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

BRIEF OF WASHINGTON LEGAL FOUNDATION AND ALLIED EDUCATIONAL FOUNDATION AS AMICUS CURIAE IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Whether the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act preempt a state-law claim alleging that a medical device manufacturer violated a duty under federal law to report adverse-event information to the Food and Drug Administration.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases:

Page(s)

Statutes:

Regulations:

BRIEF OF WASHINGTON LEGAL FOUNDATION AND ALLIED EDUCATIONAL FOUNDATION AS AMICI CURIAE IN SUPPORT OF PETITIONER

INTERESTS OF *AMICI CURIAE*

The Washington Legal Foundation (WLF) is a non-profit public interest law and policy center with supporters in all 50 states.[1] WLF devotes a substantial portion of its resources to defending free-enterprise, individual rights, and a limited and accountable government.

To that end, WLF has frequently appeared as *amicus curiae* in this and other federal courts in cases involving preemption issues, to point out the economic inefficiencies often created when multiple layers of government seek simultaneously to regulate the same business activity. *See, e.g., Mutual Pharmaceutical Co. v. Bartlett*, No. 12-142 (decision pending); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008)*; Bates v. Dow AgroSciences LLC,* 544 U.S. 431 (2005); *Buckman Co. v. Plaintiffs' Legal Comm.,* 531 U.S. 341 (2001); *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000); *United States v. Locke,* 529 U.S. 89 (2000).

The Allied Educational Foundation (AEF) is a

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[1] Pursuant to Supreme Court Rule 37.6, *amici* state that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than *amici* and their counsel, made a monetary contribution intended to fund the preparation or submission of this brief. All parties have consented to this filing; letters of consent have been lodged with the Court. More than 10 days prior to the due date, counsel for *amici* provided counsel for Respondents with notice of *amici*'s intent to file.

non-profit charitable foundation based in Englewood, New Jersey. Founded in 1964, AEF is dedicated to promoting education in diverse areas of study, such as law and public policy, and has appeared as *amicus curiae* in this Court on a number of occasions.

At issue here is whether Congress intended to preempt Respondents' causes of action. *Amici* agree with Petitioner that review is warranted in order to resolve the deep circuit split regarding the preemptive scope of the Medical Devices Amendments of 1976 (MDA), a split that encompasses both the circumstances under which the MDA impliedly preempts state-law tort actions and the scope of the MDA's express preemption provision, 21 U.S.C. § 360k(a).

In addition to demonstrating the disarray among the federal courts regarding MDA preemption, the Petition discusses at length the conflict between the decision below and several of this Court's preemption decisions. *Amici* write separately to focus on those preemption decisions, which discerned in the MDA a congressional intent to broadly preempt state-law tort claims against the manufacturers of medical devices approved for marketing under the Food and Drug Administration's (FDA) rigorous pre-market approval (PMA) process. *Amici* are concerned that if the decision below is allowed to stand, MDA preemption of state-law tort claims will be rendered largely illusory.

Amici have no direct interests, financial or otherwise, in the outcome of this case. They are filing due solely to their interests in the important preemption issues raised by this case.

STATEMENT OF THE CASE

This case involves a state-law personal injury suit seeking damages from Petitioner Medtronic, Inc., the manufacturer of a Class III medical device (the SynchroMed Pump & Infusion System) that was implanted into Respondent Richard Stengel in order to deliver pain medication directly into his spine. FDA approved the SynchroMed Pump for marketing in 1988 (and issued a supplemental approval in 1999) following a safety and effectiveness review in accordance with the agency's rigorous PMA process. *See* 21 U.S.C. § 360c(a)(1)(C). Stengel contends that medical complications caused by the device led to his paralysis.

Stengel is an Arizona resident. He and his wife filed suit against Medtronic alleging violation of a number of common law duties, including negligence in having failed to warn doctors regarding the full risks of the device. They later sought to amend their complaint to add a claim that Medtronic breached a continuing duty under federal law to monitor the device's post-approval performance and to report to 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. They contended that this alleged federal violation constituted actionable negligence under Arizona law.

The district court dismissed the complaint on the pleadings, determining that the Stengels' claims were barred by the MDA's express preemption clause, 21 U.S.C. § 360k(a). Pet. App. 52a-58a. It also denied their motion to amend the complaint, finding that the

proposed new claims were both expressly and impliedly preempted. *Id.* at 56a-57a.

