No. 24-737

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

REPLY BRIEF FOR PETITIONER

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REPLY BRIEF FOR PETITIONER

I. Introduction

The Davidsons' attempt to recast the decision below as a routine application of existing law defies the actual text and structure of the Food Drug & Cosmetic Act ("FDCA"). The Davidsons seem to believe that 21 U.S.C. § 343-1 is an express *permission* provision inviting states and private citizens alike to link arms with the Food and Drug Administration ("FDA") in a united front to enforce FDCA food labeling regulations. To the extent such belief envisions private enforcement of FDA regulations (whether alone or co-opted as state law), that vision directly conflicts with 21 U.S.C. § 337(a) and is thus preempted.

In reality, § 343-1 is an express *preemption* provision and when interpreted in conjunction with § 337's exclusive enforcement provision, Congress's directive, grounded in FDCA's text, is clear: enforcement of FDCA and its promulgated regulations "shall be by and in the name of the United States" with limited federally-coordinated state enforcement pursuant to § 337(b). The Davidsons' suggestion that § 343-1 is a unique statute or somehow exempt from this Court's FDCA preemption precedent is belied by similar express preemption provisions of other FDCA regulated products. *Compare* 21 U.S.C. § 343-1 *with id.* § 360k (medical devices); *id.* § 364j (cosmetics); *id.* § 379r (nonprescription drugs); and *id.* § 379s (cosmetic labelling or packaging).

Relying on California's Sherman Law wholesale co-opting of all FDCA food labeling regulations, the Davidsons' claim directly conflicts with § 337(a)'s directive that the Federal Government exclusively enforce non-compliance with FDCA provisions. The

Davidsons' reliance on § 343-1's express preemption provision does not cure this conflict, fails to interpret both provisions harmoniously, renders § 337 superfluous, and disregards this Court's precedent. The Court should grant review and reject their untenable construction of FDCA.

II. The Decision Below is Egregiously Wrong.

1. Sprout does not dispute that the preemption analysis here must "be grounded in the text and structure of the statute at issue." *Kansas v. Garcia*, 589 U.S. 191, 208 (2020). However, the Ninth Circuit's interpretation of § 337 and § 343-1 ignores this canon by disregarding the critical structural interplay between the two provisions, seeking to untether one from another, and failing to give each its full textual effect. *See Virginia Uranium, Inc. v. Warren*, 587 U.S. 761, 767 (2019) (analysis of a statute's preemptive effect is "guided by the traditional tools of statutory interpretation."). Under the Supremacy Clause, "[i]f federal law 'imposes restrictions or confers rights on private actors' and 'a state law confers rights or imposes restrictions that conflict with the federal law,' 'the federal law takes precedence and the state law is preempted.'" *Kansas*, 589 U.S. at 202 (quoting *Murphy v. National Collegiate Athletic Assn.*, 584 U. S. 453, 477 (2018)). Indeed, a state law is rendered inoperative when it "directly conflict[s]" with federal law. *See AT&T Co. v. Central Office Tele.*, 524 U.S. 214, 227 (1998).

Section 337(a) provides that "all proceedings for the enforcement…of [FDCA] shall be by and in the name of the United States." And, the Sherman Law equally prohibits private enforcement of FDCA provisions incorporated into California law. *See* Cal. Health & Safety Code § 110045; § 110100(a). Yet here, the

Davidsons have sought to bypass both statutory directives as their complaint plainly seeks to find Sprout liable for FDCA violations as incorporated *by reference* into California's Sherman Law. *See* Pet.App. 87a—93a at ¶¶ 21, 22, 23, 27, 41, 42, 43, 44, 45, 46 (citing to FDCA, FDA food labeling regulations, and FDA regulatory decisions). The Davidsons' Sherman Law claim seeks to enforce FDCA and directly conflicts with § 337(a). Consequently, it is preempted. The Davidsons fail to acknowledge the direct conflict present in this case, hoping to sweep it aside by defending the Ninth Circuit's cabined interpretation of § 343-1.

2. The Davidsons' argument that § 343-1 expressly permits their Sherman Law claim collapses under scrutiny. Section 343-1 simply prohibits states from establishing requirements that are "not identical" to the food labeling requirements provided in various FDCA sections, including § 343(q) and § 343(r). That the Sherman Law itself may be permitted under § 343-1 does not shield the Davidsons' claim which is premised on that law from preemption under § 337(a) as improper private enforcement of FDCA. Yet the Ninth Circuit seemed to divine Congress's intent for private enforcement of such a claim from § 343-1 alone. Opp. 16 ("And, in 'permitting parallel state laws, the FDCA did not even purport to limit enforcement of such parallel state laws *in any way*' in either the text of § 343 or § 337."). This is simply not true.

