No. 24-737

IN THE

Supreme Court of the United States

SPROUT FOODS, INC.,
Petitioner,

v.

GILLIAN DAVIDSON & SAMUEL DAVIDSON,
Respondents.

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

RESPONDENT'S BRIEF IN OPPOSITION

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QUESTION PRESENTED

The Nutrition Labeling and Education Act of 1990 ("NLEA") expressly permits states to adopt food labeling regulations "identical" to those contained in federal law. 21 U.S.C. § 343-1. In turn, the Food Drug and Cosmetic Act ("FDCA," of which the NLEA is a part) bans the private enforcement of the federal law, 21 U.S.C. § 337(a), but does not mention states' enforcement of their identical laws. The question presented is: does § 337(a) impliedly preempt the private enforcement of the very laws the NLEA explicitly allows states to adopt through § 343-1?

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INTRODUCTION

Petitioner Sprout Foods, Inc., manufactures and sells baby food products that it prominently advertises with front label nutrient content claims such as "3g of Protein, 5g of Fiber and 300mg Omega-3 from Chia ALA." Parallel federal and California regulations explicitly provide, however, that "no nutrient content claims may be made on food intended specifically for use by infants and children less than 2 years of age." 21 C.F.R. § 101.13(b)(3); Cal. Health & Safety Code § 110100. Sprout's blatant violation of these parallel rules gives it a marketplace advantage over its law-abiding competitors; enables it to drive up demand for its products; and, as a result, charge consumers higher prices. Respondents Gillian & Samuel Davidson filed this class action complaint under California's Unfair Competition Law ("UCL") to restore to consumers the money Sprout was able to overcharge them as a result of its unlawful competition for their business.

The court of appeals held that Respondents' claims were neither expressly nor impliedly preempted by the FDCA. Its rationale was based on the plain statutory text and this Court's existing case law. Section 343-1 of the NLEA allows states to adopt food labeling laws identical to those in the federal scheme, which California has done via the Sherman Food, Drugs, and Cosmetics Law (the "Sherman Law"). Moreover, the FDCA provision that gives rise to implied preemption, 21 U.S.C. § 337(a), prohibits private enforcement only of the FDCA itself, not identical state laws. As a result, this Court has long-recognized that § 337 does not impliedly preempt "state law causes of actions that parallel federal [FDCA] requirements." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001).

Despite this well-established precedent, Sprout argues that the decision below "conflicts with . . . and incorrectly applies *Buckman* . . . to reject implied preemption under § 337 of the FDCA." Pet. at 3. It points to one sentence from *Buckman* where this Court explained that § 337(a) impliedly preempts any state law claim that "exists solely by virtue of" FDCA "requirements." Pet. at 3 (quoting *Buckman*, 531 U.S. at 353). Sprout reasons that, since the Sherman Law copies federal food labeling regulations, it must, thereby, exist solely by virtue of federal law. *Id.*

But Sprout ignores that the sole sentence from *Buckman* on which its argument rests related to claims alleging direct violation of *federal law* while committing fraud on a *federal agency*. Specifically, the plaintiff's "fraud-on-the-FDA" claim was based on defendants' failure to abide by FDCA requirements to disclose certain facts to the FDA during pre-market approval of its product. 531 U.S. at 347. Yet, as this Court explained, states have no authority to govern "the relationship between a federal agency and the entity it regulates," as that relationship is "inherently federal in character." *Id.* It was the dearth of state authority over what a manufacturer must say to a federal agency that led this Court to hold that the fraud claim there existed "solely by virtue of the FDCA disclosure requirements." *Id.* at 353.

By contrast here, there is nothing "inherently federal" about the relationship between food manufacturers and consumers, and states have long used their traditional police powers to govern what such manufacturers may say to state citizens about their products. *E.g.*, *Plumley v. Massachusetts*, 155 U.S. 461, 472 (1894) (recognizing states' "plenary" power over food labeling). So, unlike in *Buckman*,

where, absent the FDCA, the states' ability to "polic[e] fraud on a federal agency" would *disappear entirely*, 531 U.S. at 347, here, absent the FDCA, California could *still have* the exact same prohibition on baby food advertising currently at issue in this case due to its own inherent authority. That necessarily precludes a determination that the Sherman Law exists "solely by virtue of the FDCA."

Sprout's next assertion, that the decision below "creates a circuit split" is false. Pet. at 4. *Every* court of appeals to address the question has, like the Ninth Circuit below, held that § 337(a) does not impliedly preempt private enforcement of state law requirements that parallel federal requirements under the FDCA. The cases to which Sprout points are, like *Buckman*, cases where a plaintiff attempted to use state law to enforce federal law *in the absence* of any parallel state duty.