A Ninth Circuit panel affirmed. Pet. App. 26a-51a. The proposed amended complaint alleged that Medtronic was negligent in failing to send a "medical device correction notice" to doctors "whether or not the FDA ordered it." *Id.* at 31a. The panel held that that claim was expressly preempted by § 360k(a) because it sought to impose requirements beyond those imposed by FDA. *Id.* at 31-32. The panel stated that the failure-to-warn-FDA portions of the amended complaint "could be interpreted to survive express preemption," but were in any event impliedly preempted. *Id.* at 32a-39a. Citing *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), the panel concluded, "the Stengels' failure-to-warn claims, to the extent they survive express preemption, exist solely by virtue of the FDCA disclosure requirements and are, therefore, impliedly preempted." *Id.* at 36a. Judge Noonan dissented. *Id.* at 43a-48a.

The Ninth Circuit subsequently voted to rehear the case, and an 11-judge *en banc* panel reversed the district court's dismissal. Pet. App. 1a-25a. Although acknowledging this Court's decision in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), that § 360k(a) expressly preempts many tort claims involving devices that have undergone the rigorous PMA approval process, the *en banc* court noted that *Riegel* expressly preserved claims alleging violation of state duties that "parallel," rather than add to, federal requirements applicable to the device. *Id.* at 14a (citing *Riegel*, 552 U.S. at 330). It held that the Stengels' failure-to-warn-FDA claim escapes express preemption because it is

based on a state-law duty that parallels a federal requirement. *Id.* at 20a. It further held that the claim is not impliedly preempted because the claim "is independent of the pre-market approval process that was at issue in *Buckman*." *Id.*

A concurring opinion, joined by seven of the 11 members of the *en banc* panel, indicated that while the claims of the Stengels and similarly situated plaintiffs are not subject to dismissal on preemption grounds, they do "face a causation hurdle." *Id.* at 23a. "To prevail, they will 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.* The opinion concluded that a finding of implied preemption "would require an unwarranted expansion of *Buckman*'s rationale," because Medtronic's failure to report to FDA not only was an alleged violation of federal law "but also simultaneously misled the device's current and potential users, to whom Medtronic owed an independent duty under state law." *Id.* at 24a.

SUMMARY OF ARGUMENT

As the Petition amply demonstrates, the federal appeals courts have issued sharply conflicting opinions regarding the circumstances under which the MDA preempts personal injury claims filed under state law. That conflict encompasses rules governing both express and implied preemption. The Ninth Circuit has aligned itself with the Fifth and Seventh Circuits in concluding that the MDA does not impliedly preempt state-law claims alleging a failure to report adverse

events to FDA. Pet. App. 20a. The now-vacated panel decision had previously aligned the Ninth Circuit with the Sixth and Eighth Circuits' diametrically opposed position regarding implied preemption of such failure-to-report claims. *Id.* at 34a, 39a. The federal circuit courts face an equally sharp divide on express preemption, with the Fifth, Sixth, Seventh, and Ninth Circuits sharply (and expressly) disagreeing with the Eighth and Eleventh Circuit regarding whether a tort plaintiff may successfully invoke the parallel claims exception when the federal requirement is a generalized federal duty, rather than one that is specific to the medical device at issue. Review is urgently needed to provide the lower federal courts with guidance on these issues.

Further guidance is also needed because the Ninth Circuit appears to have gone out of its way to evade the clear import of the Court's holdings on MDA preemption. For example, *Riegel* established a general rule of express preemption under 28 U.S.C. § 360k(a) for medical devices that have received pre-market approval. Yet, the Ninth Circuit latched onto *Riegel*'s brief discussion of a "parallel claim" exception to turn *Riegel* on its head, thereby suggesting that "no preemption" is the general rule for such devices. The "parallel claim" exception was not at issue in *Riegel* so the Court mentioned it only in passing in a single paragraph, stating that: (1) truly "parallel claims" would not be preempted; but (2) it declined to address the plaintiffs' assertion that their state-law claims qualified as parallel claims because they had not raised that assertion in their briefs below or in their certiorari petition. *Riegel*, 552 U.S. at 330. Given the frequency with which personal-injury plaintiffs seek to invoke the

"parallel claim" exception, and the Ninth Circuit's use of that exception to swallow the *Riegel* rule, further guidance from the Court is fully warranted.

