

United States Court of Appeals  
for the Fifth Circuit

United States Court of Appeals  
Fifth Circuit

**FILED**

April 14, 2023

Lyle W. Cayce  
Clerk

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No. 22-50593

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JEFF SPANO, INDIVIDUAL and *as next friend of C.S., a minor child*;  
DEBBIE SPANO, INDIVIDUAL and *as next friend of C.S., a minor child*,

*Plaintiffs—Appellants,*

*versus*

WHOLE FOODS, INCORPORATED,

*Defendant—Appellee.*

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Appeal from the United States District Court  
for the Western District of Texas  
USDC No. 1:21-CV-748

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Before HIGGINBOTHAM, SMITH, and ENGELHARDT, *Circuit Judges*.

KURT D. ENGELHARDT, *Circuit Judge*:

A child experienced a severe allergic reaction after consuming a cupcake allegedly mislabeled as “vegan” by a Whole Foods store. The child’s mother subsequently left her job to provide full-time care for her traumatized son. The family sued Whole Foods under theories of negligence and strict liability, among others. In response to a motion to dismiss filed by Whole Foods, the district court held that the suit was preempted by the Federal Food, Drug, and Cosmetic Act (“FDCA”) and thus granted dismissal. This appeal followed.

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### **Factual Background**

C.S., a seven-year old at the time of the incident at issue, has “life-threatening allergies to dairy, tree nuts, and fish.” Mindful of these allergies, the Spano family would on occasion purchase products labeled “vegan” from their local Whole Foods store, as those products were held out as not containing any of the allergens to which C.S. would react. In September of 2018, a family friend purchased a “vegan”-labeled cupcake from Whole Foods for C.S.’ consumption at a birthday party.<sup>1</sup> C.S. consumed the cupcake and had an allergic reaction. Debbie Spano, his mother, promptly administered epinephrine. C.S. was then treated by medical professionals and released from care later that evening.

The Spanos allege that the cupcake in question was mislabeled and was, in fact, a non-vegan version of the cupcake. C.S. thereafter experienced a number of psychological challenges relating to social relations and consumption of food. Because of these challenges, Debbie Spano resigned from her job and devoted herself to full-time care for C.S.

### **Procedural History**

The Spanos – Debbie and Jeff, individually and on behalf of their minor son – filed suit against Whole Foods, claiming negligence, violations of strict liability, manufacturing and marketing defects, breaches of express and implied warranties, loss of earning capacity, vicarious liability, and

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<sup>1</sup> The Amended Complaint implies, but does not state, that Debbie Spano bought the cupcake herself, and the district court assumed as much. On appeal, the Appellants clarify that it was the family friend who purchased the cupcake. There is language deep in the complaint that, if read carefully, suggests that the family friend was indeed the purchaser (“[t]he purchaser visited [Whole Foods] and ... purchase[d] non-allergenic cupcakes to provide the following day to C.S. at *their child’s* birthday party”) (emphasis added). Nonetheless, the natural reading of the complaint, as Whole Foods rightly notes, is that Debbie Spano purchased the cupcakes at issue.

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deceptive trade practices under Texas law.<sup>2</sup> Whole Foods filed a motion to dismiss in which it claimed that “Plaintiffs’ claims, which are derived from and based on the [FDCA,] are preempted and should be dismissed because there is no private cause of action under the FDCA.” The district court agreed: “Upon review, the Court finds that all of Plaintiffs’ causes of action are entirely dependent upon an FDCA violation. In other words, the only reason Whole Foods’s cupcakes were allegedly ‘unlawful’ or deceptive were because they failed to comply with FDCA labeling requirements for food allergens. This theory of liability is impliedly preempted by federal law.” The Spanos filed a timely notice of appeal.

### **Standard of Review**

A district court’s dismissal under Rule 12(b)(6) is reviewed *de novo*. See *Cicalese v. Univ. of Texas Med. Branch*, 924 F.3d 762, 765 (5th Cir. 2019). “To survive a motion to dismiss, a complaint must contain sufficient factual matter which, when taken as true, states ‘a claim to relief that is plausible on its face.’” *Innova Hosp. San Antonio, Ltd. P’ship v. Blue Cross & Blue Shield of Ga., Inc.*, 892 F.3d 719, 726 (5th Cir. 2018) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A complaint “does not need detailed factual allegations,” but the facts alleged “must be enough to raise a right to relief above the speculative level.” *Twombly*, 550 U.S. at 555 (citation omitted).