Finally, Sprout's assertions that the decision below will disrupt the NLEA's national uniform food labeling scheme is greatly overstated. Pet. at 4. Under § 343-1, any state food labeling requirements must still be *identical* to federal law. And although "judges and juries in courts throughout the country" applying an identical standard "may give rise to some variation in outcome", that is "quite different from the disuniformity that would arise from the multitude of state laws, state regulations, state administrative agency rulings, and state-court decisions that are partially forbidden by the FDCA's preemption provision." *Pom Wonderful v Coca Cola,* 573 U.S. 102, 117 (2014).

The petition should be denied.

STATEMENT

Statutory and Regulatory Background

The Federal Preemption Provisions

The FDCA governs food, drugs, cosmetics, and medical devices, and grants the FDA implementation authority. However, each category is regulated and preempted differently. For example, medical devices fall under the Medical Device Amendments ("MDA"), whereas food products and labeling fall under the Nutrition Labeling & Education Act of 1990 ("NLEA").

Congress passed the NLEA to prescribe national, uniform nutrition labeling on all foods. To accomplish this objective, Congress included an express preemption clause providing that "no State or political subdivision of a State may directly or indirectly establish . . . as to any food in interstate commerce . . . any requirement for the labeling of food . . . that is not identical to the requirement[s] of [the federal scheme]." 21 U.S.C. § 343-1(a)(4). Notably, Congress still saw and reserved a role for state law. Section 343-1 expressly allows states to adopt food labeling requirements so long as they are identical to those in the federal scheme. *Id.*

The FDCA also contains a provision that this Court has interpreted as giving rise to implied preemption. Section 21 U.S.C. § 337(a) states that "[e]xcept 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." Put simply, there is no private right of action to enforce the FDCA itself. However, § 337 does not mention the private enforcement of state law requirements identical to those in the FDCA, such as those that § 343-1 of the NLEA expressly allows states to adopt.

California's Food Labeling Laws

California has long regulated food labeling. For example, since 1939, California has provided that "[a]ny food is misbranded if its labeling is false or misleading in any particular." Cal. Health & Safety Code § 110660, previously codified as Cal. Health & Safety Code § 26490. In 1970, California enacted the Sherman Food Drug & Cosmetic Law to introduce comprehensive food and drug regulations. *See* Cal Stats. 1970 ch. 1573.

In the early 1990s, in direct response to the NLEA, California amended the Sherman Law to, as § 343-1 required, make its food-labeling regulations "identical to" the newly-enacted federal labeling scheme. 1992 Cal Stats. ch. 843. Accordingly, it adopted as "the food labeling regulations of" California, "[a]ll 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." Cal. Health & Safety Code § 110100.

California's UCL, enacted in 1933, in turn, provides a private remedy for California consumers who have lost money or property as a result of any unlawful competition, including violations of the Sherman Law's food labeling requirements. Cal. Bus. & Prof. Code § 17200, et seq.

The Specific Food Labeling Regulations at Issue

In implementing the NLEA, the FDA promulgated regulations governing nutrient content claims, i.e., advertising claims that describe or characterize the nutrient levels in the product. 21 C.F.R. §§ 101.13(b) & (c). One of these regulations states that: "no nutrient content claims may be made on food intended specifically for use by infants and children less than 2

years of age." 21 C.F.R. § 101.13(b)(3). The FDA prohibited these claims because it "lack[ed] evidence that . . . an increased intake for nutrients such as fiber are appropriate and recommended for infants and toddlers"; FAC ¶ 44 (citing 56 Fed. Reg. 60421), and because such claims can mislead consumers to believe that a product will help their child maintain "healthy dietary practices relative to the amount of the nutrient consumed" when that is not true, "since many consumers have a limited knowledge and understanding of the amounts of nutrients that are recommended for daily consumption." *Id.* ¶ 41 (quoting 56 Fed. Reg. 60426). In short, "[t]he 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." Pet. App. 7a.

California has, through the Sherman Law, enacted an identical prohibition on such claims, creating a parallel state-law duty to refrain from advertising baby food products with nutrient content claims.

Factual background

Sprout, Inc., manufactures and sells baby food pouch products containing pureed foods specifically intended for children under two. FAC ¶¶ 13-20. For example, it advertises its Products with nutrient content claims such as "3g of Protein, 4g of Fiber and 300mg Omega-3 from Chia ALA." *Id.* These claims violate parallel state and federal laws that prohibit nutrient content claims on products intended for children under two. Cal. Health & Safety Code § 110100; 21 C.F.R. § 101.13(b)(3). Plaintiffs purchased the Products in reliance on the nutrient content claims and paid more money for them as a result. FAC ¶¶ 70,

76. Plaintiffs bring a claim under the UCL for violation of the Sherman Law's prohibition on advertising baby foods with nutrient content claims.