The Petition provides an excellent vehicle for addressing the issues that have divided the appeals courts. It addresses both express and implied preemption under the MDA. Both issues were raised and expressly addressed by the courts below. Moreover, as illustrated by the conflicting judgments issued by the Ninth Circuit panel and the *en banc* court, the resolution of these issues is outcome-determinative. If the Court adopts the views of the Sixth and Eighth Circuits regarding implied MDA preemption, or the views of the Eighth and Eleventh Circuits regarding express preemption, the Stengels' claims will be preempted and the district court's dismissal will be affirmed.

Review is also warranted because, if the Ninth Circuit's decision remains in effect, the ability of medical device companies to win dismissal of product liability claims on preemption will have largely been eliminated, and the Court's decisions in *Riegel* and *Buckman* will have been rendered dead letters. In upholding MDA preemption in *Riegel*, the Court discerned from the congressional text that "the solicitude for those injured by FDA-approved devices . . . was overcome in Congress's estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations." 552 U.S. at 1099. That congressional purpose is thwarted by Ninth Circuit MDA preemption rulings that, as a practical matter, will allow *any* products liability claimant to escape

preemption (certainly at the pleadings stage and most likely at the summary judgment stage as well) provided only that they follow the blue-print laid out by the appeals court. Moreover, the effect of defining "parallel claims" as broadly as the Ninth Circuit has done will be to drag FDA into the middle of many of these lawsuits, thereby bringing about the interference with agency activities that *Buckman* warned against.

REASONS FOR GRANTING THE PETITION

This case presents issues of exceptional importance to medical device companies as well as to health-care consumers throughout the country: when is it an appropriate function of judges and juries hearing state-law causes of action to impose liability based on their interpretations of federal medical device laws? The Court held in *Buckman* that state-law fraud-on-the-FDA claims "inevitably conflict with the FDA's responsibility to police fraud consistently with the Agency's judgment and objectives" and also "dramatically increase the burdens" facing companies applying for approval to market new drugs – and thus that Congress had impliedly preempted such claims when it established FDA's regulatory authority by enacting the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 *et seq.* *Buckman*, 531 U.S. at 350. It further held in *Riegel* that Congress sought to limit product liability suits because, to the extent that state courts ended up imposing more stringent safety requirements on medical device manufacturers than those imposed by FDA, other patients "who are not represented in court" would be denied access to more "effective" devices. *Riegel*, 552 U.S. at 325. Review is warranted to determine whether the decision below –

which virtually eliminates device manufacturers' ability to win dismissal of product liability suits on preemption grounds – is consistent with Congress's plan.

Review is warranted to resolve the federal appeals courts' sharply conflicting answers to the questions presented. The Petition provides a full explication of that conflict. Accordingly, *amici* will not repeat it here, except to note that the *en banc* Ninth Circuit's suggestion that no conflicts exist is not credible. Indeed, the conflicts were expressly noted by the Ninth Circuit panel. Pet. App. 38a (noting the acknowledged conflict between the Fifth and Eighth Circuits regarding *Buckman*'s applicability to failure-to-report-to-FDA claims and ultimately siding with the Eighth Circuit after determining that the Fifth Circuit decision "is not persuasive").

Rather than acknowledging a conflict, the *en banc* Ninth Circuit sought to distinguish the Eighth Circuit's decision in *In re Medtronic, Inc., Sprint Fidelis Leads Product Liability Litigation* ["*Sprint Fidelis*"], 623 F.3d 1200 (8th Cir. 2010), by asserting that the Eighth Circuit plaintiffs "sought to bring actions based solely on the MDA rather than on state law, which the court found foreclosed by *Buckman*." Pet. App. 18a (citing 623 F.3d at 1205-06). That assertion is a clear misreading of the Eighth Circuit opinion, which stated unequivocally that the plaintiffs were asserting "some twenty distinct state law causes of action including failure to warn, defective design and manufacturing, breach of express warranty, and fraud," and made no mention of any federal claims. 623 F.3d at 1203. Moreover, the section of the opinion

that discusses the plaintiffs' failure-to-warn-FDA claim is entitled, "Parallel Claims Issues," *id*. at 1205-06; by definition, "parallel claims" are *state-law* claims that are alleged to be "parallel" to the requirements of federal law. The *en banc* Ninth Circuit did not even address other conflicting decisions from the Sixth and Eleventh Circuits, even though it had to have been well aware of the Sixth Circuit decision, which was cited favorably by the Ninth Circuit panel, Pet. App. 34a, and the Eleventh Circuit decision, which was cited in Medtronic's brief.

