, DC. Available at: https://doi.org/10.52570/DGAC2020

47. Children under two have unique dietary needs because they are experiencing huge amounts of growth, but eating relatively little solid food. Therefore, it is important that children under two receive the "most nutrient dense foods available in the household." Dewey KG. *The challenge of meeting nutrient needs of infants and young children during the period of complementary feeding: an evolutionary perspective.* J Nutr. 2013 Dec;143(12):2050-4. doi: 10.3945/jn.113. 182527. Epub 2013 Oct 16. PMID: 24132575; PMCID: PMC3827643.

48. Dietary needs for children under two are also different from those of adults because the optimal diet for children under two also has to address needs beyond mere nutrition, such as developing neural pathways in the brain to establish healthy eating habits and developing gross and fine motor skills. The USDA-recommended diet for children under two includes nutrient-dense foods that promote exposure to new flavors and textures. Dietary Guidelines for Americans, 2020-2025. 9th Edition. December 2020. Available at DietaryGuidelines.gov (hereinafter "USDA Dietary Guidelines"). The Dietary Guidelines emphasize that the period of 0-24 months "is key for establishing healthy dietary patterns that may influence the trajectory of eating behaviors and health throughout the life course. . . . Children in this age group consume small quantities of foods, so it's important to make every bite count!" Dietary Guidelines at 53. By making nutrient content claims on its packages' front labels, Defendant misleads consumers into believing that foods for children under two should be purchased based on the quantities of the listed nutrients, when other considerations are just as, or more, important.

49. The World Health Organization has also recognized the dangers inherent in pouch products. Recognizing that "[p]ureeing foods means much of the intrinsic sugar (within cell walls of fruit and vegetables) is liberated and readily available," the WHO—while endorsing the consumption of whole fruits and vegetables—has stated that "pureed foods" "sold in pouches with spouts present[] several issues[,]" including "exposure to high concentrations of free sugars that may quickly be absorbed," "lower nutrient density," and "issues with sucking directly from the pouches," such as "t[oo]th decay" from "sucking these [sugary] foods across the teeth."[2]

50. The Products have high amounts of free sugars. For example, the Power Pak pouch Products have 10-14 grams of sugar, the Apricot Banana Chickpea Fig pouch has 10 grams of sugar, and the Apple Banana Butternut Squash pouch has 12 grams of sugar. *See also* Exhibit A, listing sugar content for the Products.

51. The impact of sugar from whole fruits is different than the impact of pureed fruits on the body. This is mainly due to the transformation of the fiber in the food. In a whole apple, for example, the fiber comes in two forms: soluble and insoluble. Having both forms of fiber is important to the body's ability to process the sugars in the fruit in a way that promotes satiety and protects the liver. When pureed, the apple is stripped of insoluble fiber and the liver is no longer protected

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[2] World Health Organization, "Ending inappropriate promotion of commercially available complementary foods for infants and young children between 6 and 36 months in Europe (2019)" available at https://www.euro.who.int/en/health-topics/disease-prevention/nutrition/publications/2019/ending-inappropriate-promotion-of-commercially-available-complementary-foods-for-infants-and-young-children-between-6-and-36-months-in-europe-2019.

from the sugar in the food. This is, in part, why consumption of pouches may lead to long term health risks.[3]

52. This concept is also known as the "food matrix" of a food, which is defined by the USDA as "the nutrient and non-nutrient components of foods and their molecular relationships, i.e., chemical bonds, to each other."[4] The effect of the food matrix is that two foods of identical chemical composition, but with different structures, may have significantly different outcomes for health.

53. The Guidelines also recognize that it is not just what infants and toddlers are fed, but how they are fed, that matters. While some parents begin exposure to solids through the use of purees, purees are not recommended for long-term use because children under two are at a crucial stage of feeding and oral development. Learning to chew and swallow soft foods helps develop speech and multi-sensory experiences that contribute to a palate for a wide range of foods later in life.

54. "In addition, feeding experiences with foods provided in different textures and forms (such as 'finger foods') help to develop manual dexterity, hand-eye coordination, and dexterity of the tongue and other mechanical features involved in chewing and swallowing. The timely introduction and progression of textures helps to support the development of appropriate feeding and eating behaviors during childhood." 2020 Scientific Report, Part D. Ch. 7.