Plaintiffs' complaint expressly states: "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." FAC ¶¶ 89-90.

Proceedings below

Sprout moved to dismiss Plaintiffs' UCL unlawful prong claim on the ground of implied preemption, and the district court granted the motion. Pet. App. 59a. It did so based entirely on its own decision in a prior case, which held that this Court's opinion in *Buckman* impliedly preempted California state food-mislabeling claims because the Sherman Law "'is entirely dependent upon the FDCA, in that it expressly adopts the FDCA and regulations as state law.'" *Id.* at 60a. (quoting *Chong v. Kind LLC*, 585 F. Supp. 3d 1215, 1219 (N.D. Cal. 2022) (citing *Buckman*, 531 U.S. at 353)). The district court believed 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," *Buckman* meant that "Plaintiffs' claim is preempted." *Id.*

The court of appeals reversed. It concluded that the NLEA "expressly permits states to enact standards identical to the federal standards"; that plaintiffs here "are attempting to enforce identical standards set forth in a state statute" rather than to enforce federal

law; and that "federal law does not limit the manner in which the state statute [can be] enforced" since "the text of § 337(a) [] addresses only enforcement of the federal law." Pet. App. 4a–5a; 17a. In so holding, the court of appeals analyzed and applied several of this Court's preemption decisions.

Because the district court had relied on *Buckman* to find implied preemption, the court of appeals began its analysis with that case. It explained that "[p]laintiffs there were attempting to use causes of action available under state law to claim damages for violations of duties owed under the federal FDCA" without a parallel state duty. Pet. App. At 11a–12a. *Buckman* had found implied preemption because "the claims existed 'solely by virtue of FDCA requirements' to make disclosures to the FDA during the pre-market approval process" for medical devices rather than any reporting duties arising under state law. *Id.* at 12a (quoting *Buckman*, 531 U.S. at 353). This meant that "the duties allegedly violated were duties owed to the federal agency," making the claim "in essence a claim of violation of federal law" not state law, which "inevitably conflict[ed]" with § 337(a). *Id.* at 12a (citing *Buckman*, 531 U.S. at 348, 353). By contrast here, the court of appeals held that "plaintiffs are claiming violations of California law, the Sherman Law, not the federal FDCA." *Id.* at 13a.

Moreover, the court of appeals noted that "where private plaintiffs claimed violations of state law, as opposed to federal standards," this Court has "held the claims are not preempted." *Id.* at 14a. In *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), for example, this "Court interpreted a preemption provision similar to § 343-1 [] in this case, as permitting states to enact requirements identical to those imposed by the federal

law." *Id.* at 14a (citing *Lohr*, 518 U.S. at 496–97). This Court further interpreted that provision (which arose under the medical device amendments to the FDCA) as allowing states "'the right to provide a traditional damages remedy for violations of [state law] duties when those duties parallel federal requirements'", i.e., as allowing private enforcement of the state parallel. *Id.* (quoting *Lohr*, 518 U.S. at 495). This Court has likewise interpreted other statutory schemes with similar provisions "to permit private enforcement of parallel state requirements." Pet. App. 18a–19a (discussing *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) and *Bates v. Dow Agrosciences*, 544 U.S. 431, 432 (2005)).

Finally, the court of appeals explained that in keeping with the "longstanding presumption against preemption" in implied preemption cases, "even if [it] were to conclude that there is some doubt as to whether § 337 permits private enforcement of [identical] state laws," it "would still have to reverse the district court and hold the plaintiffs' claim is not preempted." Pet. App. 19a. As this Court explained in *Bates*, when courts "are faced with 'plausible alternative readings' of a statute's preemptive effect, [they] apply this presumption and 'have a duty to accept the reading disfavoring pre-emption.'" *Id.* 20a (quoting *Bates*, 544 U.S. at 432). "Thus, even if Sprout's interpretation of § 337 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." *Id.*

