No. 12-1351

IN THE

# Supreme Court of the United States

MEDTRONIC, INC.,

*Petitioner*,

*v.*

RICHARD STENGEL AND MARY LOU STENGEL,

*Respondents*.

**On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit**

## REPLY BRIEF FOR PETITIONER


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## RULE 29.6 STATEMENT

The corporate disclosure statement included in the petition for a writ of certiorari remains accurate.

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## REPLY BRIEF FOR PETITIONER

The Ninth Circuit held in this case that respondents may invoke state tort law to enforce generalized *federal* duties applicable to all medical devices. As the petition demonstrated, that conclusion is flatly contrary to 21 U.S.C. § 337(a), which provides that the Food, Drug and Cosmetic Act, including the Medical Device Amendments ("MDA") thereto, must "be enforced *exclusively* by the Federal Government." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001) (emphasis added). Respondents' use of a state-law label cannot obscure the fact that, as they ultimately admit, the essence of their claim is that Medtronic committed a tort "*by violating the federal [adverse-event reporting] requirements.*" Opp. 5 (emphasis added). Indeed, but for the MDA, respondents would have no claim at all. Thus, in form and in substance, the Ninth Circuit gave respondents a private cause of action that is forbidden by federal law.

The decision below also plots an end-run around this Court's express-preemption analysis in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), and *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). Those decisions permit tort actions if the state duties at issue parallel federal "requirements," but they make clear that only *device-specific* duties qualify as "requirements" under 21 U.S.C. § 360k(a). The federal duties alleged by respondents are concededly *not* device-specific.

*Each* of these issues—implied and express preemption—is the subject of an acknowledged circuit split. Indeed, this Court has already recognized the need for further guidance with respect to the

former issue. *See Warner-Lambert Co. v. Kent*, 551 U.S. 1190 (2007) (granting review of Second Circuit decision reversing dismissal of claim under *Buckman* and § 337(a)), *aff'd by an equally divided Court*, 552 U.S. 440 (2008) (per curiam).

The factual distinctions respondents offer to explain away these circuit conflicts are either trivial, demonstrably false, or both. That presumably explains respondents' decision to devote the bulk of their opposition to supposed waiver and finality problems that, they contend, render this case unsuitable for review. But both the implied and express preemption issues were fully aired below and were passed upon by the Ninth Circuit. Those issues are therefore ripe for consideration by this Court. As it has repeatedly done in other preemption cases in identical postures, this Court should grant review now to restore the "delicate balance of statutory objectives" struck by Congress and the FDA. *Buckman*, 531 U.S. at 348.

## I. THE DECISION BELOW DEEPENS TWO ACKNOWLEDGED CIRCUIT SPLITS.

A. The panel in this case recognized that the circuits are divided on the scope of implied preemption under the MDA. Pet. App. 38a. Respondents nevertheless assert that there is no conflict because the "different outcomes" result from "differences in the plaintiffs' pleadings." Opp. 15, 17. But respondents fail to identify any material difference in the pleadings on each side of the split, and even a cursory examination of the decisions demonstrates that there is none.

Respondents do not dispute that the Sixth and Eighth Circuits have held that the MDA impliedly

preempts state-law claims alleging that a medical device manufacturer was negligent because it violated federal adverse-event reporting requirements. *See* Opp. 15-17; *see also In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1205-06 (8th Cir. 2010); *Cupek v. Medtronic, Inc.*, 405 F.3d 421, 423-24 (6th Cir. 2005). Respondents contend, however, that the Fifth and Ninth Circuits have not addressed this question because the claims in this case and in *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011), were "not based on a violation of the reporting requirement" but were instead "based on a failure to fulfill a state-law duty." Opp. 17.

That argument is misplaced because the alleged "failure[s] to fulfill a state-law duty" (Opp. 17) in this case and in *Hughes* were *based on* alleged violations of the federal requirement to report adverse events to the FDA. Respondents concede as much regarding their own claim. *See id.* at 5 ("*by violating the federal [reporting] requirements*, Medtronic breached its state-law duty to use reasonable care") (emphasis added); *see also* Pet. App. 19a, 23a. Similarly, in *Hughes*, the plaintiff's claim was "based on [the defendant's] violation of applicable FDA regulations requiring accurate reporting" to the FDA. 631 F.3d at 771; *see also id.* at 775. The claims permitted to proceed in this case and *Hughes* are therefore indistinguishable from the claims held preempted in *Sprint Fidelis* and *Cupek*, in which the plaintiffs alleged that Medtronic breached a state-law duty of reasonable care *because* it violated federal requirements to submit information to the FDA. *Sprint Fidelis*, 623 F.3d at 1205; *see also* Brief for Appellants at 9, *Cupek*, 405 F.3d 421 (No. 04-3201).

