No.

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

In *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), this Court held that the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act impliedly preempt state-law tort suits that are based on federal requirements to disclose information to the Food and Drug Administration ("FDA"). *Id.* at 353. Such claims, this Court concluded, conflict with 21 U.S.C. § 337(a), which "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Id.* at 349 n.4. In *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), this Court further held that the express preemption provision of the MDA, 21 U.S.C. § 360k(a), bars state common-law claims regarding medical devices that the FDA has determined to be safe and effective pursuant to its rigorous premarket approval process, unless those claims are based on state-law duties that "parallel" federal requirements. *Id.* at 330.

In this case, respondents claim that Medtronic, Inc. was negligent under Arizona law because it allegedly violated federal requirements to report adverse-event information to the FDA regarding a medical device that had received premarket approval. The Ninth Circuit nevertheless held that the MDA neither impliedly nor expressly preempted that claim.

The question presented is whether the MDA preempts a state-law claim alleging that a medical device manufacturer violated a duty under federal law to report adverse-event information to the FDA.

PARTIES TO THE PROCEEDING AND RULE 29.6 STATEMENT

All parties to the proceedings below are named in the caption.

Pursuant to this Court's Rule 29.6, undersigned counsel state that Medtronic, Inc. is a publicly held company. It has no parent corporation, and no publicly held company owns 10% or more of its stock.

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PETITION FOR A WRIT OF CERTIORARI

Petitioner Medtronic, Inc. respectfully submits this petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Ninth Circuit.

OPINIONS BELOW

The en banc opinion of the court of appeals is reported at 704 F.3d 1224. Pet. App. 1a. The court of appeals' order granting rehearing en banc is reported at 686 F.3d 1121. Pet. App. 59a. The panel opinion of the court of appeals is reported at 676 F.3d 1159. Pet. App. 26a. The relevant order of the district court is unofficially reported at 2010 WL 4483970. Pet. App. 52a.

JURISDICTION

The court of appeals filed its en banc opinion and entered its judgment on January 10, 2013. Pet. App. 1a. On April 1, 2013, Justice Kennedy granted an extension of time for filing a petition for a writ of certiorari until May 10, 2013. No. 12A931. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL PROVISIONS, STATUTES, AND REGULATIONS INVOLVED

All pertinent constitutional provisions, statutes, and regulations are reproduced in the Petition Appendix at 60a-127a.

STATEMENT

The Ninth Circuit's decision in this case deepens two direct and acknowledged circuit splits concerning the preemptive effect of the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA"). It also directly contra-

venes, and effectively nullifies, this Court's holdings in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), and *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

Respondents contend that Medtronic was negligent under Arizona law because it allegedly failed to provide the FDA with information about adverse events involving one of its medical devices. The Ninth Circuit held that this state-law claim was not impliedly or expressly preempted by the MDA. In reaching that conclusion, the Ninth Circuit held that the general duty of care under Arizona common law incorporated a requirement to furnish adverse-event information to the FDA.

This attempt to use general principles of state law to enforce federal reporting requirements conflicts with 21 U.S.C. § 337(a), which provides that the MDA must "be enforced exclusively by the Federal Government." *Buckman*, 531 U.S. at 352. Congress granted exclusive enforcement authority to the FDA so that it could establish a uniform federal regulatory framework and strike a balance that both promotes safety and ensures that the development of innovative devices is not "stifled by unnecessary restrictions." H.R. Rep. No. 94-853, at 12 (1976). Private enforcement, in contrast, would jeopardize the public health by permitting lay juries to second-guess the FDA's expert regulatory judgment. Those jury trials would enmesh federal regulators in litigation as fact witnesses needed to prove what the agency would have done differently in the absence of alleged MDA violations, and interfere with the FDA's carefully calibrated enforcement decisions. For those reasons, several circuits have held that virtually

identical claims are impliedly preempted under the MDA and this Court's decision in *Buckman*.

Multiple circuits have also held that virtually identical claims are expressly preempted by 21 U.S.C. § 360k(a) and this Court's decision in *Riegel*. The Ninth Circuit's contrary decision eviscerates § 360k(a) and ignores Congress's intent to subject medical devices to uniform national regulation.

A. Regulatory Background

When Congress enacted the MDA in 1976, it sought to "provide for the safety and effectiveness of medical device[s]" (Pub. L. No. 94-295, 90 Stat. 539, 539 (1976)), while simultaneously "encourag[ing] the[ ] research and development" of "sophisticated, critically important" devices. S. Rep. No. 94-33, at 2 (1975). To achieve that regulatory balance, the MDA "swept back" state regulation of medical devices and "imposed a regime of detailed federal oversight" by the FDA. *Riegel*, 552 U.S. at 316. For example, § 360k(a) expressly preempts state-law requirements applicable to medical devices that are "different from, or in addition to," requirements established by the FDA. 21 U.S.C. § 360k(a). Similarly, § 337(a)—which was enacted as part of the FDCA in 1938 and extended by the MDA to medical devices—establishes that there is no private right of action to enforce the MDA, and that, apart from certain suits initiated by the States, "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). Section 337(a) therefore prohibits state-law claims in which the violation of an MDA requirement is a "critical element" of the plaintiff's case. *Buckman*, 531 U.S. at 353. Accordingly, in *Buckman*, this Court held that the MDA impliedly

preempted state-law claims alleging that the defendant had submitted fraudulent information to the FDA because those claims conflicted with § 337(a), which "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Id.* at 349 n.4.

The MDA subjects medical devices to detailed federal oversight by dividing them into three classes based on their potential risks, and imposing a different degree of federal regulation on each class. *See* 21 U.S.C. § 360c. Class III devices are those that present the greatest risk and that "therefore incur the FDA's strictest regulation." *Buckman*, 531 U.S. at 344; *see also* 21 U.S.C. § 360c(a)(1)(C).