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[3] Robert H. Lustig, *Metabolical*, at 238.

[4] https://agclass.nal.usda.gov/vocabularies/nalt/concept?uri=https://lod.nal.usda.gov/nalt/17238

55. Some professions have noted delays in motor development among kids overly dependent on pouches.[5]

56. A baby consuming a pouch is also more likely to eat more puree than when she is fed with a spoon. This is problematic in at least two ways: 1) babies are less likely to recognize satiety cues which can contribute to long term health risks; and 2) babies are filling up on purees which are "not good nutritional substitutes for breastmilk or formula in early life", according to the chair of the American Academy of Pediatrics' Committee on Nutrition.[6]

57. As a spokeswoman for the American Academy of Pediatrics said in 2018 of the overuse of baby food pouches, "Parents are feeling reassured that their kids are getting the fruits and vegetables . . . [but] kids need the taste of what the actual food is to come to like it later."[7]

58. Indeed, experts have cautioned that pouches like Defendants' Products can be a "gateway to bad long-term snacking habits and routine overeating."[8]

59. For these reasons, Defendant marketing the Products as providing physical health benefits for babies and toddlers is misleading to reasonable consumers and the Products are actually harmful for

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[5] Alice Callahan, "The Truth About Food Pouches," New York Times, April 17, 2020, available at https://www.nytimes.com/2020/04/17/parenting/baby-food-pouches.html.

[6] Id.

[7] Rachel Cernansky, "Rethinking Baby Food Pouches," New York Times, June 19, 2018, available at https://www.nytimes.com/2018/06/19/well/rethinking-baby-food-pouches.html.

[8] Id.

children under two both nutritionally and developmentally.

60. Defendant's marketing, advertising, and sale of the Products violates the false advertising provisions of the Sherman Law (California Health & Safety Code § 110390, *et. seq.*), including but not limited to:

a. Section 110390, which makes it unlawful to disseminate false or misleading food advertisements that include statements on products and product packaging or labeling or any other medium used to directly or indirectly induce the purchase of a food product;

b. Section 110395, which makes it unlawful to manufacture, sell, deliver, hold, or offer to sell any falsely or misleadingly advertised food; and

c. Sections 110398 and 110400, which make it unlawful to advertise misbranded food or to deliver or proffer for delivery any food that has been falsely or misleadingly advertised.

61. Defendant's marketing, advertising, and sale of the Products violates the misbranding provisions of the Sherman Law (California Health & Safety Code § 110660, *et. seq.*), including but not limited to:

a. Section 110665 (a food is misbranded if its labeling does not conform with the requirements for nutrition labeling as set forth in 21 U.S.C. Sec. 343(q));

b. Section 110760, which makes it unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any food that is misbranded;

c. Section 110765, which makes it unlawful for any person to misbrand any food; and

d. Section 110770, which makes it unlawful for any person to receive in commerce any food that is misbranded or to deliver or proffer for delivery any such food.

62. Defendant has violated 21 U.S.C. § 343(a), and the standards set by FDA regulations, including, but not limited to, 21 C.F.R. §§ 101.13(b), 101.13(c), which have been incorporated by reference in the Sherman Law, by including impermissible nutrient content claims on the labels of foods intended for children less than 2 years of age.

63. A reasonable consumer would rely on the label claims to decide to purchase the Products. For example, Defendant's nutrient content claims mislead a reasonable consumer to believe the Products provide physical health benefits for their child when in fact, the Products are harmful for children under two both nutritionally and developmentally.

64. Defendant intends for and know that consumers will and do rely upon food labeling statements in making their purchasing decisions. Label claims and other forms of advertising and marketing drive product sales, particularly if placed prominently on the front of product packaging, as Defendant has done on the Product labels.

65. Because consumers pay a price premium for Products that have a nutrient content claim, by labeling the Products as providing nutritional value, Defendant is able to both increase its sales and retain more profits.

66. Defendant engaged in the practices complained of herein to further its private interests of: (i) increasing sales of its Products while decreasing the sales of competitors' products that do not make

unlawful nutrient content claims, and/or (ii) commanding a higher price for the Products because consumers will pay more for them due to consumers' demand for healthful products for their children.