Subsequent decisions of the Sixth and Ninth Circuits do not eliminate this conflict. *See* Opp. 16, 17. In *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578 (6th Cir. 2013), the Sixth Circuit held that a claim escaped implied preemption under § 337(a) and *Buckman* because the plaintiff was pursuing an "independent, pre-existing state law cause[ ] of action" that was "not . . . premised on violation of federal law, but rather on an *independent* state duty" to warn patients about a drug's risk. *Id.* at 586-87 (emphasis altered); *see also id.* at 587 ("whether PLIVA has violated its federal duties is irrelevant to the adequacy of its warnings" under Ohio law). That conclusion is consistent with the Sixth Circuit's earlier decision in *Cupek*, as well as with *Sprint Fidelis*, which held that state-law claims were impliedly preempted because they were *dependent* on the MDA, rather than based solely on pre-existing state tort duties.

Respondents' reliance on *Perez v. Nidek Co.*, 711 F.3d 1109 (9th Cir. 2013), is equally unavailing. The Ninth Circuit in *Perez* held that the MDA preempted a claim that medical device manufacturers and physicians had committed fraud by failing to inform patients that the FDA had not approved a device for a particular treatment. *See id.* at 1117. That claim had nothing to do with the use of generalized state-law tort duties to enforce federal reporting requirements, a point underscored by the fact that *Perez* did not even cite the decision below in its implied-preemption discussion. *See id.* at 1119-20. *Perez* thus offers no hint that future panels of the Ninth Circuit will fail to adhere to the controlling en banc decision in this case.

B. The decision below also deepens an acknowledged circuit split regarding the scope of the "paral-

lel" duty exception to the MDA's express-preemption provision, 21 U.S.C. § 360k(a). *See* Pet. 19-20.

Respondents contend, as a threshold matter, that Medtronic has not preserved this question for review. Opp. 7-9. That is incorrect. As respondents acknowledge, Medtronic argued in the Ninth Circuit that the parallel-duty exception is available only if a state-law duty is parallel to a "'specific PMA requirement.'" *Id.* at 8 (quoting Medtronic Answer Br. 26). Because "requirements" imposed pursuant to the PMA process *are* necessarily device-specific, *see Riegel*, 552 U.S. at 322-23, Medtronic raised below precisely the question on which it seeks review here, and the Ninth Circuit passed on the issue when it rejected Medtronic's express-preemption defense. Pet. App. 20a; *see also*, *e.g.*, Medtronic En Banc Supp. Br. 8 (arguing that a plaintiff must "[i]dentify with particularity a specific federal requirement applicable to the device") (emphasis omitted). In any event, it is this Court's "traditional rule . . . that once a federal claim is properly presented, a party can make any argument in support of that claim." *Lebron v. Nat'l R.R. Passenger Corp.*, 513 U.S. 374, 379 (1995) (internal quotation marks and alteration omitted). While respondents quibble with the way in which Medtronic framed its specificity argument below, they do not—and cannot—dispute that its express-preemption defense was squarely presented to, and rejected by, the Ninth Circuit. Opp. 7-9.

Respondents also incorrectly assert that there is no conflict on the scope of the parallel-duty exception. Although they acknowledge that the Fifth, Sixth, Seventh, and Ninth Circuits have held that the parallel-duty exception applies even when the asserted federal duty is not device-specific, *see* Opp.

9-10, respondents dispute that the Eighth and Eleventh Circuits have held that a device-specific federal requirement is necessary for the exception to apply. *Id.* at 10-12. The unambiguous language of those decisions refutes respondents' reading.

Respondents suggest that the pleading deficiency in *Sprint Fidelis* was the failure to "allege the violation of *any* particular federal requirement." Opp. 12. But the plaintiffs in that case *did* allege the violation of a particular federal requirement—the FDA's Current Good Manufacturing Practices, *see* 623 F.3d at 1206—and the Eighth Circuit held that the plaintiffs had failed to plead a parallel claim under *Riegel* because they had "failed to adequately plead that Medtronic violated a federal requirement *specific to the FDA's PMA approval of th[e] Class III device*." *Id.* at 1207 (emphasis added). As the Seventh Circuit has acknowledged, that holding directly conflicts with the decisions of those circuits that have held that a device-specific federal requirement is unnecessary. *See Bausch v. Stryker Corp.*, 630 F.3d 546, 554-55 & n.1 (7th Cir. 2010).

