NOT FOR PUBLICATION

FILED

OCT 9 2025

MOLLY C. DWYER, CLERK
U.S. COURT OF APPEALS

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

VINCENZZA BUBAK, individually and on behalf of all others similarly situated, Plaintiff - Appellant, v. GOLO, LLC, a Delaware Limited Liability Company, Defendant - Appellee.	No. 24-492 D.C. No. 1:21-cv-00492-DAD-AC MEMORANDUM*

Appeal from the United States District Court
for the Eastern District of California
Dale A. Drozd, District Judge, Presiding

Argued and Submitted February 3, 2025
Submission Vacated February 7, 2025
Resubmitted April 24, 2025
Pasadena, California

Before: WARDLAW, CALLAHAN, and HURWITZ, Circuit Judges.
Concurrence by Judge CALLAHAN.

Vincenzza Bubak filed a putative class action alleging that Golo, LLC violated California law through its marketing and distribution of a dietary

* This disposition is not appropriate for publication and is not precedent except as provided by Ninth Circuit Rule 36-3.

supplement. Bubak asserted violations of California's Unfair Competition Law ("UCL"), which permits suit by private parties who have suffered an injury as a result of "any unlawful, unfair or fraudulent business act or practice." Cal. Bus. & Prof. Code §§ 17200, 17204. Bubak's UCL claim was premised on Golo's alleged violation of the Federal Food, Drug, and Cosmetic Act ("FDCA"), "as incorporated into California law in the Sherman Food, Drug, and Cosmetic Law, Cal. Health & Safety Code §§ 110100 *et seq*." ("Sherman Law").

After we decided *Nexus Pharmaceuticals, Inc. v. Central Admixture Pharmacy Services, Inc.*, 48 F.4th 1040 (9th Cir. 2022), the district court dismissed the complaint. Bubak timely appealed.

We have jurisdiction under 28 U.S.C. § 1291 and review the dismissal de novo, taking all factual allegations in the complaint as true and construing "the pleadings in the light most favorable to the nonmoving party." *Est. of Bride v. Yolo Techs., Inc.*, 112 F.4th 1168, 1175 (9th Cir. 2024) (internal quotation marks and citation omitted). We affirm.

1. The FDCA expressly prohibits private enforcement. 21 U.S.C. § 337(a)–(b). In *Nexus*, the plaintiff sought to avoid this prohibition by bringing claims under the UCL and other state laws that "incorporate" the FDCA. 48 F.4th at 1047. We explained, however, that these claims are preempted because they "rest upon a violation of the FDCA," *id.* at 1044, and proceedings to enforce or

restrain violations of the FDCA "must be by and in the name of the United States, not a private party," *id.* at 1049.

Bubak's claims face the same problem. She asserts that she may sue under the UCL because the FDCA is "incorporated into" the Sherman Law and Golo violated § 403(r) of the FDCA by representing that its dietary supplement can mitigate or prevent a disease. *See* 21 U.S.C. § 343(r)(6). Bubak's UCL claim therefore necessarily requires litigating "the alleged underlying FDCA violation," *Nexus*, 48 F.4th at 1049, and the "plain text of the FDCA leaves that determination in the first instance to the FDA's balancing of risks and concerns in its enforcement process," *id.* at 1050.

2. Bubak's attempts to distinguish *Nexus* are unpersuasive. Although Bubak argues that "*Nexus* did not address the Sherman Law," the UCL claim in that case rested on an alleged violation of the Sherman Law. *See* Case No. 8:20-cv-01506, Dkt. 13 at ¶ 90; *id.* ¶ 15 ("Defendants are engaged in unlawful and unfair business and trade practices because Defendants are compounding and selling drugs in violation of the Sherman Law"); *id.* ¶ 46 ("California's Sherman Law incorporates the FDCA's requirement that pharmaceutical manufacturers must obtain approval before selling a new drug.").