67. The market for baby food pouch products continues to grow, and because Defendant knows consumers rely on the nutrient content claims on the Product labels, Defendant has an incentive to continue to make such misleading and unlawful representations.

68. Defendant continues to launch new product lines with nutrient content claims to maintain its competitive edge, making it likely that Defendant will continue to misleadingly advertise its Products.

V. PLAINTIFFS' EXPERIENCES

Gillian Davidson

69. During the last four years, Ms. Davidson purchased several Sprout Organic food pouches for her child starting when her child was under 2 years of age, including each of the following varieties: Pumpkin, Apple, Red Lentil, and Cinnamon; Strawberry with Banana & Butternut Squash; and Sweet Potato, White Beans, and Cinnamon. She purchased the products primarily from Amazon.com.

70. Ms. Davidson made each of her purchases after reading the nutrient content claims on the product labels, including, for example, "Contains 3g of Protein." She purchased the Products instead of other products, because she believed the Products would be physically beneficial for her child.

71. As a result of Defendant's unlawful nutrient content claims, the Products have no, or at a minimum, a much lower value to Ms. Davidson.

72. Ms. Davidson not only purchased the Products because the labels contained nutrient content claims, but she also paid more money for the Products than she would have paid for them if they did not contain nutrient content claims.

73. Had Defendant not unlawfully and misleadingly labeled the Products, Ms. Davidson would not have purchased them or, at a very minimum, she would have paid less for the Products.

74. Ms. Davidson continues to desire to purchase pouch products, including those marketed and sold by Defendant. If the Products did not contain deceptive and misleading labels, Plaintiffs would likely purchase the Products again in the future. Ms. Davidson regularly shops at stores and online retailers where the Products and other baby food pouch products are sold.

Samuel Davidson

75. During the last four years, Mr. Davidson purchased several Sprout Organic food pouches for his child starting when his child was under 2 years of age, including each of the following varieties: Pumpkin, Apple, Red Lentil, and Cinnamon; Strawberry with Banana & Butternut Squash; and Sweet Potato, White Beans, and Cinnamon. He purchased the products primarily from Amazon.com.

76. Mr. Davidson made each of his purchases after reading the nutrient content claims on the product labels, including, for example, "Contains 3g of Protein." He purchased the Products instead of other products, because he believed the Products would be physically beneficial for his child.

77. As a result of Defendant's unlawful nutrient content claims, the Products have no, or at a minimum, a much lower value to Mr. Davidson.

78. Mr. Davidson not only purchased the Products because the labels contained nutrient content claims, but he also paid more money for the Products than he would have paid for them if they did not contain nutrient content claims.

79. Had Defendant not unlawfully and misleadingly labeled the Products, Ms. Davidson would not have purchased them or, at a very minimum, he would have paid less for the Products.

80. Mr. Davidson continues to desire to purchase pouch products, including those marketed and sold by Defendant. If the Products did not contain deceptive and misleading labels, Plaintiffs would likely purchase the Products again in the future. Mr. Davidson regularly shops at stores where the Products and other baby food pouch products are sold.

81. Plaintiffs and members of the Class have been economically damaged by their purchase of the Products because the advertising for the Products was and is misleading under California law and the products are misbranded; therefore, the Products are worth less than what Plaintiffs and members of the Class paid for them.

VI. CLASS ALLEGATIONS

82. Plaintiffs bring this class action lawsuit on behalf of themselves and a proposed class of similarly situated persons, pursuant to Rule 23(b)(2) and (b)(3) of the Federal Rules of Civil Procedure. Plaintiffs seek to represent the following group of similarly situated persons, defined as follows:

Class: All persons in the State of California who purchased the Products between February 18, 2018 and the present

83. This action has been brought and may properly be maintained as a class action against Defendant because there is a well-defined community of interest in the litigation and the proposed class is easily ascertainable.

84. Numerosity: Plaintiffs do not know the exact size the Class, but they estimate that it is composed of more than 100 persons. The persons in the Class are so numerous that the joinder of all such persons is impracticable and the disposition of their claims in a class action rather than in individual actions will benefit the parties and the courts.