REASONS FOR DENYING THE PETITION

I. The decision below does not create a conflict among the circuits.

When considering implied preemption under the FDCA, all federal courts of appeals apply the same precedents as in this case, state the same principles, and reach consistent conclusions. Indeed, every circuit court to address the question has held that § 337 does not impliedly preempt the private enforcement of state law requirements that mirror or parallel federal requirements under the FDCA. *E.g.*, *Bausch v. Stryker Corp.*, 630 F.3d 546, 556 & 558 (7th Cir. 2010) (rejecting argument "that only the FDA can enforce the regulations on which Bausch's claims are based" and holding that "federal law does not [impliedly] preempt parallel claims under state law based on a [defendant's] violation of federal law"); *Hughes v. Bos. Sci. Corp.*, 631 F.3d 762, 775–76 (5th Cir. 2011) (rejecting implied preemption under § 337(a) because "parallel state claims survive a defendant's preemption defense" and "because states may impose an additional 'damages remedy for claims premised on violation of FDA regulations"); *LeFaivre v. KV Pharm. Co.*, 630 F.3d 733, 742 (8th Cir. 2011) (8th Cir. 2011) ("[S]imply because conduct violates the FDCA does not mean a state-law claim based on that same conduct depends on the FDCA's existence. . . . implied preemption does not bar Lefaivre's [parallel] state law claims")); *Dumont v. Reily Foods Co.*, 934 F.3d 35, 41 (1st Cir. 2019) (rejecting argument that "chapter 93A . . . is impliedly preempted as an attempt to use a state law to enforce federal requirements"). So too has this Court. *E.g.*, *Buckman*, 531 U.S. at 353 (recognizing that § 337 allows "state law causes of actions that

parallel federal [FDCA] requirements."). No decision that the petition cites suggests otherwise.

Sprout spends most of its argument discussing *DiCroce v. McNeil Nutritionals, LLC*, 82 F.4th 35 (1st Cir. 2023), but its reliance on that case is misplaced. Far from being "nearly identical" to this case, as the petition claims (Pet. at 14), the only similarity is the fact that *DiCroce* also involved food labeling claims. The underlying state law regimes in each case are very different, and that difference is what resulted in the First Circuit's conclusion of implied preemption. But reaching an opposite conclusion based on different facts is not a conflict.

The plaintiff in *DiCroce* had challenged claims on the package of Lactaid that it could "prevent 'gas,' 'bloating,' and 'diarrhea' 'associated with digesting dairy.'" 82 F.4th at 38. According to plaintiff, those are claims that the product can treat the "disease" of "lactose intolerance," which the NLEA prohibits on dietary supplements. *Id.*; *see also* 21 U.S.C. § 343(r)(6) (providing that dietary supplements "may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases."). However, although federal law clearly prohibited the claims, *Massachusetts had no parallel duty*. It has no corollary to California's Sherman Law or UCL. Instead, under Massachusetts' consumer protection regime, "a violation of a law or regulation . . . will be a violation of c. 93A, §2(a) only if the conduct leading to the violation is unfair or deceptive." *Klairmont v. Gainsboro Rest., Inc.*, 987 N.E.2d 1247, 1255 (Mass. 2013). Accordingly, as the First Circuit explained in *Dicroce*, aside from federal law, "DiCroce provides *no other grounds* on which her claims could survive." 84 F.4th at 41 (emphasis added). Plaintiff had argued

that state law prohibited the disease claims because they were deceptive, but that failed because DiCroce did "not contend that Lactaid did not perform as promised" and, in fact, admitted that the "statements are 'literally true.'" *Id.* The only remaining reason DiCroce contended the statements were deceptive was "because they violate the FDCA." *Id.* Thus, the First Circuit concluded that DiCroce's claims "are impliedly preempted" because "DiCroce, like the plaintiffs in *Buckman* is alleging fraud under the FDCA." *Id.*[1]

However, when Massachusetts law *has* imposed a parallel food labeling duty identical to one in the federal regulations, the First Circuit, like the Ninth Circuit in the instant case, has held that the claim is not impliedly preempted. *E.g.*, *Dumont*, 934 F.3d at 43. In *Dumont*, the relevant federal regulation was 21 C.F.R. § 101.22(i), which prohibits manufacturers from labeling a product with a characterizing flavor if "none of the natural flavor used in the food is derived from the product whose flavor is simulated." 21 C.F.R. § 101.22(i)(1)(iii). Plaintiff claimed that the defendant had violated this prohibition with the statement "Hazelnut Créme" because the flavor in the product was not derived in any way from hazelnuts. *Dumont*, 934 F.3d at 37. The defendant argued that this was an impliedly preempted attempt to enforce the FDCA's food labeling regulations, but, in complete alignment with the Ninth Circuit's decision in this case, the First

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[1] Far from evidencing a conflict, the Ninth Circuit has also found implied preemption on facts similar to *DiCroce*. *See* Pet. App. 12a (explaining that in *Perez v. Nidek Co.*, 711 F.3d 1109, 1117 (9th Cir. 2013) the court held that a state law claim that "rested 'solely [upon a] failure to disclose lack of FDA approval'" existed "'solely by virtue of the FDCA . . . rather than a state law duty").