Bubak also argues that *Nexus* is distinguishable because it concerned drug regulations. But Congress's preemption of a state's food labeling regulations that

are "not identical to" FDCA requirements mirrors Congress's preemption of a state's drug regulations that are "different from, or in addition to" FDCA requirements. *Compare* 21 U.S.C. § 360k, *with* 21 U.S.C. § 343-1. As the district court correctly noted, *Nexus* "did not limit its holding to [the pharmaceutical] context."

Finally, Bubak argues that *Nexus* concerned fraudulent statements made to the FDA while her claim turns on misrepresentations made to consumers. But what matters is whether the plaintiff brings a state law claim that exists "solely by virtue of the FDCA." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001).

3. Bubak also argues that *Davidson v. Sprout Foods, Inc.*, 106 F.4th 842 (9th Cir. 2024), decided during the pendency of this appeal, requires reversal. The plaintiffs in *Davidson* brought a claim under California's UCL alleging that Sprout Foods violated the Sherman Law by including nutrition information on baby food in violation of FDA regulations. *See id.* at 846. This claim "fundamentally differs" from the claim in *Nexus* because it does not "require litigating" questions that are "reserved for the FDA," because the violation was plain. *Id.* at 849. As in *Nexus*, further analysis is needed to determine whether Golo's marketing actually violated the FDCA.[1] Because the FDCA preempts private suits seeking judicial

[1] Golo's motion for initial hearing en banc is DENIED. Dkt. 26.

resolution of such questions, this claim is preempted.

AFFIRMED.

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Bubak v. Golo, No. 24-492

CALLAHAN, Circuit Judge, concurring:

I concur in the judgment because Bubak's state law claims are preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA"). Although the issue is not critical to our disposition of this appeal, I write separately to note my disagreement with the majority's attempt to reconcile our opinions in *Nexus Pharmaceuticals, Inc. v. Central Admixture Pharmacy Servs., Inc.*, 48 F.4th 1040 (9th Cir. 2022), and *Davidson v. Sprout Foods, Inc.*, 106 F.4th 842 (9th Cir. 2024), and to suggest that in the appropriate case we should overrule *Davidson*'s limitation on the FDCA's prohibition of private actions to enforce the FDCA. Judge Collins in his dissent got it right: "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." *Davidson*, 106 F.4th at 857 (Collins, J., dissenting).

I

The tension between *Nexus* and *Davidson* is apparent. In both, plaintiffs alleged violations of Sherman Law provisions that "incorporate" the FDCA. *See* Nexus Compl. ¶ 46, Davidsons's Compl. ¶ 62. The court in *Nexus* held these allegations impliedly preempted because they are simply a roundabout way to claim violations of the FDCA, which § 337 prohibits. *Nexus*, 48 F.4th at 1048; *id.* at 1050 ("[T]he claim is that a manufacturer is harmed economically because the

defendant violated the FDCA. The purported state law violation is of a law that says in substance 'comply with the FDCA,' not a traditional common law tort."). The *Davidson* majority held the opposite. *Davidson*, 106 F.4th at 851 ("Statutory causes of action to enforce identical state standards that Congress permitted must also survive implied preemption.").

The *Davidson* majority understandably sought to distinguish its case from *Nexus*. They did this by saying the plaintiff in *Nexus* asserted a Sherman Law claim that "would require litigating whether . . . an FDCA violation had occurred," which is "a task reserved for the FDA," *Davidson*, 106 F.4th at 849, and that the Davidsons were "claiming violations of California law, the Sherman Law, not the federal FDCA." *Id.* This distinction ultimately fails, however, because the plaintiffs in *Davidson* also asserted a Sherman Law claim that "would require litigating whether . . . an FDCA violation had occurred," *id.*, namely, whether Sprout Foods made "nutrient content claims" in violation of the FDCA. *See, e.g.*, Davidsons's Compl. ¶ 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.").