85. Common Questions Predominate: This action involves common questions of law and fact to the Class because each class member's claim derives from the deceptive, unlawful and/or unfair statements and omissions that led them to rely on the unlawful nutrient content claims on the Product labels. The common questions of law and fact predominate over individual questions, as proof of a common or single set of facts will establish the right of each member of the Class to recover. The questions of law and fact common to the Class are:

a. Whether the marketing, advertising, packaging, labeling, and other promotional materials for the Products are deceptive and/or unlawful;

b. Whether Defendant's actions violate Federal and California laws invoked herein;

c. Whether labeling the Products with unlawful nutrient content claims causes the Products to command

a price premium in the market as compared with similar products that do not make such unlawful claims;

d. Whether Defendant's advertising and marketing regarding the Products was likely to deceive reasonable consumers;

e. Whether representations regarding the nutrient content of the Products are material to a reasonable consumer;

f. Whether Defendant engaged in the behavior knowingly, recklessly, or negligently;

g. The amount of profits and revenues earned by Defendant as a result of the conduct;

h. Whether class members are entitled to restitution, injunctive and other equitable relief and, if so, what is the nature (and amount) of such relief; and

i. Whether class members are entitled to payment of actual, incidental, consequential, exemplary and/or statutory damages plus interest thereon, and if so, what is the nature of such relief.

86. Typicality: Plaintiffs' claims are typical of the claims of the other members of the Class because, among other things, all such claims arise out of the same wrongful course of conduct engaged in by Defendant in violation of law as complained of herein. Further, the damages of each member of the Class were caused directly by Defendant's wrongful conduct in violation of the law as alleged herein.

87. Adequacy of Representation: Plaintiffs will fairly and adequately protect the interests of all class members because it is in their best interests to prosecute the claims alleged herein to obtain full compensation due to them for the unfair and illegal conduct of which they complain. Plaintiffs also have no

interests that are in conflict with, or antagonistic to, the interests of class members. Plaintiffs have retained highly competent and experienced class action attorneys to represent their interests and that of the class. By prevailing on their own claims, Plaintiffs will establish Defendant's liability to all class members. Plaintiffs and their counsel have the necessary financial resources to adequately and vigorously litigate this class action, and Plaintiffs and counsel are aware of their fiduciary responsibilities to the class members and are determined to diligently discharge those duties by vigorously seeking the maximum possible recovery for class members.

88. Superiority: There is no plain, speedy, or adequate remedy other than by maintenance of this class action. The prosecution of individual remedies by members of the class will tend to establish inconsistent standards of conduct for Defendant and result in the impairment of class members' rights and the disposition of their interests through actions to which they were not parties. Class action treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of effort and expense that numerous individual actions would engender. Furthermore, as the damages suffered by each individual member of the class may be relatively small, the expenses and burden of individual litigation would make it difficult or impossible for individual members of the class to redress the wrongs done to them, while an important public interest will be served by addressing the matter as a class action.

89. Plaintiffs are unaware of any difficulties that are likely to be encountered in the management of this

action that would preclude its maintenance as a class action.

VII. CAUSES OF ACTION

Plaintiffs do not plead, and hereby disclaim, causes of action under the FDCA and regulations promulgated thereunder by the FDA. Plaintiffs rely on the FDCA and FDA regulations only to the extent such laws and regulations have been separately enacted as state law or regulation or provide a predicate basis of liability under the state and common laws cited in the following causes of action.

PLAINTIFFS' FIRST CAUSE OF ACTION
(Violation of the Consumers Legal Remedies Act (the "CLRA"), California Civil Code § 1750, *et seq.*)
On Behalf of Themselves and the Class

90. Plaintiffs reallege and incorporate the paragraphs of this Class Action Complaint as if set forth herein.

91. Plaintiffs and Class members are "consumers" as that term is defined by the CLRA in California Civil Code § 1761(d).

92. The Products that Plaintiffs (and other similarly situated Class members) purchased from Defendant were "goods" within the meaning of California Civil Code § 1761(a).

93. Defendant's actions, representations and conduct have violated, and continue to violate the CLRA, because they extend to transactions that are intended to result, or which have resulted, in the sale or lease of goods or services to consumers.