Circuit ruled against implied preemption. It held that Massachusetts' chapter 93A imposed an identical duty on food manufacturers not to use claims about characterizing flavors when they were not derived from the actual source because doing so is deceptive. *Id.* at 43. As a result, the complaint alleged liability "not because the label constitutes misbranding under federal law," but because it violated "chapter 93A" which meant that the claim was "not impliedly preempted by federal law." *Id.* It was of no moment that the state standard would need to reference and copy the federal regulations, as that was necessary "to counter a claim of express preemption" under § 343-1. *Id.* The FDCA's "dual preemptive force" required determining "whether conduct that does violate the federal regulations" also violates state law. *Id.* In short, the First Circuit is in full agreement with the Ninth Circuit in this case, as well as all other circuits.

Sprout spends less time on the Sixth Circuit's unpublished decision in *Loreto v. Procter & Gamble Co.*, 515 F. App'x 576, 579 (6th Cir. 2013), but it is similar to *DiCroce* and evidences no conflict with the Ninth Circuit's decision in this case. In *Loreto*, the Sixth Circuit analyzed two theories of liability relating to the defendants' use of "vitamin C" claims to advertise its products, and held that only one was impliedly preempted. *Id.* The first was that certain "products were 'illegal' . . . because their labeling did not comply with the FDCA's requirements" surrounding the use of Vitamin C claims to treat the common cold. *Id.* The court concluded that this theory was impliedly preempted. *Id.* That is unsurprising, since the plaintiff made no argument that state law imposed any similar labeling duties, and therefore the "theory of liability depend[ed] entirely upon an FDCA

violation—*i.e.*, the *only* reason Proctor & Gamble's products were allegedly 'illegal' was because they failed to comply with FDCA labeling requirements." *Id.* However, the court held that the plaintiff's second theory was *not* preempted because it *was* based on a parallel state law duty. The second theory was that it was misleading to represent "that taking Vitamin C can blunt the effects of a cold" which the Sixth Circuit concluded was a parallel state law duty and therefore not preempted. *Id.* That is perfectly in line with the Ninth Circuit's ruling here.

Sprout also suggests that the Second Circuit's decision in *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105 (2d Cir. 1997), is in conflict with the decision below, but that case has no bearing on the issue here. *PDK Labs* involved an appeal from a grant of summary judgment that the plaintiff lacked standing under either the Lanham Act or Georgia's consumer protection statutes to challenge how the defendant advertised its diet pill because the plaintiff had no product in the market and was therefore not a competitor of the defendant; the court of appeals affirmed summary judgment on this ground. *Id.* at 1111–13. The court did observe, in one sentence of dicta, that "Friedlander's dogged insistence that PDK's products are sold without proper FDA approval *suggests* . . . . that [his] true goal is to privately enforce alleged violations of the FDCA." *Id.* at 1113 (emphasis added). But the Second Circuit did not analyze implied preemption, whether there were any parallel state duties at play, nor issue any ruling on the subject. *Id.* In fact, the court specifically held that "Friedlander's arguments with respect to this complex web of federal regulations are beside the point" because he lacked standing. *Id.* at 1112.

In sum, each court of appeals' decision that Sprout cites states the same legal standard as the decision below and reaches results fully consistent with the outcome here. There is accordingly no conflict among the circuit courts on the issue of implied preemption under the FDCA.

II. The decision below faithfully applied this Court's precedents, including *Buckman*.

A. Sprout repeatedly claims that the decision below "conflate[s] the scope of the FDCA's express preemption with the scope of its implied preemption" and that the court of appeals "sidestepped" the implied preemption analysis due to concluding that Plaintiffs' claims were not expressly preempted. Pet. 16–17. Sprout even accuses the decision below of using "§ 343-1's express preemption provision" to "nullify[] § 337's implied preemptive effect." Pet. 18. In fact, the decision below explicitly recognizes that state law may be impliedly preempted even when it is not expressly preempted, explaining that, even though "[t]he parties agree that the federal statute does not expressly preempt private enforcement of the state statute . . . . Still the Supreme Court has recognized that preemption of state law may be implied where preemption 'was the clear and manifest purpose of Congress.'" Pet. App. 8a (quoting *Altria Grp., Inc. v. Good*, 555 U.S. 70, 77 (2008)). Thus, far from supplanting implied preemption with express preemption, the court of appeals simply concluded that implied preemption did not arise under the circumstances here.