If a new Class III device is not "substantially equivalent" to a device that was already on the market when the MDA was enacted, 21 U.S.C. § 360e(b)(1)(B), it must undergo a "rigorous" regulatory-review process known as "premarket approval." *Riegel*, 552 U.S. at 317. In that process, the FDA spends hundreds of hours comprehensively reviewing the clinical studies and medical literature regarding the device, and thoroughly examining its design, manufacturing, and labeling. 21 U.S.C. § 360e(d)(2); *see also Riegel*, 552 U.S. at 318. The FDA approves a device only if it finds that there is a reasonable assurance of the device's safety and effectiveness. 21 U.S.C. § 360e(d)(1)(A)(i), 360e(d)(2). Once a device receives premarket approval, the MDA prohibits the manufacturer from making any changes to the device—including its labeling—that would affect its safety and effectiveness; such changes can only be made after the FDA has approved an application for supplemental premarket approval, which is "evalu-

ated under largely the same criteria as an initial application." *Riegel*, 552 U.S. at 319; *see also* 21 U.S.C. § 360e(d)(6). Because devices that have received premarket approval are subject to these device-specific federal "requirements," § 360k(a) preempts state common-law claims concerning such devices unless the state-law duties are "'parallel'" to the federal requirements. *Riegel*, 552 U.S. at 322-23, 330 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)).[1]

The MDA requires that manufacturers report information to the FDA even after a device's approval. For example, a manufacturer must submit an adverse-event report to the FDA whenever it

> receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices—
>
> (A) may have caused or contributed to a death or serious injury, or
>
> (B) has malfunctioned and that such device or a similar device marketed by the manufacturer . . . would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

21 U.S.C. § 360i(a)(1); *see also* 21 C.F.R. § 803.50(a). The FDA must withdraw premarket approval for a device if it determines that the manufacturer has "repeatedly or deliberately" violated its duty to sub-

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[1] The MDA also authorizes a new Class III device to be marketed without FDA review for safety and effectiveness if it is "substantially equivalent" to a device that was already on the market in 1976. 21 U.S.C. § 360e(b)(1)(B). This form of review is known as the § 510(k) process. *Riegel*, 552 U.S. at 317.

mit adverse-event reports regarding that device. 21 U.S.C. § 360e(e)(1)(D)(i); *see also*, *e.g.*, *id.* §§ 360e(e)(1)(A), 360h; *Riegel*, 552 U.S. at 319-20.

B. Proceedings Below

1. Medtronic's SynchroMed Pump & Infusion System is a Class III medical device that received premarket approval from the FDA in 1988. Pet. App. 6a-7a. When implanted, the SynchroMed Pump delivers pain medication directly into the spine. *Id.* at 6a, 27a. The version of the device at issue here—the SynchroMed EL Pump and Catheter—received supplemental premarket approval from the FDA in 1999. *Id.* at 6a.

Respondents allege that, in October 2000, a SynchroMed EL Pump and Catheter was implanted in Richard Stengel's abdomen. Pet. App. 6a. In February 2005, Mr. Stengel was diagnosed with ascending paralysis caused by an inflammatory mass, known as a granuloma, at the tip of the catheter. *Id.* at 6a, 28a. Surgeons removed the device and most of the granuloma, but only after the granuloma rendered Mr. Stengel permanently paraplegic. *Ibid.*

2. Respondents filed a complaint against Medtronic asserting, among other things, that Medtronic was negligent because it failed to provide warnings to physicians regarding the risk of granulomas that were stronger than the warnings approved by the FDA. Pet. App. 28a, 31a. Medtronic moved to dismiss respondents' claims as preempted. *Id.* at 52a.

Respondents opposed that motion and moved to file an amended complaint, and then a substitute amended complaint. The last-proposed complaint added an allegation that, "[u]nder federal law and regulation," Medtronic had "a continuing duty to . . .

report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product." Pet. App. 32a. Respondents alleged that Medtronic was negligent under Arizona law because it violated this federal duty after Mr. Stengel's device was implanted, and that this violation caused Mr. Stengel's injuries. *See id.* at 23a, 28a.

The district court ruled that the claims in respondents' original complaint were expressly preempted. Pet. App. 56a. The district court also denied respondents' motion to amend their complaint because it ruled that the newly proposed claims were both expressly and impliedly preempted. *Id.* at 56a-57a.

3. A divided panel of the Ninth Circuit affirmed. Although the panel assumed that respondents' proposed negligence claim based on an alleged failure to submit adverse-event information to the FDA could survive express preemption, *see* Pet. App. 32a, it held that this claim was foreclosed under § 337(a) and *Buckman*. *Id.* at 33a. The panel reasoned that there was "no meaningful distinction" between respondents' claim that Medtronic was negligent because it violated federal reporting requirements, and "the 'fraud-on-the-FDA' claims held to be preempted in *Buckman*." *Id.* at 34a. The panel explained that, although Arizona common law imposed a duty on manufacturers to provide adequate warnings to consumers, it did not impose a duty, independent of the requirements of the MDA, to provide information to the FDA. *See id.* at 36a. "The policing of" those MDA requirements, the panel concluded, "is committed exclusively to the federal government, and recog-

nizing a state cause of action based on such conduct would conflict with the statutory scheme established by Congress." *Id.* at 34a.

The panel "acknowledge[d] that there is a division among the circuits whether state failure-to-warn claims are preempted by *Buckman*." Pet. App. 38a. It pointed to the Eighth Circuit's holding that state-law claims based on an alleged failure to submit adverse-event reports to the FDA were impliedly preempted, as well as the Fifth Circuit's contrary conclusion. *Ibid.* (citing *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200 (8th Cir. 2010); *Hughes v. Bos. Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011)). The panel "join[ed] the Eighth Circuit" and rejected the conflicting decision of the Fifth Circuit. *Id.* at 39a.

4. The Ninth Circuit granted rehearing en banc. Applying a "presumption against federal preemption" found in neither *Buckman* nor *Riegel*, the en banc court held that, to the extent respondents alleged that Medtronic was negligent under a generalized state-law duty of care because it violated federal reporting requirements, their claim was "not preempted, either expressly or impliedly, by the MDA." Pet. App. 7a, 20a.

The Ninth Circuit held that respondents' negligence claim was not impliedly preempted under *Buckman* because it was based on duties imposed by Arizona common law—the "general duty of reasonable care" and the duty to provide "appropriate warning[s]"—and was not brought exclusively under federal law. Pet. App. 19a (internal quotation marks omitted). The Ninth Circuit "join[ed]" the Fifth Circuit's decision reaching the same result in *Hughes*. *Id.* at 20a. It also declared that *Hughes* was "not in-

consistent" with the Eighth Circuit's decision in *Sprint Fidelis*—which had held state-law claims based on a failure to submit adverse-event reports to be preempted—because the plaintiffs in *Sprint Fidelis* supposedly "sought to bring actions based solely on the MDA rather than on state law." *Id.* at 18a. The Ninth Circuit further held that respondents' negligence claim was not expressly preempted under § 360k(a) and *Riegel* because the court deemed the state-law duties of reasonable care on which respondents relied to be "parallel[ ]" to the federal duty to report information to the FDA. *Id.* at 20a.