Similarly, in *Wolicki-Gables v. Arrow International, Inc.*, 634 F.3d 1296 (11th Cir. 2011), the Eleventh Circuit held that, to satisfy the parallel-duty exception, the plaintiff must "set forth facts pointing to specific [premarket approval] requirements that have been violated." *Id.* at 1301 (internal quotation marks omitted). Respondents do not dispute that this language conflicts with the interpretation of the parallel-duty exception adopted by the Fifth, Sixth, Seventh, and Ninth Circuits. Instead, they argue that the decision in *Wolicki-Gables* ultimately rested on other grounds. Opp. 11. But there is no indication in *Wolicki-Gables* (or any other Eleventh Circuit

decision) that its construction of the parallel-duty exception is anything other than the Eleventh Circuit's definitive view.

## II. THE DECISION BELOW CANNOT BE RECONCILED WITH *BUCKMAN* OR *RIEGEL*.

Respondents' effort to square the Ninth Circuit's decision with this Court's holdings in *Buckman* and *Riegel* is also flawed.

A. Respondents acknowledge that the decision below "held that a parallel claim, not expressly preempted by the MDA, is also not impliedly preempted under *Buckman*." Opp. 15. That amounts to a concession that the Ninth Circuit's decision effectively nullifies *Buckman*. If all "parallel" claims that escape express preemption were "also not impliedly preempted," plaintiffs would need to do nothing more than identify parallel state and federal duties to evade both express *and* implied preemption under the MDA.

In fact, *Buckman* held that a "parallel" state-law claim must satisfy an *additional* condition to escape implied preemption: the state-law duty on which the claim is based must be *independent* of any duty imposed by the MDA. *Buckman* explained that § 337(a)—which respondents do not even cite in their opposition—requires that the MDA "be enforced exclusively by the Federal Government." 531 U.S. at 352. When a violation of a duty imposed by the MDA is a "critical element" of the plaintiff's case, the plaintiff is attempting to enforce the MDA, and that claim is therefore barred. *Id.* at 353. Thus, a state-law claim against a medical device manufacturer can survive § 337(a) only if liability can be established *independently* of any requirement under federal law.

Respondents ignore this independence requirement when they argue that "the essence of [their] claim is not that Medtronic breached a duty to the FDA, but that it breached a duty to Mr. Stengel." Opp. 19. Elsewhere, however, respondents admit they are claiming that Medtronic violated a duty to Mr. Stengel "*by violating the federal requirements*" regarding the submission of adverse-event reports to the FDA. *Id.* at 5 (emphasis added). Respondents cannot demonstrate—and do not even contend—that Arizona law imposed a duty, independent of the MDA, to submit such information to the FDA. *See* Pet. 24-26; *see also PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2578 (2011) (recognizing that state law did not impose a duty to communicate with the FDA). Respondents' claims are therefore impliedly preempted because the federal reporting requirements are a "critical element" of those claims. *Buckman*, 531 U.S. at 353.[1]

Respondents further contend that their suit would not permit lay juries to "second-guess" the FDA's expert decision-making because respondents, unlike the plaintiffs in *Buckman*, are not bringing a "fraud-on-the-FDA claim." Opp. 19-20. But implied preemption does not turn on the label attached to the plaintiff's claim. Rather, it turns on whether the

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[1] Respondents cannot avoid preemption by arguing that Medtronic allegedly breached an independent state-law duty "to warn the *plaintiffs* of dangers" (Opp. 19)—either directly or through Mr. Stengel's physicians. The Ninth Circuit correctly held that such a claim would be *expressly* preempted because it would impose a requirement that is "different from, or in addition to," 21 U.S.C. § 360k(a), the warning requirements imposed by the PMA process. *See* Pet. App. 20a-21a; *see also id.* at 22a.

plaintiff's claim, like the preempted claim in *Buckman*, would interfere with the FDA's exclusive enforcement of the MDA under § 337(a). In that respect, respondents' theory of negligence—that a device manufacturer violates a highly generalized state-law duty of care when it breaches the MDA's adverse-event reporting requirements—is no different from the "fraud-on-the-FDA" claim in *Buckman* because it would allow state-law juries to find MDA violations where the FDA has found none.