Moreover, Sprout's desire to ignore the NLEA's express preemption provision is itself wrong. "The ultimate touchstone in every pre-emption case" is

giving effect to "the purpose of Congress." *Wyeth v. Levine*, 555 U.S. 555, 565 (2009). And, when a statute contains an express preemption provision, Congress's preemptive purpose is "primarily discerned" from the text of that provision itself. *Lohr*, 518 U.S. at 485. The decision below correctly determined that the text of § 343-1 "expressly permit[s]" states to adopt "food labeling requirements . . . 'identical' to federal standards." Pet. App. 11a. And, in "permitting parallel state laws, the FDCA did not even purport to limit enforcement of such parallel state laws in any way"—either in the text of § 343 or § 337. *Id.* That certainly suggests that Congress did *not* intend to preempt the private enforcement of such identical state laws. *See Chamber of Commerce of the U.S. v. Whiting*, 563 U.S. 582, 600–01 (2011) ("Given that Congress specifically preserved such authority for the States, it stands to reason that Congress did not [impliedly] intend to prevent the States from using appropriate tools to exercise that authority.").

The decision below also explained that "Section 343-1 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." Pet. App. 18a (citation omitted). These include the express preemption provision of the Medical Device Amendments to the FDCA, § 360k(a)—which is also subject to § 337's ban on private enforcement of the FDCA itself—and the express preemption provision of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)). *Id.* 18a–19a. In *Lohr*, this Court interpreted § 360k of the MDA, which preempts "non-identical" state requirements as allowing "state rules

that merely duplicate some or all of those federal requirements." 518 U.S. at 495. Then, in *Rigel*, this Court held that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations." 552 U.S. at 330. And, in *Bates*, this Court interpreted FIFRA's ban on "non-identical" state requirements as allowing "[t]he imposition of state sanctions for violating state rules that merely duplicate federal requirements." 544 U.S. at 442.

Sprout insists, that, although "[t]he FDCA authorizes states to pass 'identical' state laws," it nevertheless intended that those state laws only "be enforced by the appropriate state authorities," Pet. 18, a position that neither this Court nor any court of appeals has ever adopted. Sprout divines this novel rule from § 337(b)'s limitation that state attorneys general can enforce only certain provisions of the federal law. *Id.* But as the decision below correctly explains, the problem with this argument is that the plain "text of § 337(b) . . . relates only to the enforcement of the federal law. It does not limit enforcement of state law." Pet. App. at 17a. Indeed, Sprout still has no answer to this basic question: if Congress intended to allow states to enact identical food labeling requirements, but to limit the enforcement of those requirements to an "appropriate state authority," then why not say so? After all, if that was Congress's true pre-emptive purpose, then, as the court of appeals observed, "its failure even to hint at it is spectacularly odd." Pet. App. 16a.

Sprout's only attempt to answer this basic question is to flip it, by arguing instead that "[i]f Congress wanted both states and their residents to enforce these [state] food labeling provisions through either a

state agency or private action, [Congress] could have easily and clearly done so when enacting the NLEA." Pet. 19. But unfortunately for Sprout, "[t]here is no federal preemption *in vacuo*." *Kansas v. Garcia*, 589 U.S. 191 (2020). Even implied preemption arguments "must be grounded in the text and structure of the statute at issue." *Id.* at 207. So, while Sprout would have federal law supplant *all* state law on an overlapping subject matter *unless* the text explicitly preserves it, this Court has held the opposite: state law is *not* supplanted in overlapping areas absent Congress's clear intention to do so. *See id.* at 211–12 ("[T]here is no basis for inferring that federal criminal statutes preempt state laws whenever they overlap."); *Lohr*, 518 U.S. at 485 ("Congress does not cavalierly pre-empt state-law causes of action."). And, in any event, § 343-1 does specifically preserve identical state food labeling laws.

B. Sprout next insists that the ban on private enforcement of identical state standards can be found in this Court's decision in *Buckman*, which Sprout contends the decision below "incorrectly applied." Pet. 16. According to Sprout, 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" because the Sherman Law copies federal requirements—as it must under § 343-1. Pet. 21. But as the court of appeals correctly determined, *Buckman* does not counsel implied preemption here. Pet. App. 12a–13a. Indeed, *Buckman* recognizes that § 337 does not impliedly preempt "state law causes of actions that parallel federal [FDCA] requirements"—as are at issue in this case. 531 U.S. at 353. *Buckman* dealt

with an entirely different situation where there was no parallel state duty.

In *Buckman* the plaintiff brought a state law fraud-on-the-FDA claim relating to the federal pre-market approval ("PMA") process for Class III medical devices. The MDA requires device-manufacturers to disclose particular facts to the FDA during the PMA process, and the plaintiffs alleged that the defendant made misrepresentations to the FDA during that process in violation of its MDA disclosure duties, which led to the device being approved. *Buckman*, 531 U.S. at 343–44, 347. Defendant was not the device manufacturer, but a third-party consultant hired to assist with PMA review. State law created no actionable duties from the third-party to the plaintiffs. So instead, the plaintiffs argued that "but for" the consultant's violation of its MDA reporting duties to the FDA, the agency would not have approved the devices, which in turn meant that the devices would not have been available to injure plaintiffs. *Id.* at 343.