Judge Watford authored a concurring opinion that was joined by six of the ten other judges on the en banc panel. Pet. App. 22a. Although he explained that respondents' negligence claim was expressly preempted to the extent that it was based on "an alleged state law duty to warn doctors directly," Judge Watford agreed that respondents' claim was not preempted to the extent that it was based on an alleged failure "to report adverse events *to the FDA*." *Id.* at 22a-23a. He also emphasized that respondents faced a "causation hurdle" because they would "ultimately have to prove that if Medtronic had properly reported the adverse events to the FDA as required under federal law, that information would have reached Mr. Stengel's doctors in time to prevent his injuries." *Id.* at 23a. Judge Watford nevertheless concluded that respondents' "allegations of causation [were] adequate" to survive a motion to dismiss. *Ibid.*

REASONS FOR GRANTING THE PETITION

This Court's review is warranted because the Ninth Circuit's decision deepens two acknowledged circuit splits regarding the preemptive scope of the

MDA, conflicts with this Court's decisions in *Buckman* and *Riegel*, and impairs the surpassingly important public-health objectives that the MDA was enacted to promote.

As the Ninth Circuit panel recognized in this case, the courts of appeals are divided on the question whether the MDA impliedly preempts state-law claims alleging that a device manufacturer violated its obligation under federal law to report adverse events to the FDA. The Sixth and Eighth Circuits have held that the MDA impliedly preempts such claims. *See 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). In contrast, the Fifth Circuit—now joined by the Ninth Circuit in the decision below—has held that such claims are not preempted. *See* Pet. App. 20a; *Hughes v. Bos. Scientific Corp.*, 631 F.3d 762, 775-76 (5th Cir. 2011).

The courts of appeals are also split on the question whether the exception to the MDA's express preemption provision for claims based on "parallel" duties under state and federal law extends to claims that rest on an alleged violation of a generalized federal duty applicable to all medical devices—as opposed to a device-specific federal requirement. The Eighth and Eleventh Circuits have held that § 360k(a) expressly preempts claims that are based on generalized federal requirements applicable to all medical devices. *See Sprint Fidelis*, 623 F.3d at 1206-07; *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301-02 (11th Cir. 2011). The Fifth, Sixth, and Seventh Circuits—as well as the Ninth Circuit below—have held, in contrast, that these claims are not expressly preempted. *See* Pet. App. 20a; *Bass v.*

Stryker Corp., 669 F.3d 501, 511-13 (5th Cir. 2012); *Hughes*, 631 F.3d at 769-70; *Howard v. Sulzer Orthopedics, Inc.*, 382 F. App'x 436, 440 (6th Cir. 2010); *Bausch v. Stryker Corp.*, 630 F.3d 546, 554-56 & n.1 (7th Cir. 2010).

In addition to exacerbating these circuit splits, the Ninth Circuit's preemption analysis effectively nullifies this Court's decisions in *Buckman* and *Riegel*, providing a roadmap for plaintiffs to circumvent the preemptive force of the MDA. Section 337(a) establishes that the MDA must "be enforced exclusively by the Federal Government." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001). The MDA therefore impliedly preempts any state-law claim against a medical device manufacturer in which an alleged violation of the MDA is a "critical element" of the plaintiff's case. *Id.* at 353. In that circumstance, the plaintiff is attempting to enforce the MDA in conflict with § 337(a) and the carefully crafted federal regulatory framework established by Congress and implemented by the FDA. *See id.* at 352-53. A state-law claim survives § 337(a) only if it is clear that liability can be established without reference to or reliance on federal law. *See ibid.* Accordingly, a state-law claim for failing to report information to the FDA is impliedly preempted unless, in the absence of the reporting requirements of the MDA, state law would *independently* impose a duty to report the information to the FDA.

The Ninth Circuit, however, held that state tort claims are not preempted whenever the plaintiff invokes a generalized common-law duty of care to enforce federal requirements—even if state law would not independently impose the duty in question in the absence of the MDA. The Ninth Circuit's decision

effectively creates a private right of action to enforce the MDA and therefore contravenes § 337(a) and *Buckman*, as well as this Court's other decisions circumscribing the availability of private rights of action to enforce federal statutes. *See*, *e.g.*, *Alexander v. Sandoval*, 532 U.S. 275 (2001).

Moreover, this Court explained in *Riegel* that state-law claims concerning devices that have received premarket approval can escape express preemption under § 360k(a) only when they are based on "parallel" duties under state and federal law. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008). A state-law duty is "parallel" to a federal-law duty only when the two duties are "identical," *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996), or "*genuinely* equivalent." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 454 (2005). Otherwise, the state-law duty is expressly preempted because it is "different from, or in addition to," the requirements of the MDA. 21 U.S.C. § 360k(a)(1). But the Ninth Circuit did not require any meaningful showing that respondents' negligence claim is based on a state-law duty that is "identical" or "*genuinely* equivalent" to federal reporting requirements—thereby opening the door to the regulatory inconsistency and inefficiency that this Court sought to foreclose in *Riegel*.

Resolution of these conflicts is exceptionally important. Congress enacted the MDA to ensure the widespread availability of safe and effective medical devices. This Court's decisions in *Buckman* and *Riegel* promote that public-health objective by foreclosing the imposition of conflicting state regulatory requirements and preventing lay juries from second-guessing the expert regulatory determinations of the FDA. The Ninth Circuit's decision, in contrast,

would subject medical device manufacturers to potentially irreconcilable state and federal regulatory requirements because juries would be empowered to impose liability even for conduct that the FDA has found does not violate the MDA. The Ninth Circuit's decision also would subject medical device manufacturers to substantial sanctions for MDA violations that federal regulators have chosen to address through different, more finely calibrated means. The result will be to complicate substantially the task of bringing new, potentially life-saving medical devices to market through the imposition of unpredictable costs and open-ended liability. This case—in which the Court has the opportunity to resolve questions of both implied and express preemption that have divided the lower courts—is the ideal vehicle for bringing clarity to this profoundly consequential area of federal law.