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<sup>2</sup> This list is taken from the operative complaint, which is the First Amended Complaint. The initial complaint listed “loss of consortium” in place of loss of earning capacity and also included a claim for deceptive trade practices under New York law

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## **Discussion**

### *A. Whether the FDCA Precludes Implied Preemption*

Title 21 U.S.C. § 337(a) provides in relevant part that there is no private right of action under the FDCA. *See also POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 109 (2014) (citing 21 U.S.C. § 337) (“Private parties may not bring enforcement suits [under the FDCA].”). It is indisputable that to the extent that the Appellants seek to enforce the FDCA against Whole Foods, they cannot maintain their claims.

Despite the bar to private enforcement actions, the Spanos claim that the FDCA does not impliedly preempt parallel state law actions. In fact, they submit that implied preemption is not applicable to claims based on food labeling. The express preemption clause of the FDCA provides, subject to certain exceptions not relevant here, that “no State ... may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce ... (2) any requirement for the labeling of food of the type required by section ... 343(w) ... that is not identical to the requirement of such section.” 21 U.S.C. § 343-1 (a).<sup>3</sup> Appellants also point to a “Construction” note contained in the relevant act in which it is noted that “[§ 343-1] 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.” Nutritional Labeling and Education Act of 1990, 101 P.L. 535, 104 Stat. 2353, § 6(a), (c); 21 U.S.C. § 343-1, Note. Moreover, the Construction note also states that “[t]he amendment made by subsection (a) and the provisions of subsection (b) shall not be construed to apply to any requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food

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<sup>3</sup> 21 U.S.C. § 343(w) applies to “major food allergen labeling requirements.”

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or component of the food.” *Id.* Taken together, the Appellants contend, these notes indicate Congress’ clear intent “that implied preemption not apply to food labeling claims.”

Whole Foods contends that this language indicates Congress’ intent to disclaim “field preemption” rather than any intent to disclaim implied preemption.<sup>4</sup> Whole Foods does not argue that the Appellants’ claims are expressly preempted, and the district court did not so hold. Instead, says Whole Foods, these provisions indicate “that preemption will only apply to state laws implicating labeling requirements found in Section 343-1, not that only ‘express preemption’ is permitted.” We adopt Whole Foods’ approach – the language of “provision[s] of State law” and “requirement[s] respecting a statement in the labeling of food” suggests duly enacted statutes which touch upon these issues. For example, a state law requiring warning labels concerning an ingredient not addressed by the FDCA would not be preempted under this construction. Under this reading, the note does not disclaim *any* preemption, but merely ensures that courts leave room for *some* regulation in this field. This comports with the Supreme Court’s decision in *Buckman Co. v. Plaintiffs’ Legal Comm.*, in which the Court held that an express preemption clause does not “‘bar[] the ordinary working of conflict pre-emption principles.’” 531 U.S. 341, 352 (2001) (quoting *Geier v. American Honda Motor Co.*, 529 U.S. 861, 869 (2000)). In sum, the FDCA permits implied preemption. What remains to be seen is whether the claims in this case are impliedly preempted.

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<sup>4</sup> In simple terms, Whole Foods claims that Congress did not mean to occupy the entire field of food labeling (that is, states can still make regulations concerning, e.g., warning labels) but that Congress did not mean to proscribe implied preemption (that is, preemption where the violations at issue are (a) covered by federal regulations and (b) not within the scope of express preemption contemplated by the FDCA).

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*B. Whether the Appellants' Causes of Action Are Impliedly Preempted*

The district court held that the Appellants' claims were preempted because they were "entirely dependent upon an FDCA violation" in that their "claims could not exist based solely on traditional state tort law" because "the standard for allergen labeling under the FDCA is critical to each of Plaintiffs' claims." The district court's decision relied heavily on *Buckman*, in which a "fraud-on-the-FDA" claim was impliedly preempted because "the existence of ... federal enactments is a critical element" of the claim. 531 U.S. at 353. The claim was that Buckman had defrauded the FDA in violation of its statutory obligations. *See id.* at 346-47. As the FDA has sole "responsibility to police fraud consistently with the Administration's judgment and objectives" under the statutory framework, the Supreme Court held a private party could not maintain a state-law fraud case on such a basis. *Id.* at 350. However, the Court left open the possibility that "traditional state tort law principles of the duty of care owed" by one party to another could support a parallel state-law claim, at least where Congress had "disclaimed any interest in promoting the [statutory goal] by means that fail to provide adequate remedies for those who are injured." *Id.* at 352 (quoting *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 257 (1984)).