Review is also warranted because, if the Ninth Circuit's decision remains in effect, the ability of medical device companies to win dismissal of product liability claims on preemption grounds will have largely been eliminated, and the Court's decisions in *Riegel* and *Buckman* will have been rendered dead letters. The remainder of this brief focuses largely on the degree to which the decision below undermines *Riegel* and *Buckman*.

I. THE DECISION BELOW CONFLICTS WITH *RIEGEL* AND THEREBY VASTLY EXPANDS THE SCOPE OF THE "PARALLEL CLAIM" EXCEPTION

Riegel, decided in 2008, marked the most recent occasion on which the Court addressed the scope of the MDA's express preemption provision, 21 U.S.C. § 360k(a). While holding that § 360k(a) expressly preempted many product liability claims against the manufacturers of PMA medical devices, *Riegel* acknowledged that certain "parallel claims" may escape § 360k(a) preemption. 552 U.S. at 330. Lower federal

courts have struggled in the ensuing years to craft a workable definition of a "parallel claim." *See. e.g.*, *Sprint Fidelis*, 623 F.3d at 1304 ("The contours of the parallel claim exception were not addressed in *Riegel* and are as-yet ill-defined.").

Section 360k(a) provides in relevant part:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement–
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

Riegel established a two-step procedure for assessing defense assertions that the MDA expressly preempts a state common law claim. First, a court is to determine whether FDA "has established requirements applicable to" the device in question. If so, the court then considers whether the common law claims are based on state requirements that are "different from, or in addition to" the federal ones *and* relate to safety and effectiveness. *Riegel*, 552 U.S. at 321-22. If each of those conditions is met, § 360k(a) expressly preempts the common law claim. *Id*.

Riegel held that when FDA grants a PMA for a medical device, it imposes federal "requirements" applicable to the device. *Id.* at 322.[2] It explained that "FDA may grant premarket approval only after it determines that a device offers a reasonable assurance of safety and effectiveness" and that "FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." *Id.* at 323.

Turning then to the second step, the Court determined that the plaintiffs' product liability claims were expressly preempted by § 360k(a) because they related to the safety and effectiveness of the device (an issue rarely disputed in cases of this sort) and were based on state common law requirements applicable to the device. *Id.* at 323-330.[3]

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[2] In contrast, the Court held in a 1996 case that FDA does *not* impose "requirements" with respect to a Class III device when the device enters the market pursuant to the § 510(k) process, a process that allows devices to be marketed if they are "substantially equivalent" to a "grandfathered" device that was already on the market when the MDA was adopted in 1976. *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). *Lohr* noted that when FDA makes a "substantially equivalent" determination, it undertakes no formal review of the safety and effectiveness of a medical device, and does not require a device "to take any form for any particular reason." *Id.* at 493.

[3] The Court held that common-law duties such as those underlying the plaintiffs' negligence, strict liability, and implied warranty claims are requirements "applicable to the device," even though those duties are general in nature and thus also apply in

The Court recognized that common law claims are preempted under the MDA only to the extent that they are "different from, or in addition to" the requirements imposed by federal law. *Id.* at 330. Thus, the Court explained, "§ 360k does 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." *Id.* (quoting *Lohr*, 518 U.S. at 495). The Court declined to consider whether the plaintiffs could avoid preemption under this "parallel claim" exception, however, because they had failed to preserve the issue on appeal. *Id.*

Riegel's preemption finding was at least to some extent influenced by its conclusion, based on the language of § 360k(a), that Congress sought to minimize litigation-based obstacles to development of innovative medical devices that would improve public health. The Court stated that the congressional text suggested that "the solicitude for those injured by FDA-approved devices . . . was overcome in Congress's estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations." *Id.* at 326. The Court also expressed concern that jury verdicts regarding the safety and effectiveness of medical devices might prove to be particularly "disrupt[ive]" of federal regulation:

[O]ne would think that tort law, applied by

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numerous contexts that are wholly unrelated to medical devices. *Id.* at 327-28.

> juries under a negligence or strict-liability standard, is less deserving of preservation. A state statute, or a regulation adopted by a state agency, could at least be expected to apply cost-benefit analysis similar to that applied by the experts at the FDA: How many more lives will be saved by a device which, along with its greater effectiveness, brings a greater risk of harm? A jury, on the other hand, sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court.