This Court held that the FDCA impliedly preempted this "fraud-on-the-FDA claim." *Id.* at 348. First, it explained "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied." *Id.* at 347. Next, it determined that states, indeed, had *no authority* to regulate what a third-party consultant must say to a federal agency *absent* the FDCA, because "the relationship between a federal agency and the entity it regulations is inherently federal in character"; it "originates from, is governed by, and terminates according to federal law." *Id.* This meant that, "the fraud claims exist *solely* by virtue of the FDCA disclosure requirements" rather than any feature of state law. *Id.* at 352–53 (emphasis added). Thus, this Court concluded that the claim was

really an attempt to privately enforce the MDA itself, in violation of § 337(a), rather than an attempt to privately enforce a parallel state requirement.

Here, by contrast, as the decision below correctly recognizes, there is nothing "inherently federal" about the relationship between food manufacturers and consumers—in fact, policing the statements such manufacturers make to consumers *is* a field the States have traditionally occupied. Pet. App. 19a. This Court has long recognized this historic police power. *See Plumley*, 155 U.S. at 472 ("If there be any subject over which it would seem the states ought to have plenary control . . . it is the protection of the people against fraud and deception in the sale of food products."). Not only does this mean that, unlike in *Buckman*, the presumption against implied preemption "applies with particular force" here, *Altria Group, Inc.*, 555 U.S. at 77, it also means that Plaintiff's Sherman law claims do not exist "solely by virtue of the FDCA [labeling] requirements." *Buckman*, 531 U.S. at 353. Instead, they exist due to California's inherent authority and historic police power over food labeling. Thus, even if the FDCA were rescinded or never existed, California could still prohibit manufacturers from advertising baby food products with nutrient content claims, which means Plaintiffs' state law claims here could still exist. That is a stark contrast to *Buckman*, where the state law "fraud-on-the-FDA claim" was premised on disclosures to a federal agency, required by federal law, during the federal PMA process. 531 U.S. at 347-48. The state clearly could not have had any such requirement in the absence of the FDCA because there would be no FDA or PMA process at all, let alone regulations about

what must be disclosed to the FDA during that process. *Id.*

Finally, the court of appeals was also correct to hold that the presumption against preemption applies, and counsels against implied preemption here. Pet. App. 19a–20a. Sprout does not dispute that the presumption applies in cases of implied preemption, or that food labeling is within the States' historic police powers; its only contention is that the "presumption is not a dispositive bar." Pet. 20. But, of course, the court of appeals did not treat it as such. It merely held, in the alternative, that "even if Sprout's interpretation of § 337" as banning the private enforcement of state law "were equally plausible,"—a conclusion the court had already rejected—then the presumption against preemption would create "a duty to accept the reading disfavoring pre-emption.'" *Id.* 20a (quoting *Bates*, 544 U.S. at 432); *see also Altria Group, Inc.*, 555 U.S. at 77 (same). That is fully consistent with this Court's precedent.

III. The consequences petitioner hypothesizes are overblown.

Sprout finally contends that this case is "exceptionally important" because it believes that the decision will "frustrat[e] the NLEA's purpose of a national uniform labeling regime" by requiring "different [food] labels based on the jurisdiction in which [the products] were sold." Pet. 23. Sprout also believes the decision will open "the floodgates" of litigation by "provid[ing] states a road map to bestow a private right of action on its citizens" to "enforce FDCA's food labeling requirements." Pet. 25; 26. These purported concerns are misplaced.

Sprout's first concern is easily dispatched. Under the NLEA's express preemption provision, any state food labeling laws must still be *identical* to those in the FDCA. So there is national uniformity in food labeling requirements even if private parties can sue to enforce those uniform requirements in different regions. Indeed, this Court has already considered and rejected a virtually identical argument regarding food mislabeling claims in *Pom Wonderful v Coca Cola,* 573 U.S. 102 (2014).

In *Pom Wonderful*, the question was whether § 337(a) of the FDCA precluded private parties (there a competitor) from bringing Lanham Act claims about misleading food labeling. 573 U.S. at 113. This Court held that it did not, and, in part, for reasons very similar to those that the decision below used to reject implied preemption here.[2] First, this Court examined the NLEA's express preemption provision and determined that "[b]y taking care to mandate express pre-emption of some state laws, Congress if anything indicated it did not intend the FDCA to preclude requirements arising from other sources." *Id.* at 114. Second this Court examined § 337(a) and concluded that the ban on private enforcement of the FDCA itself did not mean "that Congress intended to foreclose private enforcement of other" laws that touch on food mislabeling. *Id.* at 116–17.