94. Defendant's acts and practices, set forth in this Class Action Complaint, led Plaintiffs and other similarly situated consumers to falsely believe that the Products provide physical health benefits for their

child when in fact, the Products are harmful for children under two both nutritionally and developmentally. By engaging in the actions, representations and conduct set forth in this Class Action Complaint, Defendant has violated, and continue to violate, § 1770(a)(2), § 1770(a)(5), § 1770(a)(7), and § 1770(a)(8) of the CLRA. In violation of California Civil Code §1770(a)(2), Defendant's acts and practices constitute improper representations regarding the source, sponsorship, approval, or certification of the goods they sold. In violation of California Civil Code §1770(a)(5), Defendant's acts and practices constitute improper representations that the goods they sell have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities, which they do not have. In violation of California Civil Code §1770(a)(7), Defendant's acts and practices constitute improper representations that the goods it sells are of a particular standard, quality, or grade, when they are of another. In violation of California Civil Code §1770(a)(8), Defendant has disparaged the goods, services, or business of another by false or misleading representation of fact.

95. Plaintiffs request that this Court enjoin Defendant from continuing to employ the unlawful methods, acts and practices alleged herein pursuant to California Civil Code § 1780(a)(2). If Defendant is not restrained from engaging in these types of practices in the future, Plaintiffs and the other members of the Class will continue to suffer harm. Plaintiffs and those similarly situated have no adequate remedy at law to stop Defendant's continuing practices.

96. Plaintiffs provided Defendant with notice and demand that Defendant correct, repair, replace or otherwise rectify the unlawful, unfair, false and/or

deceptive practices complained of herein. Despite receiving the aforementioned notice and demand, Defendant failed to do so in that, among other things, it failed to identify similarly situated customers, notify them of their right to correction, repair, replacement or other remedy, and/or to provide that remedy. Accordingly, Plaintiffs seek, pursuant to California Civil Code § 1780(a)(3), on behalf of themselves and those similarly situated class members, compensatory damages, punitive damages and restitution of any ill-gotten gains due to Defendant's acts and practices.

97. Plaintiffs also request that this Court award their costs and reasonable attorneys' fees pursuant to California Civil Code § 1780(d).

PLAINTIFFS' SECOND CAUSE OF ACTION
(False Advertising, Business and Professions Code § 17500, *et seq.* ("FAL"))
On Behalf of Themselves and the Class

98. Plaintiffs reallege and incorporate by reference the paragraphs of this Class Action Complaint as if set forth herein.

99. Beginning at an exact date unknown to Plaintiffs, but within three (3) years preceding the filing of the Class Action Complaint, Defendant made untrue, false, deceptive and/or misleading statements in connection with the advertising and marketing of the Products.

100. Defendant made representations and statements (by omission and commission) that led reasonable customers to believe that the Products that they were purchasing were physically beneficial for their young children.

101. Plaintiffs and those similarly situated relied to their detriment on Defendant's misleading and deceptive advertising and marketing practices, including each of the unlawful claims set forth above. Had Plaintiffs and those similarly situated been adequately informed and not intentionally deceived by Defendant, they would have acted differently by, without limitation, refraining from purchasing the Products or paying less for them.

102. Defendant's acts and omissions are likely to deceive reasonable consumers and the general public.

103. Defendant engaged in these false, misleading and deceptive advertising and marketing practices to increase its profits. Accordingly, Defendant has engaged in false advertising, as defined and prohibited by section 17500, *et seq*. of the California Business and Professions Code.

104. The aforementioned practices, which Defendant used, and continue to use, to its significant financial gain, also constitute unlawful competition and provide an unlawful advantage over Defendant's competitors as well as injury to the general public.

105. As a direct and proximate result of such actions, Plaintiffs and the other subclass members have suffered, and continue to suffer, injury in fact and have lost money and/or property as a result of such false, deceptive and misleading advertising in an amount which will be proven at trial, but which is in excess of the jurisdictional minimum of this Court. In particular, Plaintiffs, and those similarly situated, paid a price premium for the Products, i.e., the difference between the price consumers paid for the Products and the price that they would have paid but for Defendant's false, deceptive and misleading advertising. This premium can be determined by using

econometric or statistical techniques such as hedonic regression or conjoint analysis. Alternatively, Plaintiffs and those similarly situated will seek a full refund of the price paid upon proof that the sale of the Products was unlawful.