Id. at 325.

Not surprisingly, virtually every plaintiff seeking to recover damages from the manufacturer of a PMA medical device asserts that his/her claims qualify under the "parallel claim" exception to § 360k(a) express preemption. *Riegel* held that the product specifications imposed by FDA on each PMA medical device are federal "requirements" applicable to the device, within the meaning of § 360k(a)(1); and that common law duties imposed by state tort law are state "requirements" within the meaning of the opening sentence of § 360k(a). Thus, if a plaintiff hopes to avoid express preemption, he must demonstrate that the state requirements on which he bases his claims are not "different from, or in addition to" the requirements imposed on the device by FDA.

And just what are the federal "requirements" referred to in § 360k(a)(1)? *Lohr* provides a relatively clear answer: a general duty imposed by the FDCA or

FDA regulation on all device manufacturers does not qualify as a § 360k(a)(1) "requirement"; in order to qualify, "federal requirements must be 'applicable to the device' in question, and . . . pre-empt state law only if they are 'specific counterpart regulations' or 'specific' to a 'particular device.'" *Lohr*, 518 U.S. at 500 (quoting 21 C.F.R. § 808.1(d) (1995)).[4]

The Eighth and Eleventh Circuits have been guided by *Lohr*'s definition of a federal "requirement" in determining the scope of the "parallel claim" exception. Under *Riegel*, a common law products liability claim against the manufacturer of a PMA medical device is expressly preempted unless the plaintiff can point to a federal "requirement" to which the claim is parallel. An allegation that the manufacturer has violated product-specific requirements imposed on it by FDA in connection with approval of the device's PMA would certainly qualify as a "parallel claim." But an allegation that the manufacturer has violated general FDA duties applicable to all medical devices (such as the FDA reporting duties at issue in this case) would not so qualify because (per *Lohr*) general FDA duties are not federal "requirements" within the meaning of § 360k(a)(1) – and in the absence of a federal "requirement" to which the common law claim can be

[4] The Court concluded that because of the "generality" of federal labeling and manufacturing rules applicable to all Class III medical devices, those duties were not "requirements" within the meaning of § 360k(a)(1); it further concluded that there could be no preemption in the absence of a federal "requirement" to which the state "requirement" could be "different from, or in addition to." *Id.* at 501.

said to be parallel, the common law claim is expressly preempted because it is "different from, or in addition to, any requirement applicable . . . to the device." § 360k(a)(1). Based on this reasoning, both the Eighth and Eleventh Circuits hold that the MDA expressly preempts state common law claims alleging a violation of a generalized, rather than a device-specific, federal requirement. *Sprint Fidelis*, 623 F.3d at 1207; *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296,1301 (11th Cir. 2011).

The *en banc* Ninth Circuit did not recognize any such limitation on the parallel claim exception. Rather, it held that any common law claim qualifies as a parallel claim so long as it is based on an allegation that the device manufacturer violated a federal law, regardless whether the law is device-specific. Pet. App. 17a-20a.

Review of the Ninth Circuit's extraordinarily broad interpretation of the parallel claims exception is warranted because it threatens to eliminate express MDA preemption as a viable defense in medical device product liability litigation and to eviscerate *Riegel*. The Stengels allege that Medtronic violated its duties under 21 U.S.C. § 360i(a)(1) by failing to submit adverse-event reports to FDA after it received information regarding risks associated with use of its SynchroMed Pump. They further allege that an "Educational Brief" sent by Medtronic to SynchroMed customers in 2003 was a "reportable correction" and thus that Medtronic was required by FDA regulations to report the information to FDA. They assert that the alleged violations of these generally applicable FDA statutes and regulations also breached Medtronic's duty of

reasonable care under Arizona negligence law.[5] If that interpretation of the parallel claim exception stands, little will be left of the protections afforded by *Riegel*.

Only a particularly dull plaintiffs' lawyer would be unable to find some basis for alleging that the manufacturer has violated some statute or regulation in its dealings with FDA, and then to assert that the client's injuries were caused by the violation. For example, device manufacturers are regularly inundated by reports regarding health setbacks among users of their products. Such information is generally not reportable to FDA until after the manufacturer has had an opportunity to analyze the case and to determine whether there exists a causal relationship between use of the medical device and the health setback. An enterprising plaintiffs' attorney can easily examine this data and make a plausible case that the manufacturer erred with respect to at least some of the cases that it decided not to report to FDA.

