No. 19-1246

In The
Supreme Court of the United States

RITA MCDANIEL, Individually and as Personal Representative of the Estate of Johnny F. McDaniel, Deceased,
Appellant,

v.

UPSHER-SMITH LABORATORIES, INC.,
Appellee.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

REPLY BRIEF OF APPELLANT

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REPLY ARGUMENT

I. Creating A Split With Other Circuits, The Sixth Circuit Held That Plaintiff's Distinctly State-Law Claims Are Preempted Because They Track Federal Regulations.

Ms. McDaniel has consistently alleged—both at the trial court and on appeal—that, when Defendant failed to ensure the provision of a medication guide to her father, it failed to adequately warn about the dangers of Amiodarone under Tennessee law.[1]

As discussed in Plaintiff's petition, the Sixth Circuit's approach differed from other circuit courts' approach. The Sixth Circuit held that—even though, "under Tennessee law, a product may also be considered defective or unreasonably dangerous if the manufacturer failed to provide adequate warnings informing users of dangers involved in using the product"—Plaintiff's claims were impliedly preempted because Tennessee law "does not create a parallel duty to provide a Medication Guide." *McDaniel v. Upsher-Smith Labs., Inc.*, 893 F.3d 941, 946 (6th Cir. 2018) (cleaned up).

Other courts of appeal, on the other hand, have held that state-law claims survive preemption *even if* they track federal regulations. *See, e.g.*, *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 86 (2d Cir. 2006)

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[1] Failing to physically provide a proper warning is just as much a failure-to-warn as failing to word a provided warning properly. As one state court memorably put it, "[N]o matter how detailed and accurate, an uncommunicated warning is no warning at all." *Baker v. St. Agnes Hosp.*, 70 A.D.2d 400, 404 (N.Y. App. Div. 1979).

(holding that *Buckman* preemption applies only if the plaintiff alleges a "newly-fashioned" claim, "no presumption against federal preemption obtain[s], and . . . the cause of action . . . impose[s] significant and distinctive burdens on the FDA and the entities it regulates.") (discussing *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001)).

Defendant seeks to paper over this circuit split by characterizing Plaintiff's state-law claim as based "solely" on the federal medication-guide regulations. Its key sleight of hand is to conceive its duty narrowly. According to Defendant, "there is no duty under Tennessee law to distribute a medication guide." Opp. at 9. Maybe not, in so many words; but Plaintiff did not claim there was.

Rather, as Chief Judge R. Guy Cole recognized in his dissent, "The crux of McDaniel's Tennessee claims is straightforward: Upsher–Smith failed to provide a medication guide to her late husband, and *that failure rendered inadequate the warnings of amiodarone's potential risks and side effects it did provide* and caused her late husband's death." McDaniel, 893 F.3d at 949 (Cole, C.J.) (dissenting) (emphasis added).

The Ninth Circuit explained—in a passage worth quoting at length—precisely what the Sixth Circuit got wrong about obstacle preemption when it created the circuit split at issue here:

> [T]he [plaintiffs] have not predicated their failure-to-warn claim on a duty to warn doctors directly. They have instead alleged that Medtronic breached its duty of reasonable care under Arizona

> negligence law by failing to report adverse events *to the FDA*. . . .
>
> Medtronic argues that the [plaintiffs'] choice to predicate their claim on a reporting duty to the FDA renders the claim impliedly preempted under [*Buckman*] . . .
>
> [But] accepting that argument would require an unwarranted expansion of *Buckman*'s rationale. . . .
>
> That Arizona law did not previously address reporting duties to the FDA specifically is irrelevant; nothing in *Buckman* suggests that the preexisting state law needs to mirror the federal requirement at that level of specificity to avoid preemption. It is sufficient here that, in contrast to *Buckman,* the [plaintiffs'] claim is grounded in a traditional category of state law failure-to-warn claims that predated the federal enactments in question, and that the claim therefore does not exist solely by virtue of those enactments.

Stengel v. Medtronic Inc., 704 F.3d 1224, 1234-35 (9th Cir. 2013) (majority concurrence).

The Sixth Circuit has now ushered in the "unwarranted expansion of *Buckman*'s rationale" that the Ninth Circuit feared. *Id.* at 1235.

Finally, in its opposition, Defendant, like the Sixth Circuit, ignores the presumption against

preemption that this Court has applied in the context of failure to warn. *See Wyeth v. Levine*, 555 U.S. 555, 579 (2009) ("Failure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times.").

Accordingly, contrary to Defendant's opposition, the Sixth Circuit created a circuit split by taking the *Buckman* decision further than any other circuit court.

This Court should grant certiorari to repair the fissure and clarify its decision in *Buckman*.

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Respectfully submitted,

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