106. Plaintiffs seek equitable relief, including restitution, with respect to their FAL claims. Pursuant to Federal Rule of Civil Procedure 8(e)(2), Plaintiffs makes the following allegations in this paragraph only hypothetically and as an alternative to any contrary allegations in their other causes of action, in the event that such causes of action will not succeed. Plaintiffs and the Class may be unable to obtain monetary, declaratory and/or injunctive relief directly under other causes of action and will lack an adequate remedy at law, if the Court requires them to show classwide reliance and materiality beyond the objective reasonable consumer standard applied under the FAL, because Plaintiffs may not be able to establish each Class member's individualized understanding of Defendant's misleading representations as described in this Complaint, but the FAL does not require individualize proof of deception or injury by absent class members. *See, e.g., Ries v. Ariz. Bevs. USA LLC*, 287 F.R.D. 523, 537 (N.D. Cal. 2012) ("restitutionary relief under the UCL and FAL 'is available without individualized proof of deception, reliance, and injury.'"). In addition, Plaintiffs and the Class may be unable to obtain such relief under other causes of action and will lack an adequate remedy at law, if Plaintiffs are unable to demonstrate the requisite *mens rea* (intent, reckless, and/or negligence), because the FAL imposes no such *mens rea* requirement and liability exists even if Defendant acted in good faith.

107. Plaintiffs seek, on behalf of themselves and those similarly situated, a declaration that the above-described practices constitute false, misleading and deceptive advertising.

108. Plaintiffs seek, on behalf of themselves and those similarly situated, an injunction to prohibit Defendant from continuing to engage in the false, misleading and deceptive advertising and marketing practices complained of herein. Such misconduct by Defendant, unless and until enjoined and restrained by order of this Court, will continue to cause injury in fact to the general public and the loss of money and property in that Defendant will continue to violate the laws of California, unless specifically ordered to comply with the same. This expectation of future violations will require current and future consumers to repeatedly and continuously seek legal redress in order to recover monies paid to Defendant to which they are not entitled. Plaintiffs, those similarly situated and/or other California consumers have no other adequate remedy at law to ensure future compliance with the California Business and Professions Code alleged to have been violated herein.

PLAINTIFFS' THIRD CAUSE OF ACTION
(Common Law Fraud, Deceit and/or Misrepresentation)
On Behalf of Themselves and the Class

109. Plaintiffs reallege and incorporate by reference the paragraphs of this Class Action Complaint as if set forth herein.

110. Defendant has fraudulently and deceptively included unlawful nutrient content claims on the Product labels.

111. The unlawfulness of the claims was known exclusively to, and actively concealed by, Defendant,

not reasonably known to Plaintiffs, and material at the time they were made. Defendant's unlawful statements concerned material facts that were essential to the analysis undertaken by Plaintiffs as to whether to purchase the Products. In misleading Plaintiffs and not so informing them, Defendant breached its duty to Plaintiffs. Defendant also gained financially from, and as a result of, its breach.

112. Plaintiffs and those similarly situated relied to their detriment on Defendant's unlawful representations. Had Plaintiffs and those similarly situated been adequately informed and not intentionally deceived by Defendant, they would have acted differently by, without limitation: (i) declining to purchase the Products, (ii) purchasing less of them, or (iii) paying less for the Products.

113. By and through such fraud, deceit, and unlawful representations, Defendant intended to induce Plaintiffs and those similarly situated to alter their position to their detriment. Specifically, Defendant fraudulently and deceptively induced Plaintiffs and those similarly situated to, without limitation, purchase the Products.

114. Plaintiffs and those similarly situated justifiably and reasonably relied on Defendant's unlawful representations, and, accordingly, were damaged by Defendant.

115. As a direct and proximate result of Defendant's unlawful representations, Plaintiffs and those similarly situated have suffered damages, including, without limitation, the amount they paid for the Products.

116. Defendant's conduct as described herein was wilful and malicious and was designed to maximize Defendant's profits even though Defendant knew that

it would cause loss and harm to Plaintiffs and those similarly situated.

PLAINTIFFS' FOURTH CAUSE OF ACTION
(Unlawful, unfair, and fraudulent trade practices violation of Business and Professions Code § 17200, *et seq.*)
On Behalf of Themselves and the Class

117. Plaintiffs realleges and incorporates by reference the paragraphs of this Class Action Complaint as if set forth herein.