Another route readily available to plaintiffs' lawyers is the FDCA's broad definition of "misbranded" medical devices. A device manufacturer has a federal duty not to market a medical device if the device is "misbranded." A device is "misbranded" if, *inter alia*, it is "dangerous to health" when used as provided in the labeling. 21 U.S.C. § 352(j). Accordingly, under the

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[5] *Amici* question the Ninth Circuit's interpretation of Arizona negligence law; there is no evidence suggesting that Arizona law imposes a duty on manufacturers to file reports with the federal government. The misinterpretation of Arizona law is not *amici*'s principal concern, however, and is not the reason why we believe that review by this Court is urgently needed.

Ninth Circuit's broad definition of a parallel claim, a plaintiff could allege that a medical device manufacturer has violated federal law by marketing a device that is misbranded because it is dangerous to health. He could then assert a parallel claim under state law for alleged violation of the federal statute. Of course, a claim that a medical device is "dangerous to health" sounds very much like the traditional common law claims that *Riegel* held were expressly preempted by § 360k(a): negligence, strict liability, breach of implied warranty, etc. Accordingly, the decision below provides a blueprint for plaintiffs to resume asserting all their traditional common law tort claims under the guise of asserting a violation of federal duties imposed generally on all device manufacturers. If the decision below stands, nothing will be left of *Riegel* and the congressionally-mandated preemption policy that the Court was attempting to enforce.[6]

The concurring opinion below seemed to suggest that there is no reason for manufacturers to be concerned by loosened preemption standards, because the Stengels will still face a daunting task in proving causation (*i.e.*, that Medtronic's alleged violation of an FDA reporting requirement was the proximate cause of the Stengels' injuries). Pet. App. 23a. That suggestion

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[6] Indeed, the *en banc* Ninth Circuit was not shy in hinting that its ultimate goal was to eliminate all preemption of product liability suits against device manufacturers. While conceding that the common law claims asserted in the Stengels' original complaint were preempted "as currently pled," the court added, "Now that we have clarified preemption law under the MDA, it is possible that the Stengels could plead nonpreempted versions of these claims." Pet. App. at 21a.

is scant comfort to device manufacturers who, unable to win dismissal on the pleadings based on preemption, will be forced to incur substantial litigation costs as they try to establish a lack of causation. More importantly, it ignores *Riegel*'s determination that Congress intended to preempt many product liability claims against the manufacturers of PMA medical devices because of its "solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations." *Riegel*, 552 U.S. at 326.

In sum, review is warranted to resolve the conflict between *Riegel* and the decision below and to determine whether the Ninth Circuit's extremely broad definition of parallel claims effectively nullifies Congress's express preemption provision. By granting review, the Court can determine whether the approach adopted by the Eighth and Eleventh Circuit, which provides a more limited definition of parallel claims, better reflects congressional intent.

II. THE DECISION BELOW CONFLICTS WITH *BUCKMAN* BY CONDONING INTERFERENCE WITH FDA ENFORCEMENT OF THE FDCA

Buckman, decided in 2001, examined the circumstances under which a products liability claim against a medical device manufacturer should be deemed impliedly preempted under conflict preemption principles. *Buckman* held that federal law preempted state-law claims that a device manufacturer made fraudulent misrepresentations to FDA for the purpose of obtaining FDA approval for its device. The Court

unanimously held that Congress had impliedly intended to preempt such fraud-on-the-FDA claims when it adopted the MDA and the FDCA because adjudication of such claims would conflict with the FDA product-approval process. *Buckman*, 531 U.S. at 348.

Medtronic argued below that, for similar reasons, the Stengels' claims were impliedly preempted by the MDA and the FDCA. The *en banc* Ninth Circuit deemed *Buckman* inapplicable, asserting that the decision has no relevance to "a state-law claim that is independent of the FDA's pre-market approval process." Pet. App. 20a. It asserted that "the plaintiffs in *Buckman* alleged no state-law claim and were concerned exclusively with alleged fraud on the FDA that had occurred as part of that approval process." *Id.* at 12a.