First, the Davidsons fail to address that *Buckman Co. v. Plaintiffs' Legal Committee* recognized that the scope of express preemption for FDCA requirements under § 360k (a similar express preemption statute as § 343-1) is not identical with the scope of implied preemption for these same requirements under § 337. *See* 531 U.S. 341, 348 n.2 (2001) ("In light of this

conclusion [implied preemption], we express no view on whether these claims are subject to express preemption."). Therefore, the fact that FDCA does not expressly preempt a private state law cause of action does not preclude a finding that the claim is preempted under § 337's private enforcement ban. Applied here, the Ninth Circuit's analysis, which the Davidsons defend, erroneously stopped short by simply determining that because § 343-1 did not expressly preempt the Davidsons' Sherman Law claim the inquiry ceases. But *Buckman* requires a determination on whether the Davidsons' attempt to privately enforce a state law that merely duplicates FDCA requirements directly conflicts with § 337(a). The Davidsons' Opposition continues to ignore this requirement.

Second, the Davidsons' discussion of § 337(b) answers their own question regarding why Congress would limit enforcement to specific state authorities. Sections 343-1 and 337(b) were enacted at the same time and thus should be construed together. *See* Nutrition Labeling and Education Act of 1990, Pub L. 101-535, §§ 4, 6(a), 104 Stat. 2362. Accordingly, at the same time Congress forbade states from enacting state requirements that were not identical to §§ 343(q) and (r), it provided that if a state wished to enforce those same requirements, it needed to do so "in its own name and within its jurisdiction." *See* 21 U.S.C. § 337(b). The Davidsons refuse to accept that here, the Sherman Law follows the directives of §§ 343-1 and 337(b) and provides that only the California Department of Health and Human Services shall enforce the law. The language and context of §§ 343-1 and 337 clearly show that any private enforcement of FDCA food labeling regulations directly conflicts with § 337 and is preempted.

3. The Davidsons' argument regarding *Buckman* permitting state law causes of action that parallel FDCA requirements distorts the meaning of key terms to bolster their position. As discussed in *Buckman* and its progeny, parallel state law claims that escape preemption under § 337 are common law tort claims that offer "an additional, and important, layer of consumer protection that complements FDA regulation." *Wyeth v. Levine*, 555 U.S. 555, 578-79 (2009). But even such common law torts will be expressly preempted if they impose state requirements that are "different from, or in addition to," FDCA requirements. *See Riegel v. Medtronic*, 552 U.S. 312, 322-24 (2008). Accordingly, to avoid preemption, a private plaintiff must sue for conduct that violates FDCA (to avoid express preemption) but cannot sue *because* the conduct violates FDCA (as such a claim is preempted by § 337). *DiCroce v. McNeil Nutritionals, LLC*, 82 F.4th 35, 41 (1st Cir. 2023) (identifying prior applications of this test to state-law negligence and failure to warn claims). The Davidsons' claim is irreconcilable with this standard.

The Davidsons have brought a claim premised on the Sherman Law's 38-word incorporation of the entire FDCA food labeling laws and regulations. The Davidsons' claim substantively relies on a state statute which itself relies on FDCA and seeks to find Sprout liable for violating FDCA requirements, not for conduct that parallels these requirements such as fraud or misrepresentation.[1] The federal nature of the Davidsons' claims is clear from their amended complaint, which cites the FDCA about 30 times to allege Sprout's

[1] The Davidsons attempted a parallel state fraud claim, but both the district court and Ninth Circuit found it failed to meet federal pleading standards. Pet.App. 20a-22a, 55a-58a.

wrongful nutrient content claims. Indeed, there is nothing more inherently federal than seeking to enforce federal food labeling laws verbatim.

4. The Davidsons' point that California has historically regulated food and food labeling is no talisman warding off preemption. Undoubtedly, the "police powers" incantation can be said about all the products and areas FDCA regulates (drugs, medical devices, cosmetics, compounding pharmacies, etc.). But FDCA ended any exclusive dominion a state's police powers may have had over these products. More importantly, the Davidsons' "police powers" argument belies their position. If the NLEA were rescinded, California could still theoretically prohibit baby food manufacturers from having nutrient content claims on the front of their products. However, the Davidsons' current claim would now no longer exist, as it fully relies on the Sherman Law's incorporation by reference of the entire FDCA food labeling provisions. California's theoretical ability to prohibit the nutrient content claims at issue here absent the NLEA does not transform the Sherman Law's actual adoption of FDA regulations into state law impervious to preemption.