118. Within four (4) years preceding the filing of this lawsuit, and at all times mentioned herein, Defendant has engaged, and continue to engage, in unlawful, unfair, and fraudulent trade practices in California by engaging in the conduct outlined in this Complaint.

119. Defendant has engaged, and continue to engage, in unfair practices as described herein, in violation of the Unfair Competition Law, California Business & Professions Code §§ 17200 *et seq.* (the "UCL"), by, without limitation, including unlawful nutrient content claims on the Product labels and thereby selling Products that were not capable of being sold or held legally and which were legally worthless.

120. Defendant has engaged, and continue to engage, in unlawful practices as described herein, in violation of the UCL, by, without limitation, violating the following laws:

> (i) the CLRA as described herein; (ii) the FAL as described herein; (iii) the advertising provisions of the Sherman Law (Article 3), including without limitation, California Health & Safety Code §§ 110390, 110395, 110398 and 110400; (iv) the misbranded food

provisions of the Sherman Law (Article 6), including without limitation, California Health & Safety Code §§ 110665, 110760, 110765, and 110770; and (v) and federal laws regulating the advertising and branding of food in 21 U.S.C. § 343, *et seq*. and FDA regulations, including but not limited to 21 C.F.R. §§ 101.13(b), which are incorporated into the Sherman Law (California Health & Safety Code §§ 110100(a), 110380, and 110505).

121. Defendant has engaged, and continue to engage, in fraudulent practices as described herein, in violation of the UCL, by, without limitation, including unlawful nutrient content claims on the Product labels and thereby selling Products that were not capable of being sold or held legally and which were legally worthless.

122. Plaintiffs and those similarly situated relied to their detriment on Defendant's unlawful, unfair, and fraudulent business practices. Had Plaintiffs and those similarly situated been adequately informed and not deceived by Defendant, they would have acted differently by, without limitation: (i) declining to purchase the Products, (ii) purchasing less of the Products, or (iii) paying less for the Products.

123. Defendant's acts and omissions are likely to deceive the general public.

124. Defendant engaged in these deceptive and unlawful practices to increase its profits. Accordingly, Defendant has engaged in unlawful trade practices, as defined and prohibited by section 17200, *et seq*. of the California Business and Professions Code.

125. The aforementioned practices, which Defendant has used to its significant financial gain, also constitute unlawful competition and provide an unlawful advantage over Defendant's competitors as well as injury to the general public.

126. As a direct and proximate result of such actions, Plaintiffs and the other subclass members, have suffered and continue to suffer injury in fact and have lost money and/or property as a result of such deceptive and/or unlawful trade practices and unfair competition in an amount which will be proven at trial, but which is in excess of the jurisdictional minimum of this Court. In particular, Plaintiffs and those similarly situated paid a price premium for the Products, i.e., the difference between the price consumers paid for the Products and the price that they would have paid but for Defendant's misrepresentation. This premium can be determined by using econometric or statistical techniques such as hedonic regression or conjoint analysis. Alternatively, Plaintiffs and those similarly situated will seek a full refund of the price paid upon proof that the sale of the Products was unlawful.

127. As a direct and proximate result of such actions, Defendant has enjoyed, and continue to enjoy, significant financial gain in an amount which will be proven at trial, but which is in excess of the jurisdictional minimum of this Court.

128. Plaintiffs seek, on behalf of themselves and those similarly situated, equitable relief, including restitution for the premium and/or the full price that they and others paid to Defendant as result of Defendant's conduct. Plaintiffs and the Class lack an adequate remedy at law to obtain such relief with respect to their "unfairness" claims in this UCL cause of action, because there is no cause of action at law for "unfair"

conduct. Plaintiffs and the Class similarly lack an adequate remedy at law to obtain such relief with respect to their "unlawfulness" claims in this UCL cause of action because the Sherman Law (Articles 3 and 6) and the Federal laws and regulations referenced herein do not provide a direct cause of action, so Plaintiffs and the Class must allege those violations as predicate acts under the UCL to obtain relief.