I. THE DECISION BELOW DEEPENS TWO CIRCUIT SPLITS REGARDING THE MDA'S PREEMPTIVE SCOPE.

Even before the decision in this case, the courts of appeals were divided regarding the applicability of both implied and express preemption under the MDA to state-law claims based on alleged violations of duties imposed by federal law. The Ninth Circuit's decision exacerbates those conflicts.

A. The Circuits Are Split On Whether The MDA Impliedly Preempts State-Law Claims Alleging A Failure To Report Adverse Events To The FDA.

1. In direct conflict with the Ninth Circuit's decision in this case and the decision of the Fifth Circuit on which it relied, the Sixth and Eighth Circuits

have held that the MDA impliedly preempts a state-law claim that a medical device manufacturer was negligent because it allegedly violated federal requirements to submit adverse-event reports to the FDA.

In *Sprint Fidelis*, the plaintiffs claimed that Medtronic was negligent because it "failed to provide the FDA with sufficient information and did not timely file adverse event reports, as required by federal regulations." 623 F.3d at 1205. The Eighth Circuit held that this claim was "simply an attempt by private parties to enforce the MDA," and was therefore "foreclosed by § 337(a) as construed in *Buckman*." *Ibid.*

Similarly, in *Cupek*, the plaintiffs claimed that Medtronic "was negligent per-se in failing to comply with the FDA's conditions of [premarket] approval." 405 F.3d at 423. The plaintiffs specifically alleged that Medtronic had "negligently failed to provide post-sale test dat[a] and information to the FDA and therefore failed to comply with the conditions of approval and applicable post-approval CFR regulations." Brief for Appellants at 9, *Cupek*, 405 F.3d 421 (No. 04-3201); *see also id.* at 24 (alleging that Medtronic violated its "duty to submit . . . information to the FDA in . . . a supplement or annual report"). The Sixth Circuit held that this claim was impliedly preempted under *Buckman* because it was "a disguised fraud on the FDA claim." *Cupek*, 405 F.3d at 424.

2. The Fifth and Ninth Circuits have reached the opposite conclusion. In *Hughes*, the plaintiff claimed that a medical device manufacturer was negligent because it had "fail[ed] to report serious injuries and malfunctions of [its] device" to the FDA, as

required by federal law. 631 F.3d at 765. The Fifth Circuit held that this "failure to report" theory was "not analogous to the 'fraud-on-the-FDA' theory in *Buckman*," and was not impliedly preempted. *Id.* at 775.

The Ninth Circuit adopted the same view below, and "join[ed]" the decision in *Hughes*. Pet. App. 20a. Like the plaintiffs in *Hughes*, respondents are pursuing a "state-law negligence claim" based on the theory that "Medtronic failed to perform its duty under federal law" to "report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product." *Id.* at 4a, 18a (internal quotation marks omitted). And, like the Fifth Circuit, the Ninth Circuit held that this claim was not impliedly preempted under § 337(a) and *Buckman*. *Id.* at 20a.

3. This split is direct and acknowledged. The Fifth, Sixth, Eighth, and Ninth Circuits each confronted claims alleging that a device manufacturer had violated state tort law by failing to comply with federal reporting obligations, and reached conflicting results as to whether those claims were impliedly preempted. In fact, in holding that the MDA impliedly preempted such claims, the Eighth Circuit cited with approval the district court decision in *Hughes*—which the Fifth Circuit subsequently *reversed* on this issue. *See Sprint Fidelis*, 623 F.3d at 1205-06 (citing *Hughes v. Bos. Scientific Corp.*, 669 F. Supp. 2d 701, 710-12 (S.D. Miss. 2009)); *see also Hughes*, 631 F.3d at 776. The Ninth Circuit panel in this case was therefore correct when it acknowledged the "division among the circuits whether state fail-

ure-to-warn claims are preempted by *Buckman*." Pet. App. 38a.

The en banc Ninth Circuit's assertion that there is no split cannot withstand scrutiny. The Ninth Circuit stated that *Sprint Fidelis* was "not inconsistent" with its decision or *Hughes* because the plaintiffs in *Sprint Fidelis* "sought to bring actions based solely on the MDA rather than state law," whereas respondents in this case and the plaintiffs in *Hughes* asserted "a state-law claim based on a state-law duty." Pet. App. 18a. But there is no difference in the claims at issue in these cases. The claims in *Sprint Fidelis* were "state law causes of action," 623 F.3d at 1203, and the claims that the Eighth Circuit held to be impliedly preempted included a claim for "negligen[ce]," *id.* at 1205, which is the same state-law claim at issue here and in *Hughes*. *See* Pet. App. 4a, 18a-19a; *Hughes*, 631 F.3d at 765. And each of those claims was based on the same theory of "negligence"—that the defendants had violated federal requirements to submit adverse-event reports to the FDA. *See* Pet. App. 18a-19a; *Hughes*, 631 F.3d at 765, 775; *Sprint Fidelis*, 623 F.3d at 1205.

Nor is there any material difference between the "state-law dut[ies]" at issue in these cases. Pet. App. 18a. The Ninth Circuit asserted that respondents' claim was based on the "general duty of reasonable care" and the duty to provide "appropriate warning[s]" under Arizona common law. *Id.* at 19a (internal quotation marks omitted). At this level of generality, however, the duties of care under Arizona law (or the Mississippi law at issue in *Hughes*) are no different from the duties of care under the law of any other State, including the state laws at issue in

Sprint Fidelis. In fact, because *Sprint Fidelis* arose from a multidistrict litigation in which complaints had been filed "across the country," 623 F.3d at 1203, the Eighth Circuit's decision was not based on the law of *any* particular State—much less a State that imposes duties different from those in Arizona or Mississippi.