The distinction fails for the additional reason that the plaintiff in *Nexus*—like the plaintiffs in *Davidson*—was "claiming violations of California law, the Sherman law, not the federal FDCA." *Davidson*, 106 F.4th at 849. *See, e.g.,* Nexus Compl. ¶ 90 ("Defendants have violated the UCL by engaging in the unlawful business practice of marketing, selling, and distributing their products in violation of the California Sherman Law.").

II

Today's memorandum disposition doesn't do any better distinguishing *Nexus* and *Davidson*. Tellingly, the memorandum disposition does not endorse the *Davidson* panel's reasoning, and instead says that in *Davidson*, the Sherman Law "violation was plain," Mem. Dispo. at 4, so did not require litigating questions that are "reserved for the FDA," *id.* (quoting *Davidson*, 106 F.4th at 849). The memorandum disposition then goes on to hold that in both this case and in *Nexus*, the alleged violation was not "plain" and that "further analysis is needed to determine whether Golo's marketing actually violated the FDCA." *Id.*

There are a few issues with this approach. For starters, the FDCA does not carve out a "plain violation" exception to its bar on private enforcement. The FDCA clearly states that "all such proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States," 21 U.S.C. § 337(a), or "[a] State," *id.* § 337(b). *See Rotkiske v. Klemm*, 589 U.S. 8, 14 (2019)

("It is a fundamental principle of statutory interpretation that absent provisions cannot be supplied by the courts. To do so is not a construction of a statute, but, in effect, an enlargement of it by the court.") (cleaned up).

Second, there is no principled basis for concluding that some FDCA violations involve litigating questions "reserved for the FDA" while others do not. Mem. Dispo. at 4. Congress made the FDA "the primary enforcer of the FDCA," *Kroessler v. CVS Health Corp.*, 977 F.3d 803, 809 (9th Cir. 2020), so all alleged violations of the FDCA require litigating questions "reserved for the FDA."

Finally, even if there were a "plain violation" exception hidden in § 337, this wouldn't distinguish the present appeal from *Davidson*. The alleged FDCA violation in *Davidson* required us to look at Sprouts Food packages and to decide whether Sprouts Food made "nutrient content claims" in violation of federal regulations. 21 C.F.R. § 101.13(b)(3). Here, the alleged FDCA violation requires us to look at Golo's website and decide whether Golo is making "implied disease claims" in violation of federal regulations. 21 C.F.R. § 101.93(g). There is no meaningful distinction between the two cases in this respect.

III

Notwithstanding the tension between *Nexus* and *Davidson*, they are arguably not irreconcilable, but for different reasons than those in the *Davidson* opinion and today's memorandum disposition.[1]

Recall that plaintiffs may not allege violations of Sherman Law provisions that "exist solely by virtue of the FDCA." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001). All of the alleged Sherman Law violations in *Nexus* fall into this category. The alleged Sherman Law violations in *Davidson* did not. In *Davidson*, the plaintiffs alleged that Sprout Foods violated certain Sherman Law provisions that "predate the enactment of the Sherman Law." Davidsons's Compl. ¶ 26. For example, plaintiffs alleged that Sprout Foods violated the "advertising provisions of the Sherman Law." *Id.* ¶ 120(ii); *see* Cal. Health & Safety Code §§ 110390, 110395, 110398, 110400. These state laws predate, and thus exist independently of, the federal law at issue in that case. *Cf. Buckman*, 531 U.S. at 353. *See Comm. On Children's Television, Inc. v. Gen. Foods Corp.*, 673 P.2d 660, 668 (Cal. 1983) (explaining how, before enactment of the NLEA, the Sherman Law prohibited "false, unfair, misleading, or deceptive advertising"). Accordingly, plaintiffs' Sherman Law claims based on these provisions were not impliedly preempted. *See Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1340 (10th

[1] I therefore join the denial of Golo's motion for initial hearing en banc. Mem. Dispo. at 4 n.1.

Cir. 2015) (Gorsuch, J.) ("[W]e must ask whether [the state claim] exists 'solely by virtue' of the federal statutory scheme (unacceptable) or 'predates' the scheme (acceptable)."); *id.* at 1352 (Lucero, J., concurring in part) (a state law claim is not impliedly preempted if it "predate[es] the FDCA, and would exist in the absence of the Act.") (citation omitted).