5. As for the presumption against preemption, the doctrine does not provide an automatic safe harbor in conflict preemption cases. *See Geier v. Am. Honda Motor Co., Inc,* 529 U.S. 861, 906 (2000) (Stevens, J., dissenting); *see also Mut. Pharm. Co., Inc. v. Bartlett,* 570 U.S. 472, 498 n.1 (2013) (Sotomayor, J., dissenting); *PLIVA, Inv. v. Mensing*, 564 U.S. 604, 642 (2011) (Sotomayor, J., dissenting). The Court applied these same principles in *Buckman*. 531 U.S. at 347-48. Moreover, this presumption is merely an "assumption" that can be refuted by "the clear and manifest purpose of Congress." *Altria Group, Inc. v. Good*, 555 U.S. 70, 77 (2008). As

discussed above, it is plainly apparent in the statutory scheme and text of the NLEA and § 337 that Congress has prohibited private citizens from bringing state law claims to enforce FDCA requirements. The presumption against preemption is inapplicable here.

III. The Circuits are Divided on the Question Presented.

1. At the outset, the Davidsons cite to a few appellate opinions boldly asserting that every circuit court considering the issue has held that § 337 does not impliedly preempt private enforcement of state laws that parallel FDCA requirements. Opp. 10. That is simply not true. The Davidsons' cited cases are inapposite as they all discuss tort claims rather than statutory claims based exclusively on federal regulations wholesale adopted into state law. *See, e.g., Bausch v. Stryker Corp.*, 630 F.3d 546, 557 (7th Cir. 2010) (assessing preemption in the context of "tort law claims based on manufacturing defects"); *Hughes v. Bos. Sci. Corp.*, 631 F.3d 762, 775 (5th Cir. 2011) (claim based on "'recognized state-law duty' rather than 'an implied right of action under federal law'" not preempted); *Lefaivre v. KV Pharm. Co.*, 636 F.3d 935, 937 (8th Cir. 2011) (claims based on breach of the implied warranty of merchantability and state tort law not preempted). These cases are fundamentally distinct from the Ninth Circuit's ruling in this case.

2. In attempting to distinguish *DiCroce*, the Davidsons' discussion rests on a superficial reading of the claims at issue, deliberately sidestepping a deeper analysis in an effort to obscure the clear split between the First and Ninth Circuits. The Davidsons assert that *DiCroce*'s food labelling claim, premised on a violation of FDCA's regulations, is dissimilar because

there was no "parallel duty" under state law (i.e., no Massachusetts counterpart to the Sherman Law). But this is a distinction without a difference. In *DiCroce*, the claims were based on Massachusetts state law that specifically incorporated FDCA food labeling regulations. *See* Mass. Gen. Laws Ann. ch. 93A; Mass. Gen. Laws Ann. ch. 266, § 91; 105 Code Mass. Regs 500.004(B)(5) (requiring compliance with listed "federal regulations" including "21 C.F.R. Part 101: Food Labeling"); *DiCroce*, 82 F.4th at 38 n.2. Here, the Davidsons' Sherman Law claim is likewise premised on a violation of a California statute incorporating all FDCA food labeling regulations. Because the claims both here and in *DiCroce* are based on state statutes adopting federal food labelling requirements as state law, the disparate rulings establish a quintessential circuit split.

3. The Davidsons' discussion of *Dumont v. Reily Foods Co.*, 934 F.3d 35 (1st Cir. 2019), likewise obfuscates the similar claims at issue. *Dumont* held that "any claim premised on the violation of federal law will remain dismissed, albeit on the alternative grounds of preemption and waiver." *Id*. at 42. While finding that Dumont's claim was not impliedly preempted insofar as it was based on violations of independent state deceptive practices only, the First Circuit explicitly held that FDCA limited the scope of Dumont's claims. *Id*. at 43. The court explained that FDCA's "dual preemptive force will restrict the factfinder to determining whether conduct that does violate the federal regulations is also deceptive under Massachusetts law by virtue *of its nature rather than its federal illegality*." *Id*. (emphasis added). *Dumont* showcases the proper interplay between § 337 and § 343-1 with state tort law. *See id.* at 42 (food labeling claims preempted "unless the

conduct it pleads: (1) violates FDCA labeling requirements and (2) would also violate chapter 93A even if the FDCA did not exist."). As explained previously, if the NLEA was rescinded today, the Davidsons' Sherman Law claims would cease to exist. Contrary to the Davidsons' position, *Dumont* actually further supports a circuit split.