The Ninth Circuit also asserted that "Arizona law contemplates a warning to a third party," which can satisfy "a manufacturer's duty if . . . there is 'reasonable assurance that the information will reach those whose safety depends upon their having it.'" Pet. App. 20a (quoting *Anguiano v. E.I. DuPont de Nemours & Co.*, 808 F. Supp. 719, 723 (D. Ariz. 1992)). This principle, however, was taken verbatim from the Restatement (Second) of Torts, and thus is also a general proposition of tort law that is not peculiar to Arizona. *See Anguiano*, 808 F. Supp. at 723 (quoting Restatement (Second) of Torts § 388 cmt. n), *aff'd*, 44 F.3d 806 (9th Cir. 1995).

B. The Circuits Are Split On Whether The MDA Expressly Preempts State-Law Claims Alleging A Violation Of A Generalized, Rather Than A Device-Specific, Federal Requirement.

There is also pervasive disagreement in the lower courts regarding the scope of the "parallel" duty exception to the MDA's express preemption provision recognized by this Court in *Riegel*. 552 U.S. at 330. Section 360k(a) expressly preempts any state-law "requirement" concerning a medical device that is "different from, or in addition to, any requirement applicable under this chapter to the device." In *Riegel*, this Court held that premarket approval imposes federal "requirements" on medical devices, and that

state common-law claims also impose "requirements" on those devices. 552 U.S. at 322-24. The Court concluded that § 360k(a) therefore expressly preempts state common-law claims regarding medical devices that have received premarket approval, unless those claims are based on state-law duties that are "parallel" to—and thus do not impose requirements "different from, or in addition to"—"federal requirements." *Id.* at 330.

Two circuits have held that this "parallel" duty exception is not applicable where a state-law duty is alleged to be parallel to a generalized federal duty that applies to all medical devices, rather than to a device-specific federal requirement. Four circuits—including the Ninth Circuit in the decision below—have held to the contrary, rejecting the distinction between general and device-specific federal duties in this setting.

1. In *Sprint Fidelis*, the Eighth Circuit held that the plaintiffs' manufacturing-defect claims were not based on state-law requirements parallel to federal requirements—and were therefore preempted—because the federal requirements at issue were not device-specific. 623 F.3d at 1207. In an effort to satisfy *Riegel*'s parallel-duty exception, the plaintiffs alleged that Medtronic had violated the FDA's Current Good Manufacturing Practices, which provide "'general objectives' for all device manufacturers" and are "applicable to all medical devices." *Id.* at 1206. The Eighth Circuit affirmed the district court's ruling that these claims were expressly preempted because the plaintiffs had not alleged that "Medtronic violated a federal requirement specific to the FDA's [premarket] approval of" the device at issue. *Id.* at 1207.

The Eleventh Circuit adopted the same approach in *Wolicki-Gables*. To "allege[ ] a parallel claim," the Eleventh Circuit held, the plaintiff must allege that the "defendant violated a particular federal specification referring to the device at issue," and must "set forth facts pointing to specific [premarket approval] requirements that have been violated." 634 F.3d at 1301 (internal quotation marks omitted). Because the plaintiffs in *Wolicki-Gables* had not satisfied that burden, the Eleventh Circuit held that their claims were expressly preempted. *See id.* at 1301-02.

2. In contrast, prior to the decision below, the Fifth, Sixth, and Seventh Circuits had all held that § 360k(a) does not expressly preempt state-law claims that are based on alleged violations of federal regulations generally applicable to all medical devices. *See Hughes*, 631 F.3d at 769-71 (holding that the plaintiff's claim was not expressly preempted to the extent that it was based on the generally applicable federal requirement to submit adverse-event reports to the FDA); *Howard*, 382 F. App'x at 440 (rejecting the defendant's argument that the Current Good Manufacturing Practices were "'simply too generic, standing alone, to serve as the basis for Plaintiffs' manufacturing-defect claims'") (citation omitted); *Bausch*, 630 F.3d at 554-56 & n.1 (holding that the plaintiff's claims, which were based on alleged violations of the Current Good Manufacturing Practices, were not expressly preempted); *see also Bass*, 669 F.3d at 511 (same).

Moreover, both the Fifth and Seventh Circuits acknowledged the existence of a conflict on this question. In *Bausch*, the Seventh Circuit recognized that the Eighth Circuit and several district courts had held that "a plaintiff must allege and prove violation

of a device-specific requirement to avoid the preemption defense," but that the Sixth Circuit had "rejected this approach" in *Howard*. 630 F.3d at 554 & n.1. Similarly, in *Bass*, the Fifth Circuit acknowledged that "the circuits are not in complete agreement as to what constitutes a sufficient pleading with regard to a CGMP." 669 F.3d at 511.

The Ninth Circuit deepened that existing conflict by "join[ing]" the view of the Fifth, Sixth, and Seventh Circuits in the decision below. Pet. App. 20a. Although respondents' claim is based on a generalized federal duty that applies to all medical devices—namely, the requirement to submit adverse-event reports to the FDA (*see* 21 U.S.C. § 360i(a)(1); 21 C.F.R. § 803.50(a))—the Ninth Circuit held that respondents' state-law negligence claim was "parallel" to the federal reporting requirements and therefore was not expressly preempted. Pet. App. 20a.

* * *

These divisions on basic questions regarding the MDA's preemptive scope produce widespread uncertainty and unfairness. Medical device manufacturers, and plaintiffs seeking to pursue claims against them, are currently confronted with a patchwork of conflicting approaches to implied and express preemption. For example, respondents' claim in this case would be impliedly preempted in the Sixth Circuit, expressly preempted in the Eleventh Circuit, and both impliedly and expressly preempted in the Eighth Circuit, but not preempted under either doctrine in the Fifth and Ninth Circuits and, at a minimum, not expressly preempted in the Seventh Circuit.

It is untenable to subject litigants to this hodgepodge of inconsistent outcomes based solely on geography. Such legal uncertainty would be unacceptable on any question of federal law, but it is particularly intolerable here because the MDA was intended to promote the availability of safe and effective medical devices by *eliminating* conflicting regulatory requirements and replacing them with a *uniform* federal regulatory framework. Only this Court can provide the much-needed clarity on these vitally important issues and effectuate the regulatory uniformity that the MDA was designed to establish.

II. THE DECISION BELOW SQUARELY CONFLICTS WITH THIS COURT'S DECISIONS IN *BUCKMAN* AND *RIEGEL*.

The need for this Court's review is all the more pressing because the Ninth Circuit's decision would effectively eviscerate *Buckman* and *Riegel*. Those decisions "create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption." *Sprint Fidelis*, 623 F.3d at 1204 (internal quotation marks omitted). A claim concerning a device that has received premarket approval can avoid preemption only if it is based on a state-law duty that is both (1) independent of (*Buckman*), and (2) parallel to (*Riegel*), a duty imposed by federal law.