The decision below, however, failed to address (and deemed irrelevant) the key issue in any implied conflict preemption claim: does the state requirement conflict with federal policy? Conflict preemption arises when "compliance with both federal and state regulation is a physical impossibility," *Florida Lime and Avocado Growers, Inc. v. Paul,* 373 U.S. 132, 142-143 (1963), or when a state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz,* 312 U.S. 52 (1941). The Stengels' claims present precisely the same types of conflicts with federal policy identified by the Court in *Buckman*, yet the Ninth Circuit gave no consideration to those conflicts in determining whether Congress impliedly intended to preempt such claims when it adopted the MDA and the FDCA. Review is

warranted to address the conflict between *Buckman* and the decision below.

The Stengels do not contend that Medtronic's duty to supply safety data to the federal government exists independently of federal law. Rather, their contention is that Arizona law requires compliance with federal law, and that it is § 519 of the FDCA, 21 U.S.C. § 360i, that imposes reporting responsibilities on device manufacturers. *Buckman* indicates that such common law claims based on federal duties are impliedly preempted because they interfere with FDA's exclusive authority to enforce the FDCA and the MDA. *See* 21 U.S.C. § 337(a) (providing that "all" proceedings to enforce the FDCA and the MDA "shall be by and in the name of the United States."). *Buckman* deemed § 337(a) to be "clear evidence that Congress intended that the MDA be enforced exclusively by the Federal Government." 531 U.S. at 352. The Court held that Congress, in adopting the MDA, had intended to create a careful balance between ensuring product safety and promoting development of new, life-saving products, and that that balance "can be skewed by allowing fraud-on-the-FDA claims under state tort law." *Id.* at 348.

The *en banc* Ninth Circuit did not assert that common law claims other than fraud-on-the-FDA-at-the-product-approval-stage claims could not similarly skew the congressional balance. Rather, it simply declared an unwillingness to examine potential conflicts between the MDA and common law claims outside the context of claims that FDA would never have approved the device had the manufacturer not

defrauded the agency. Pet. App. 20a.[7] Nothing in the *Buckman* decision suggests that Congress's implied preemption had such a narrow sweep. Rather, the Court made clear that any effort to enforce the MDA by means of common law claims is preempted to the extent that it interferes with FDA's ability to maintain the balance among the competing policy concerns that are embodied in the MDA. *Buckman*, 531 U.S. at 348.

Moreover, by interpreting *Buckman* so narrowly, the Ninth Circuit provides plaintiffs' lawyers with a roadmap that allows them to avoid implied preemption rulings. While claims identical to those in *Buckman* – claims that initial PMA approval was a result of a manufacturer's fraud in its dealing with FDA – will continue to be off the table, the Ninth Circuit now authorizes juries to second-guess any manufacturer interaction with FDA that post-dates product approval. Plaintiffs may assert claims based on speculation regarding how FDA might have reacted had the manufacturer been more forthcoming in its post-approval communications with the agency.

As the Petition demonstrates, such claims are likely to interfere with FDA enforcement of the MDA for the very reasons articulated in *Buckman*. *See, e.g.,*

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[7] The Court's assertion that "the plaintiffs in *Buckman* alleged no state-law claim," Pet. App. 12a, was plain error. *All* the claims asserted in *Buckman* arose under state law. There, as here, the plaintiffs asserted that their state-law claims were not preempted because they were parallel to requirements imposed on medical device manufacturers by federal law. They asserted that a fraud-on-the-FDA claim was simply a specific application of longstanding common law prohibitions against fraud. *Buckman*, 531 U.S. at 351-53.

Pet. 28-29 ("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 best positioned to answer that question – the FDA – thereby exposing the agency to the discovery process and its massive associated burdens."). Furthermore, permitting what amounts to private enforcement of the MDA would impose costs on manufacturers that would likely discourage the development of new, life-saving products:

> As a practical matter, complying with FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants – burdens not contemplated by Congress in enacting the FDCA and the MDA. Would-be applicants may be discouraged from seeking [FDA] approval of devices.

Buckman, 531 U.S. at 350.

In sum, review is warranted to resolve the conflict between *Buckman* and the decision below and to determine whether the Ninth Circuit's endorsement of what amounts to private enforcement of the FDCA and the MDA in all post-product-approval situations effectively nullifies Congress's unspoken but implied intent to preempt litigation that "would exert an extraneous pull on the scheme established by Congress." *Id.* at 353.

CONCLUSION

The Washington Legal Foundation and the Allied Educational Foundation respectfully request that the Court grant the Petition.

Respectfully submitted,

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