129. Plaintiffs also seeks equitable relief, including restitution, with respect to their UCL unlawfulness claims for violations of the CLRA, FAL and their UCL "fraudulent" claims. Pursuant to Federal Rule of Civil Procedure 8(e)(2), Plaintiffs make the following allegations in this paragraph only hypothetically and as an alternative to any contrary allegations in their other causes of action, in the event that such causes of action do not succeed. Plaintiffs and the Class may be unable to obtain monetary, declaratory and/or injunctive relief directly under other causes of action and will lack an adequate remedy of law, if the Court requires them to show classwide reliance and materiality beyond the objective reasonable consumer standard applied under the UCL, because Plaintiffs may not be able to establish each Class member's individualized understanding of Defendant's misleading representations as described in this Complaint, but the UCL does not require individualized proof of deception or injury by absent class members. *See, e.g., Stearns v Ticketmaster*, 655 F.3d 1013, 1020, 1023-25 (distinguishing, for purposes of CLRA claim, among class members for whom website representations may have been materially deficient, but requiring certification of UCL claim for entire class). In addition, Plaintiffs and the Class may be unable to obtain such relief under other causes of action and will lack an adequate remedy at law, if Plaintiffs are unable to demonstrate the requisite

mens rea (intent, reckless, and/or negligence), because the UCL imposes no such *mens rea* requirement and liability exists even if Defendant acted in good faith.

130. Plaintiffs seek, on behalf of themselves and those similarly situated, a declaration that the above-described trade practices are fraudulent, unfair, and/or unlawful.

131. Plaintiffs seek, on behalf of themselves and those similarly situated, an injunction to prohibit Defendant from continuing to engage in the deceptive and/or unlawful trade practices complained of herein. Such misconduct by Defendant, unless and until enjoined and restrained by order of this Court, will continue to cause injury in fact to the general public and the loss of money and property in that Defendant will continue to violate the laws of California, unless specifically ordered to comply with the same. This expectation of future violations will require current and future consumers to repeatedly and continuously seek legal redress in order to recover monies paid to Defendant to which they were not entitled. Plaintiffs, those similarly situated and/or other consumers nationwide have no other adequate remedy at law to ensure future compliance with the California Business and Professions Code alleged to have been violated herein.

PLAINTIFFS' FIFTH CAUSE OF ACTION
(Unjust Enrichment)
On Behalf of Themselves and the Class

132. Plaintiffs reallege and incorporate by reference all paragraphs alleged herein.

133. Plaintiffs and members of the Class members conferred a benefit on the Defendant by purchasing the Products.

134. Defendant has been unjustly enriched in retaining the revenues from Plaintiffs' and Class Members' purchases of the Products, which retention is unjust and inequitable, because Defendant sold Products that were not capable of being sold or held legally and which were legally worthless. Plaintiffs paid a premium price for the Products.

135. Because Defendant's retention of the non-gratuitous benefit conferred on them by Plaintiffs and Class members is unjust and inequitable, Defendant must pay restitution and nonrestitutionary disgorgement of profits to Plaintiffs and the Class members for its unjust enrichment, as ordered by the Court. Plaintiffs and those similarly situated have no adequate remedy at law to obtain this restitution.

135. Plaintiffs, therefore, seek an order requiring Defendant to pay nonrestitutionay disgorement of profits and make restitution to them and other members of the Class.

VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and those similarly situated, respectfully request that the Court enter judgement against Defendant as follows:

A. Certification of the proposed Class, including appointment of Plaintiffs' counsel as class counsel;

B. An order temporarily and permanently enjoining Defendant from continuing the unlawful, deceptive, fraudulent, and unfair business practices alleged in this Com-plaint;

C. An award of compensatory damages in an amount to be determined at trial;

D. An award of statutory damages in an amount to be determined at trial;

E. An award of punitive damages in an amount to be determined at trial;

F. An award of treble damages;

G. An award of restitution in an amount to be determined at trial;

H. An award of nonrestitutionary disgorgement of profits in an amount to be determined at trial;

I. An order requiring Defendant to pay both pre- and post-judgment interest on any amounts awarded;

J. For reasonable attorney's fees and the costs of suit incurred; and

J. For such further relief as this Court may deem just and proper.

IX. JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury.

DATED: August 10, 2022

GUTRIDE SAFIER LLP

/s/ Seth A. Safier /s/

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