Although respondents' negligence claim does not satisfy either requirement, the Ninth Circuit rejected Medtronic's implied and express preemption defenses. If permitted to stand, the Ninth Circuit's decision will provide a roadmap for circumventing federal preemption, disrupt the delicate regulatory balance established by the MDA, and transform the "narrow

gap" left open by *Buckman* and *Riegel* into a gaping hole.

A. Respondents' Claim Is Impliedly Preempted Under *Buckman* And § 337(a).

1. In *Buckman*, this Court held that the MDA impliedly preempts a state-law claim against a medical device manufacturer that is based on an alleged violation of the requirements of the MDA. *See* 531 U.S. at 352-53; *see also PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2578 (2011) (interpreting *Buckman* to hold "that federal drug and medical device laws preempted a state tort-law claim based on failure to properly communicate with the FDA"). Thus, a state-law claim against a device manufacturer is impliedly preempted unless it is based on a state-law duty that is *independent* of the MDA's requirements.

The plaintiffs in *Buckman* brought state-law claims alleging that the defendant had submitted fraudulent information to the FDA during the § 510(k) process. 531 U.S. at 343-44. This Court held that those claims conflicted with § 337(a), which provides that "all" proceedings to enforce the MDA "shall be by and in the name of the United States." 21 U.S.C. § 337(a). The Court deemed that provision to be "clear evidence that Congress intended that the MDA be enforced exclusively by the Federal Government." *Buckman*, 531 U.S. at 352; *see also id.* at 349 n.4. The plaintiffs' "fraud-on-the-FDA claims" invaded the FDA's exclusive authority to enforce the MDA, the Court concluded, because "traditional state tort law which had predated the federal enactments" did not impose an independent duty to provide truthful information to the FDA. *Id.* at 348, 353. Rather,

the existence of the requirements of the MDA was a "critical element" of the plaintiffs' case. *Id.* at 353.

The plaintiffs' claims conflicted with the "federal statutory scheme," the Court continued, because the MDA "amply empowers the FDA to punish and deter fraud against the Administration," and the balance of statutory objectives sought to be achieved by the FDA "can be skewed by allowing fraud-on-the-FDA claims under state tort law." 531 U.S. at 348. State-law claims for fraud on the FDA would "dramatically increase the burdens facing potential applicants," and thus might discourage applicants from seeking to market potentially beneficial devices, or might give them "an incentive to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA's evaluation of an application." *Id.* at 350-51.

2. The Court's reasoning in *Buckman* applies equally in this case. Rather than bringing a claim based on a state-law duty that would exist independently of the MDA, respondents claim that Medtronic was negligent because it allegedly violated its duty under *federal* law to submit adverse-event reports to the FDA. Pet. App. 18a-19a. That claim conflicts with § 337(a), and is therefore impliedly preempted, because the federal reporting requirement is a "critical element" of respondents' case, *Buckman*, 531 U.S. at 353, which is nothing more than an attempt to enforce the provisions of the MDA using a generalized state-law duty of care.

Like the claims in *Buckman*, respondents' claim therefore directly conflicts with the "federal statutory scheme" governing medical devices, which "amply empowers" the FDA to enforce the federal duty to submit adverse-event reports. *Buckman*, 531 U.S. at

348. For example, federal law requires the FDA to withdraw premarket approval if it determines that a manufacturer has "repeatedly or deliberately" failed to report adverse events. 21 U.S.C. § 360e(e)(1)(D)(i); *see also*, *e.g.*, *id.* §§ 360e(e)(1)(A), 360h. State-law claims for violations of the MDA's reporting requirements would interfere with the FDA's measured and deliberate exercise of that authority. Here, no less than in *Buckman*, the potential for state-law liability would "dramatically increase the burdens" on manufacturers, which might discourage them from seeking approval of particularly risky, life-saving devices, or might induce them to "submit a deluge" of adverse-event reports that the FDA "neither wants nor needs." 531 U.S. at 350-51; *cf. Arizona v. United States*, 132 S. Ct. 2492, 2502 (2012) ("Permitting the State to impose its own penalties for the federal offenses here would conflict with the careful framework Congress adopted.").

Moreover, it would be highly anomalous to conclude that the MDA preempts state-law liability for fraudulently withholding information from the FDA, *Buckman*, 531 U.S. at 348, but not for negligently failing to disclose the same information to the FDA. Congress could not have intended the MDA to preempt state-law claims only with respect to the *more* culpable conduct at issue in *Buckman*.

3. The Ninth Circuit nevertheless held that respondents' claim was not impliedly preempted under *Buckman* because respondents alleged that Medtronic had violated duties imposed by Arizona common law. Pet. App. 19a-20a. That ruling is flawed because Arizona common law would not *independently* impose a duty on Medtronic to submit adverse-event

reports to the FDA if the MDA reporting requirements did not exist.

There is nothing unusual about Arizona law in this respect. In fact, it would defy settled principles of sovereignty and federalism for a *state* law to impose a duty to submit information to the *federal* government. As a general matter, each sovereign decides what information *it* must be provided—not what information must be provided to *other* sovereigns. Thus, as *Buckman* recognized, the relationship between a regulated entity and the federal government is "inherently federal in character." 531 U.S. at 347.[2]

Arizona law comports with these well-established principles. The only potentially relevant state-law duties that respondents and the court of appeals identified were the "general duty of reasonable care" and the duty to provide "appropriate warning[s]." Pet. App. 19a (internal quotation marks omitted). The Ninth Circuit did not conclude—nor could it plausibly have done so—that, in the absence of the requirements imposed by the MDA, these highly generalized state-law duties would require Medtronic to submit adverse-event reports to the FDA. To the contrary, the common-law duties of care and to warn typically run to persons such as consumers and physicians—not the government. As in *Buckman*,

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[2] For these reasons, the Ninth Circuit erred in applying a presumption against preemption. *See* Pet. App. 7a. *Buckman* held that there is no such presumption when, as here, the plaintiff's claim concerns "the relationship between a federal agency and the entity it regulates." 531 U.S. at 347. *Riegel* also rejected the presumption against preemption because § 360k(a) "by its terms" displaces "the tort law of 50 States." 552 U.S. at 326.

policing what information flows to federal agencies "is hardly 'a field which the States have traditionally occupied.'" 531 U.S. at 347 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Indeed, even if state common law, in some circumstances, might impose a duty to provide information to the *state* government, there is no basis for concluding that this state-law reporting obligation would extend to the provision of warnings to the *federal* government. State tort law is concerned with the safety of a manufacturer's labeling—not with a manufacturer's communications to the federal government regarding that labeling. *See Mensing*, 131 S. Ct. at 2578 ("State law demanded a safer label; it did not instruct the Manufacturers to communicate with the FDA about the possibility of a safer label.").