4. Finally, the Davidsons' remaining arguments concerning a circuit split fail. The Davidsons argue that *Loreto v. Procter & Gamble Co.*, 515 F. App'x 576 (6th Cir. 2013) is distinguishable because the Sixth Circuit held that an alternative theory was not preempted by federal law. However, the Sixth Circuit made clear that the alternative theory was not preempted because the theory "relie[d] solely on traditional state tort law predating the FDCA, and would exist in the absence of the Act." *Id*. at 580. Thus, *Loreto* is on point, as the labeling claims premised on FDCA regulations were preempted. *Id*. at 579.

Likewise, in *PDK Labs, Inc. v. Friedlander*, the Davidsons ignore that the Second Circuit recognized § 337 would prohibit the claims at issue. 103 F.3d 1105, 1113 (2d Cir. 1997). Although the claims, based on violation of the Georgia Uniform Deceptive Trade Practices Act and False Advertising Law, were ultimately dismissed for lack of standing, the Second Circuit made clear that the "true goal [was] to privately enforce alleged violations of the FDCA. However, no such private right of action exists." *Id*. at 1113.

IV. The Question Presented Is Recurring, Important, And Squarely Presented Warranting This Court's Immediate Intervention.

1. The Davidsons' attempt to "dispatch" concerns regarding the explosion of private actions seeking to enforce FDCA food labeling as "overblown" fails. Opp. 22. As both Sprout and amicus explained, private enforcement of FDCA will balkanize FDA's centralized enforcement authority. This, in turn, will supplant FDA's science-driven determinations and expertise in enforcing labeling regulations with plaintiffs motivated by litigation, thereby opening the floodgates of labeling litigation.[2]

The Davidsons' reliance on *POM Wonderful, LLC v. The Coca-Cola Co.*, for the notion that this Court has already blessed private enforcement of FDCA through state statutes is unquestionably false. 573 U.S. 102, 117 (2014) ("The centralization of FDCA enforcement authority in the Federal Government does not indicate that Congress intended to foreclose private enforcement of other federal statutes."). In *POM Wonderful*, this Court held that FDCA did not preclude a Lanham Act misrepresentation claim because the statutory schemes "complemented each other with respect to remedies." *Id.* at 115 (explaining that FDA is tasked with enforcement of FDCA regulations and Lanham Act allows private parties remedies for unfair business practices). Because the Lanham Act claim sought complimentary remedies for a misleading food label,

[2] Notably, the Davidsons do not dispute the surge of food and beverage labeling litigation as outlined in the petition (Pet. 22-23), but figuratively shrug, as if this must be what Congress intended (Opp. 23-24).

the claim was accordingly not precluded. *Id.* at 117 ("POM seeks to enforce the Lanham Act, not the FDCA or its regulations."). The Court's analysis of the interplay of the FDCA and Lanham Act is no different than Sprout's argument regarding parallel common law claims discussed above. *Supra* at 5.

2. Contrary to the Davidsons' suggestion to wait for a "more complicated or less clear-cut case" warranting "specialized [FDA] expertise" (Opp. 25), this case presents the perfect vehicle to review the question presented now. First, disparate from cases concerning the use of common-law tort claims encroaching on FDCA requirements, this case places § 337(a) squarely within the context of a state statute wholesale co-opting federal regulations for enforcement purposes. Second, the Court's direction on § 337's application is potentially case dispositive as the Ninth Circuit affirmed the dismissal of the remaining fraud claims. Finally, the current procedural landscape in the appellate courts warrants review. The Ninth Circuit has vacated submission of *Bubak v. Golo, LLC*, 24-492, holding the proceedings in abeyance pending this petition for writ of certiorari. Order Vacating Submission of the Case, *Bubak v. Golo, LLC*, No. 24-492 (9th Cir. Feb. 7, 2025), (ECF No. 48.1). Further still, the Fifth Circuit held oral arguments on September 5, 2024, on a similar issue of § 337's preemption of a claim under state unfair-competition laws incorporating FDCA requirements for drug-approval in *Zyla Life Sciences v. Wells Pharma*, 23-20533, and has yet to decide that matter. Oral Argument, *Zyla Life Sciences v. Wells Pharma*, No. 23-20533 (5th Cir. Sep. 5, 2024), (ECF No. 66), https://www.ca5.uscourts.gov/OralArgRecordings/23/23-20533_9-5-2024.mp3. This Court should now review this ripe legal question.

CONCLUSION

The Court should grant the petition.

Respectfully submitted,

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