Relying on that possibility, this court has rejected the argument that negligence claims are always impliedly preempted by the FDCA. In *Hughes v. Bos. Sci. Corp.*, we held that a "Mississippi tort claim based on the underlying state duty to warn about the dangers or risks of product" was not preempted by the FDCA even though the plaintiff "[sought] to prove Boston Scientific's breach of the state duty by showing that Boston Scientific violated the FDA's [Medical Device Reporting] regulations." 631 F.3d 762,

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775 (5th Cir. 2011).<sup>5</sup> *Hughes* also relied on a later Supreme Court decision in which it was noted that the relevant statute “d[id] not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case ‘parallel,’ rather than add to, federal requirements.” *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008). Therefore, an independent state-law duty may form the basis of a tort claim for which violations of the FDCA may be presented as evidence of breach, assuming that the state-law claims do not (a) “add to” federal requirements or (b) impinge on the FDA’s sole authority over food-labeling requirements.<sup>6</sup>

Those latter requirements appear to be met: no party asserts that the Spanos seek to enforce labeling requirements above and beyond those imposed by the FDA. Nor is there any claim here – like a “fraud-on-the-FDA” claim – that would impinge on the FDA’s authority over food labeling. Appellants do not assert that Whole Foods submitted false evidence to the FDA, for example, and their claims “do[] not depend on speculation that the FDA would have taken any particular regulatory action in response to violation of the regulations at issue.” *Hughes*, 631 F.3d at 775. So the question is whether Appellants have pled tort claims which have an independent state-law basis.

They have. Each of their tort claims is “a recognized state tort claim” rather than “a freestanding federal cause of action based on violation of the

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<sup>5</sup> Bizarrely, Whole Foods neglects to address *Hughes* whatsoever in its brief.

<sup>6</sup> There is no dispute that both *Buckman* and *Hughes* are controlling. Both of those cases addressed preemption under the FDCA as amended by the Medical Device Amendments of 1976 (“MDA”) as both cases involved allegedly defective medical equipment. *See Hughes*, 631 F.3d at 764, *Buckman*, 531 U.S. at 343. Here, the question is about the FDCA’s food labeling requirements. As the statutory provisions on which implied preemption is based are similar in both instances, the reasoning in *Hughes* and *Buckman* applies with equal force here.

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FDA’s regulations.” *Hughes*, 631 F.3d at 775. Appellants ably lay out in their brief that each of their allegations is based in state law. In response, Whole Foods contends that “[e]very one of the ... causes of action is specifically based on federally mandated allergen warnings under the FDCA.” While each of the causes of action does reference violations of FDA regulations, violations can only be, and only are, presented as evidence to “prove [Whole Foods’] breach of the state duty by showing that [Whole Foods] violated the FDA’s [food labeling] regulations.” *Id.* If, as the case develops, it becomes clear that there is no independent state duty upon which the Spanos can hang a particular claim, that claim will be preempted. On the pleadings, none appear to contain that fault. Thus, the district court erred in finding their claims preempted.<sup>7</sup>

### **Conclusion**

Accordingly, we REVERSE the district court’s dismissal of the case and REMAND for further proceedings.

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<sup>7</sup> The district court declined to “reach the merits of Whole Foods’s other proffered grounds for dismissal.” We likewise decline to reach the merits of the other issues raised in the motion to dismiss. *See, e.g., Rutila v. Dep’t of Transportation*, 12 F.4th 509, 511 n.3 (5th Cir. 2021) (quoting *Cutter v. Wilkinson*, 544 U.S. 709, 718 n.7 (2005)) (“But, ‘mindful that we are a court of review, not of first view,’ we opt not to seek out alternative grounds on which we might uphold the judgment.”); *Montano v. Texas*, 867 F.3d 540, 546–47 (5th Cir. 2017) (noting that we are a “court of review, not of first view” and remanding a matter not addressed by the district court for examination in the first instance (quotation omitted)).