However, the *Davidson* plaintiffs also alleged that Sprout Foods violated certain Sherman Law provisions that did not "predate," or exist independently of, the FDCA, *Caplinger*, 784 F.3d at 1340. For example, the plaintiffs alleged that Sprout Foods violated a Sherman Law provision that "[a]ny food is misbranded if its labeling does not conform with the requirements for nutrition labeling as set forth in [the FDCA]." Cal. Health & Safety Code § 11065. This provision necessarily exists "solely by virtue of the FDCA," *Buckman*, 531 U.S. at 353, and would necessarily "require litigating whether . . . an FDCA violation has occurred," *Davidson*, 106 F.4th at 849. *See also, e.g.*, Davidsons's Compl. ¶ 3 (alleging that Sprout Foods "misbrands its baby and toddler food products by making nutrient content claims on the product packages that are strictly prohibited by the [FDA].").

Thus, *Nexus* and *Davidson* may be reconciled on the ground that at least some of the Sherman Law provisions alleged in *Davidson* predate and exist independently of the FDCA. In *Nexus*, and here, the opposite is true: all of the

alleged Sherman Law violations "exist solely by virtue of the FDCA." *Buckman*, 531 U.S. at 353.

IV

The *Davidson* majority departed from *Nexus* and created an intra-circuit split when it held that "[s]tatutory causes of action to enforce identical state standards that Congress permitted must also survive implied preemption." *Davidson*, 106 F.4th at 851. The *Nexus* court had held just two years earlier that alleging violations of "identical state standards" to the FDCA unavoidably requires litigating an alleged violation of the FDCA. *Nexus*, 48 F.4th at 1048 (explaining that "a necessary element of Nexus's [Sherman Law] claim is the alleged violation of the FDCA"); *id.* at 1050 ("The purported state law violation is of a law that says in substance 'comply with the FDCA'"). I agree with the *Nexus* panel's determination that § 337's prohibition of private enforcement applies to Sherman Law provisions that "incorporate" the FDCA, and that state law claims relying on these provisions are impliedly preempted. *Id.* at 1050–51.

"'[T]he purpose of Congress is the ultimate touchstone' in every pre-emption case." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963)). Congress's purpose in passing the FDCA, and especially the twin NLEA and DSHEA amendments, was to promote national uniformity and standards for the manufacture and distribution of

food, drugs, and cosmetics. *See, e.g.*, 21 U.S.C. § 323-1 ("National uniform nutrition labeling"); 21 U.S.C. § 379r ("National uniformity for nonprescription drugs"). This court even recognized in *Davidson* that Congress enacted the NLEA and DSHEA "to provide nationally uniform standards for nutrition labeling . . . to displace disparate state standards." *Davidson*, 106 F.4th at 845. Permitting private enforcement of the state laws that "exist solely by virtue of the FDCA," *Buckman*, 531 U.S. at 353, frustrates the goal of national uniformity, and raises the prospect for inconsistent application of the FDCA through the guise of "identical state standards." *Cf. Davidson*, 106 F.4th at 851. These state law claims are therefore preempted by the FDCA's bar on private enforcement. 21 U.S.C. § 337.

The enforcement scheme outlined in § 337 reflects Congress's concern for national uniformity. Section 337(a) reserves enforcement of the FDCA to the federal government, and § 337(b)(1) carves out an exception for States to bring enforcement actions for food-related violations "if the food that is subject of the proceedings is located in the States." The exception in subsection (b)(1) is then limited by subsection (b)(2), which provides that States cannot commence proceedings until "after the State has given notice to the Secretary [of Health and Human Services]," *id.* at § 337(b)(2)(A)-(B), and even after notice is given, cannot commence proceedings "if the Secretary is diligently prosecuting a proceeding in court pertaining to such food," *id.* § 337(b)(2)(C). This means that even when

Congress gave States the power to enforce the FDCA, it limited that power and made it dependent on coordinating with the federal government. *See also* 58 Fed. Reg. 2457, 2460 (Jan. 6, 1993) ("[T]he agency believes that close cooperation between [the] FDA and the States will ensure that goals of uniformity are met while still addressing the concerns of citizens of a State.").