According to respondents, the Court should overlook this interference with the FDA's regulatory prerogatives because, in this case, "the FDA has already decided that Medtronic had not adequately complied with the federal reporting requirements." Opp. 20. But that argument relies on an FDA letter to Medtronic (*see ibid.*), issued after Mr. Stengel's alleged injury, that does not constitute final agency action and thus does not represent a "decision" by the agency that Medtronic violated the MDA's reporting requirements. *See*, *e.g.*, *Schering-Plough Healthcare Prods., Inc. v. Schwarz Pharma, Inc.*, 586 F.3d 500, 508 (7th Cir. 2009); FDA, *Regulatory Procedures Manual* § 4-1-1 (2012), http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074330.pdf. Moreover, even where the FDA has made a final determination that a manufacturer has violated the MDA, a state-law claim premised on that violation would still intrude on the FDA's exclusive enforcement authority by inviting a lay jury to second-guess the FDA's carefully calibrated choice of remedy. *Buckman*, 531 U.S. at 349.

Respondents also provide no meaningful assurance that a jury could resolve their negligence claim

without attempting to "reconstruct what the agency would have done" in a counterfactual set of circumstances. Opp. 20. As recognized by the concurring opinion below, which was joined by a majority of the en banc panel, respondents can prove causation only by establishing how the FDA would have responded in the hypothetical circumstance in which Medtronic submitted adverse-event reports prior to Mr. Stengel's injury. Pet. App. 23a. That inquiry would ensnare agency personnel in burdensome discovery and divert the agency from its regulatory mission. Pet. 28-29.

B. Nor do respondents rebut Medtronic's showing that the decision below would eviscerate *Riegel* and dramatically narrow the scope of the MDA's express-preemption provision. *See* Pet. 29-32. *Riegel* held that § 360k(a) expressly preempts state-law claims regarding medical devices that have received premarket approval, unless they are based on state-law duties that "parallel" federal requirements. 552 U.S. at 330. Respondents argue that, under *Lohr*, the parallel-duty exception is met when a state-law duty allegedly parallels a generalized federal duty applicable to all medical devices. Opp. 12-13. *Lohr*, however, held that only a *device-specific* federal duty constitutes a federal "requirement" under § 360k(a). 518 U.S. at 501. And the parallel-duty exception applies only when a state-law duty parallels a federal "requirement" under § 360k(a). *Id.* at 495; *Riegel*, 552 U.S. at 330. *Lohr* therefore establishes that the parallel-duty exception is limited to device-specific federal duties, and does not extend to the generally applicable federal reporting duty on which respondents' negligence claim is based. The Ninth Circuit's contrary decision would grant juries sweeping discretion to interpret highly generalized federal duties in

ways the FDA has not and thereby impose different duties from those imposed by the FDA. Pet. 30-31.[2]

## III. RESPONDENTS' ASSERTED FINALITY PROBLEM IS ILLUSORY.

Respondents also fail in their last-ditch effort to evade review based on the procedural posture of this case. *See* Opp. 20-22. This Court often grants certiorari—particularly on preemption questions—when the district court has granted a motion to dismiss and the court of appeals has reversed. In fact, this case arises in precisely the same posture as *Buckman*, in which the district court dismissed the plaintiffs' state-law claims on preemption grounds and the Third Circuit reversed. *See* 531 U.S. at 347. Similarly, in *Lohr*, the district court granted Medtronic's summary-judgment motion, the Eleventh Circuit reversed in part, and this Court granted certiorari. *See* 518 U.S. at 481-84; *see also*, *e.g.*, *Altria Grp., Inc. v. Good*, 555 U.S. 70, 74-75 (2008); *Warner-Lambert Co.*, 552 U.S. 440. In such circumstances, the "interlocutory" posture of the case is "no impediment to certiorari [because] the opinion of the court below has decided an important issue, otherwise worthy of review, and Supreme Court intervention [would] serve to hasten or finally resolve the litigation." Eugene Gressman et al., *Supreme Court Practice* § 4.18,

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[2] Respondents' reliance on *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), is also misplaced. *See* Opp. 13-14. Although *Bates* held that a preemption provision similar to § 360k(a) had a parallel-duty exception, this Court remanded without applying that exception to the claims at issue. *See* 544 U.S. at 453.

at 282 (9th ed. 2007); *see also id.* (citing analogous cases).

In fact, the procedural posture of this case is an important reason that the Court should grant review now. It is critical that preemption defenses under the MDA be vindicated at the outset of the case under Rule 12(b)(6), as opposed to later in the litigation. Permitting discovery to proceed will unduly entangle the FDA in the litigation process and impose unnecessary costs on manufacturers that will discourage the marketing of life-saving medical devices and undermine the public health.

## CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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