The Ninth Circuit asserted, based on a 1992 federal district court decision, that Arizona law "contemplates a warning to a third party such as the FDA." Pet. App. 20a (citing *Anguiano*, 808 F. Supp. 719). The *Anguiano* decision, however, addressed whether a manufacturer whose product "is incorporated into a second product by another party" must provide a warning to that other party. 808 F. Supp. at 723. Here, respondents are not alleging that Medtronic had a duty to provide a warning to another manufacturer, but that Medtronic had a duty to provide a warning to a *federal regulator*. *Anguiano* does not hold or even suggest that Arizona law imposes the latter duty, and *Buckman* squarely holds that the relationship between device manufacturers and the FDA is exclusively governed by federal law. 531 U.S. at 347-48.

The Ninth Circuit's erroneous reasoning would allow plaintiffs to evade *Buckman* with impunity.

Every State imposes generalized duties of care on medical device manufacturers. Thus, in virtually every case, the plaintiff would be able to identify a generalized duty that, under the Ninth Circuit's decision, could be used as a basis for enforcing a claim that a manufacturer violated a requirement imposed by the MDA. If plaintiffs are allowed to manipulate generalized state-law duties in this manner to enforce federal regulatory requirements, *Buckman*'s requirement that a claim be based on an independent state-law duty will be rendered a dead letter.

In addition to nullifying *Buckman*, the Ninth Circuit's reasoning also would allow plaintiffs to bypass this Court's decisions establishing stringent standards for finding private rights of action to enforce federal statutes. *See*, *e.g.*, *Alexander*, 532 U.S. at 286-87. A private right of action is available only if "the statute Congress has passed . . . displays an intent to create not just a private right but also a private remedy." *Id.* at 286. The MDA displays the opposite intent because Congress provided in § 337(a) that *only* the federal government can bring suit to enforce the MDA. This Court recently rejected the notion that parties can invoke generalized state-law duties to evade Congress's decision not to create private enforcement rights. *Astra USA, Inc. v. Santa Clara County*, 131 S. Ct. 1342 (2011) ("third party" beneficiary contract theory). The Ninth Circuit's decision in this case evades congressional intent—and this Court's decisions—in precisely the same manner.

4. The seven concurring judges below recognized that the theory adopted by the majority would require respondents "to prove that if Medtronic had properly reported the adverse events to the FDA as

required under federal law, that information would have reached Mr. Stengel's doctors in time to prevent his injuries." Pet. App. 23a. Causation thus depends on proof that the FDA would have done something other than what it actually did. This recognition highlights the depth of the intrusion into federal authority—and disruption of agency processes—inherent in the majority's approach. Far from constituting a ground for endorsing the majority's reasoning, the causation issue identified by the concurring judges is another reason why this entire enterprise must be held to be preempted at the outset under Rule 12(b)(6).

Congress assigned the FDA the exclusive authority to enforce the MDA because it recognized that private enforcement would allow lay juries to second-guess the agency's regulatory judgments and disrupt the regulatory balance sought to be achieved by the FDA. *See Buckman*, 531 U.S. at 348, 350; *Riegel*, 552 U.S. at 325. Congress also recognized that private enforcement of the MDA could impose unwarranted burdens on the FDA that would divert the agency's time and resources away from its essential regulatory responsibilities. *See Buckman*, 531 U.S. at 351.

The causation inquiry identified by the concurring judges would impose precisely the burdens that Congress sought to avoid. Respondents must prove that, if Medtronic had submitted adverse-event reports to the FDA, the FDA would have responded in a manner that enabled the "information [to] reach[ ] Mr. Stengel's doctors in time to prevent his injuries." Pet. App. 23a. Respondents and other private litigants attempting to establish how the FDA would have exercised its discretion in this "but for" world

would undoubtedly seek discovery from the party in the best position to answer that question—the FDA—thereby exposing the agency to the discovery process and its massive associated burdens. Agency personnel inevitably would be asked to respond to voluminous discovery requests and deposition notices, which in turn would generate satellite litigation over issues such as confidentiality. The agency would be required to reallocate scarce resources to comply with these burdens—resources that would otherwise be devoted to fulfilling the FDA's regulatory mission. It was precisely these types of burdens on the agency that prompted this Court in *Buckman* to reject the argument that the prosecution of claims to enforce the MDA would affect only private litigants. *See* 531 U.S. at 351 n.6.

Even if these burdens could be countenanced, the causation inquiry required by the Ninth Circuit would still violate the MDA because it would allow juries to second-guess the considered judgment of the FDA. To decide what would have happened in the "but for" universe in which adverse-event reports were submitted to the FDA, a jury would be required to adjudicate how the agency should have reacted in these hypothetical circumstances. This inquiry would authorize lay juries to superintend the FDA's decision-making and disrupt the "somewhat delicate balance of statutory objectives" sought to be struck by the agency. *Buckman*, 531 U.S. at 348. Such intrusions into the FDA's regulatory judgment are flatly at odds with the letter and spirit of the MDA.

B. Respondents' Claim Is Expressly Preempted Under *Riegel* And § 360k(a).

The Ninth Circuit's decision also conflicts with *Riegel*. In that case, this Court held that the MDA's

express preemption provision, § 360k(a), generally bars common-law claims regarding devices that have received premarket approval from the FDA. 552 U.S. at 322-25. The limited exception, this Court explained, is for common-law claims that are based on state-law duties that "'parallel'" duties imposed by the MDA. *Id.* at 330 (quoting *Lohr*, 518 U.S. at 495). As this Court made clear in *Lohr*, state-law and federal-law duties are only "parallel" if they impose "identical" requirements. 518 U.S. at 495; *see also Bates*, 544 U.S. at 447, 454 (interpreting a "similarly worded pre-emption provision" to preempt state labeling requirements unless they were "*genuinely* equivalent" to and "fully consistent" with federal requirements).