The defendant nevertheless argued that allowing such claims would undermine the goal of national

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[2] Although this Court explained that the preclusion of one federal statute by another is "not govern[ed]" by "the Court's pre-emption precedent" it found those "principles are instructive insofar as they are designed to assess the interaction of laws that bear on the same subject." *Pom Wonderful,* 573 U.S. at 111–12.

uniformity in food labeling and lead to "a patchwork of requirements" depending on jurisdiction. *Id.* at 117. This Court rejected that argument, holding that "[a]lthough the application of a federal" standard by "judges and juries in courts throughout the country may give rise to some variation in outcome" that is "quite different from the disuniformity that would arise from the multitude of state laws, state regulations, state administrative agency rulings, and state-court decisions that are partially forbidden by the FDCA's preemption provision." *Id.* at 117. Instead, the only variability that arises is due to the fact that the same federal standard is "enforced on a case-by-case basis," which this Court found to be insufficient. *Id.* at 118. The same holds true here.[3]

As for Sprout's concern that the decision below will open the floodgates of litigation, that argument is speculative and overstated. The simple fact is that parallel state laws have been privately enforceable for 30 years and the court system has not been overloaded with private suits.

In any event, the argument overlooks a more fundamental point. Even if there were an abundance of food-labeling lawsuits, *that would be perfectly in line with the purpose of Congress*. As explained above, § 343-1 of the NLEA expressly permits states to adopt identical requirements, and nothing in the NLEA or the FDCA prohibits the private enforcement of those

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[3] The amicus's "California Effect" argument, whereby California will purportedly supplant, nationwide, the FDA's labeling regime with its own "more stringent" "California requirements" is completely unfounded. It ignores that § 343-1 prohibits any state, including California, from adopting more stringent requirements.

identical state standards. It is not this Court's place to expand preemption beyond what Congress intended just because the Court believes that Congress's current regime might allow for too many lawsuits. As this Court has repeatedly held, "it is Congress rather than the courts that preempts state law." *Whiting*, 563 U.S. at 607. In other words, if Congress believes that the current preemption regime allows for too many lawsuits, Congress can respond by expanding the scope of preemption, not this Court.[4]

Finally, the amicus argues that preemption should expand to supplant *all* private food labeling lawsuits because it believes "that food labeling often involves complex, science-driven determinations about nutrition, health impacts, and consumer understanding" that requires "specialized judgment and the balancing of policy considerations" all within the "specialized expertise" of the FDA. Amicus at 9–10.[5] But, again, this Court has already rejected a similar argument in *POM Wonderful*, explaining that "[u]nlike other types of labels regulated by the FDA, such as drug labels," the "FDA does not preapprove food and beverage labels under its regulations." 573 U.S. at 116. In fact, the FDA plays a much "less

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[4] For a similar reason, the amicus' policy based arguments for why it believes the FDCA *should* preempt all private lawsuits relating to food mislabeling (Amicus at 12-18), despite being speculative and overblown, do not justify the preemption of state law that Congress did not intend. Those arguments are, again, suited for Congress not this Court.

[5] The amicus' position is not the law anywhere. As explained above, every court to consider the question, including this Court, has held that the FDCA does not preempt private enforcement of parallel state requirements that touch on food, drugs, or medical devices. *Supra*, p. 10.

extensive role . . . in the regulation of food than in the regulation of drugs" or medical devices in general. *Id.* at 109. Thus, precluding any private food mislabeling lawsuits (there based on competitor Lanham Act claims) would leave "the public at large" with "less effective protection in the food and beverage labeling realm" than in many other industries, and this Court believed it "unlikely that Congress intended the FDCA's protection of health and safety to result in less policing of misleading food and beverage labels than in competitive markets for other products." *Id.* at 116; *accord Lohr*, 518 U.S. at 487 (finding it implausible that "Congress effectively precluded state courts from affording state consumers any protection from injuries resulting from a defective medical device").

In any event, even the amicus acknowledges that the regulation at issue here prohibiting nutrient content claims on baby food is "straightforward." Amicus at 8. Amicus simply speculates that there may be "future suits on more complicated or less clear-cut labeling issues" that warrant specialized expertise. *Id.* If such a case arises (which is unlikely given that *Buckman* already impliedly preempts claims that are "inherently federal in character," such as those requiring FDA input or discretionary determinations), then this Court could take the issue up at that time. There is no need for the Court to weigh in on protecting the FDA's specialized expertise in a case where everyone agrees no such expertise is required.

CONCLUSION

For the foregoing reasons, the petition should be denied.

Respectfully submitted,

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