The majority in *Davidson* believed that § 337 "implicates only enforcement of the federal, not enforcement of identical state requirements." *Davidson*, 106 F.4th at 850. But such a reading ignores that Congress allowed States to enact standards that are "identical to" certain FDCA standards. *See* 21 U.S.C. § 341. It makes little sense to think Congress would so carefully prohibit private enforcement of the federal standards but not be concerned with private enforcement of *identical* state standards. "Federal law does not support such a strange result." *Cf. Davidson*, 106 F.4th at 849. Had Congress intended private enforcement of state laws that are identical to the FDCA, "it would have said so expressly, and not left the matter to mere implication." *Palmore v. United States*, 411 U.S. 389, 395 (1973). Indeed, it "expressly" permitted States to enforce state laws that are identical to the FDCA. 21 U.S.C. § 337(b). Congress's decision to omit private enforcement of these identical standards should be respected. *Cornell v. Lima Corporate*, 988 F.3d 1089, 1099 (9th Cir. 2021) (reading Congress's "omission to be intentional").

The *Davidson* majority did not understand why Congress would allow States to have food labeling requirements that are "identical to" FDCA requirements, 21 U.S.C. § 341-a, while at the same time not allow individuals in that State to enforce the identical requirements. *Davidson,* 106 F.4th at 849 ("There is no reason we can perceive why Congress would permit states to enact particular legislation and then deny enforcement by their citizens."). But there are a number of reasons why Congress would do this, not the least of which is to ensure consistent application of FDCA food labeling requirements across the country. Several states in addition to California have "incorporated" these FDCA requirements into state law.[2] If individual plaintiffs could bring suit, defendant corporations would be subject to conflicting interpretations of federal law throughout the country; for instance, a state court in California might find that Golo made "implied disease claims" while a state court in Florida finds that Golo did not make "implied disease claims." Congress sought to prevent such inconsistent application of FDCA standards through § 337(a)-(b).

There is yet another clue that Congress permitted States to enact parallel food labeling requirements while not permitting private citizens to enforce those requirements. It is axiomatic that "Congress legislates against the backdrop of

[2] *See, e.g.*, Fla. Stat. Ann. § 499.023; Conn. Gen. Stat. § 21a-110; Ariz. Rev. Stat. § 32-1962; 35 Pa. Stat. Ann. § 780-11.

existing law," *McQuiggin v. Perkins*, 569 U.S. 383, 398 n.3 (2013), and Congress passed the NLEA and DSHEA "against the backdrop" of state governments enforcing their own food labeling laws. For instance, California's Sherman Law does not contemplate a private right of action, but instead contemplates government enforcement of the state's food labeling requirements. *See, e.g.*, Cal. Health & Safety Code §§ 111840, 111900. This settled expectation, along with Congress's longstanding desire for national uniformity, demonstrates Congress's intent to prohibit individuals from enforcing state food labeling laws that are "identical to" the FDCA.[3]

V

I concur in the affirmance of the district court's order of dismissal because Bubak's state law claims are preempted by the FDCA. I write separately to draw attention to contrasting perspectives on the FDCA's preemption of state laws that "incorporate" the FDCA and to encourage my colleagues to, in the appropriate case, reaffirm our holding in *Nexus* that the FDCA prohibits private enforcement of any state law that incorporates the FDCA.

[3] I do not take issue with California Supreme Court's holding that "private parties may assert UCL claims based on violations of the Sherman Law," *Farm Raised Salmon Cases*, 175 P.3d at 1084 n.5, so long as the alleged Sherman Law violation predates, and exists independently of, the federal law at issue.