The Ninth Circuit erred in holding that respondents' state-law negligence claim is sufficiently parallel to a federal requirement to escape express preemption under § 360k(a). *See* Pet. App. 20a. The federal duty at issue in this case is a duty to provide adverse-event reports *to the FDA*, but the only state-law duty that is conceivably relevant is the duty to exercise reasonable care when determining whether to provide warnings *to consumers and physicians*. *See supra* pp. 25-26. These duties are not "identical" or "genuinely equivalent" because they impose different obligations on medical device manufacturers. *See Mensing*, 131 S. Ct. at 2578.

Moreover, even assuming *arguendo* that Arizona law requires a manufacturer to submit adverse-event reports to the FDA, respondents' claim would still be expressly preempted. As the Eighth and Eleventh Circuits have held, a plaintiff must allege a violation of a device-specific federal requirement—as opposed to generalized requirements applicable to all medical

devices—to satisfy the parallel-duty exception. *See Sprint Fidelis*, 623 F.3d at 1206-07; *Wolicki-Gables*, 634 F.3d at 1301. In the absence of such a device-specific federal requirement, the jury would possess wide discretion to impose a duty that is *different* from the one imposed by federal law—thereby contravening *Riegel* and disrupting the FDA's carefully calibrated regulation of medical devices.

Indeed, this Court held in *Lohr* that generalized federal duties that apply to all medical devices are not federal "requirements" within the meaning of § 360k(a). *See* 518 U.S. at 501. The parallel-duty exception, however, applies only when a state-law requirement is parallel to a federal "requirement[ ]." *Id.* at 495; *Riegel*, 552 U.S. at 330. Thus, a plaintiff cannot satisfy the parallel-duty exception by alleging the violation of a generalized federal duty that applies to all medical devices because, according to *Lohr*, that generalized duty is not a "requirement" within the meaning of § 360k(a).

Lohr establishes that the federal duty at issue here—which requires a manufacturer to submit reports to the FDA whenever it "becomes aware of information that reasonably suggests that one of its marketed devices . . . may have caused or contributed to a death or serious injury," 21 U.S.C. § 360i(a)(1)—is too generalized to be a federal "requirement" under § 360k(a) and satisfy the parallel-duty exception because it applies to all medical devices. A lay jury would have far-ranging discretion in enforcing this duty to mandate the submission of adverse-event reports in circumstances in which the FDA has determined, in its expert regulatory judgment, that such reports should *not* be submitted.

The Ninth Circuit did not require any meaningful showing that the respective state and federal duties are "identical" or "genuinely equivalent." Rather, under the Ninth Circuit's approach, the parallel-duty exception to express preemption under § 360k(a) is satisfied whenever the plaintiff can identify highly generalized duties under federal and state law that superficially overlap with each other. That would convert the limited exception for claims based on parallel duties into the general rule, and throw open the floodgates to potentially massive state-law liability imposed by lay juries asked to second-guess the FDA's expert regulatory oversight of complex, and potentially life-saving, medical devices.

III. THIS CASE IS AN IDEAL VEHICLE FOR ADDRESSING A RECURRING QUESTION OF EXCEPTIONAL IMPORTANCE TO DEVICE MANUFACTURERS AND THE PUBLIC HEALTH.

The question presented has profound implications for the medical device industry as well as for the public-health interests that the MDA is designed to promote.

Congress enacted the MDA to facilitate the development, production, and availability of safe and effective medical devices by establishing a uniform federal regulatory framework. *See* S. Rep. No. 94-33, at 2 (1975) (the MDA "encourages the[ ] research and development" of "sophisticated, critically important" devices); H.R. Rep. No. 94-853, at 12 (1976) (the MDA is a "balanced regulatory proposal" that both promotes safety and ensures that the development of innovative devices is not "stifled by unnecessary restrictions"). This Court's decisions in *Buckman* and *Riegel* advance this public-health objective by preventing lay juries from displacing the FDA's expert

decision-making through the imposition of potentially conflicting state-law requirements or excessive penalties for MDA violations. *See Buckman*, 531 U.S. at 350; *Riegel*, 552 U.S. at 325. By permitting plaintiffs to circumvent *Buckman* and *Riegel* with ease, the Ninth Circuit's decision will inevitably generate widespread regulatory confusion and frustrate attempts to bring new, and potentially life-saving, medical devices to the market.

The frequently recurring—and highly consequential—question presented by the Ninth Circuit's decision is ripe for this Court's review. Numerous courts of appeals have already addressed whether the MDA preempts a claim that, as here, is based on an alleged violation of the federal reporting requirements or other similarly generic federal regulations, such as the FDA's Current Good Manufacturing Practices. *See supra* pp. 14-15, 18-20. This issue is likely to arise with even greater frequency in the wake of the Ninth Circuit's decision, which provides a blueprint for evading preemption under the MDA. In fact, "[a] raft of lawsuits" was recently filed against St. Jude Medical Inc. in state and federal court in California based on the theory endorsed by the decision below—that St. Jude failed to "report device flaws" to the FDA. *See* Christopher Weaver & Jennifer Smith, *St. Jude Hit by Suits*, Wall St. J., Apr. 5, 2013, at B4. And because all Class III medical devices are subject to the MDA's reporting requirements, the number of cases in which plaintiffs could seek recovery under the Ninth Circuit's preemption analysis is limitless.

Finally, this case is an excellent vehicle for addressing the question presented. The preemption issue was fully briefed below and addressed by both the panel and the en banc court of appeals. It is also

outcome-determinative—Medtronic will immediately prevail if respondents' claim is preempted, but will be required to return to the district court for discovery under the Ninth Circuit's contrary decision. Moreover, this case presents issues of both implied and express preemption, and therefore offers an ideal opportunity for this Court to provide urgently needed guidance on two interrelated issues that have sharply divided the lower courts and that implicate far-reaching jurisprudential, economic, and public-health considerations.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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May 10, 2013