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

RESPONDENTS' BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether state-law claims against medical device manufacturers based on duties that parallel federal requirements are preempted, notwithstanding the Court's unanimous holdings to the contrary in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), and *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

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INTRODUCTION

This case arises from Medtronic's failure to inform physicians and patients about a known risk of a medical device, which caused severe injury to Richard Stengel. Although the Food and Drug Administration (FDA) initiated enforcement action against Medtronic for failing to inform its customers about the risk, and although Medtronic then sent an "urgent" letter to physicians to notify them and, soon thereafter, changed the warnings provided with the product through a recall, Medtronic argues that the Stengels' state-law claims based on failure to warn about the risk are expressly and impliedly preempted by the Medical Device Amendments of 1976 (MDA) to the Food, Drug, and Cosmetic Act. Medtronic is wrong. The decision below is correct on the merits under this Court's precedents and implicates no conflict among the circuits. The petition should be denied.

STATEMENT OF THE CASE

Preemption Under the Medical Device Amendments

In 1976, in response to serious injuries caused by dangerous medical devices, Congress enacted the MDA to provide a federal regulatory regime, including a system of premarket review for devices that present the greatest potential risks. In addition to provisions addressing device classification, approval, and reporting requirements, among other things, the MDA contains a provision that preempts any state-law requirement with respect to a medical device that is "different from, or in addition to, any requirement" applicable to the device under the MDA and that "relates to the safety or effectiveness of the device." 21 U.S.C. § 360k(a).

In three prior decisions, this Court has considered the MDA's preemptive scope. In the first, *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the Court unanimously

held that the MDA does not expressly preempt state-law requirements that parallel federal requirements. *Id.* at 494-97 (majority opinion); *id.* at 513 (O'Connor, J., concurring in part and dissenting in part). The Court also unanimously held that state law is not preempted if no relevant federal requirement is in place. *Id.* at 492-94 (majority opinion) (design defect claim not preempted where federal law places no design requirements on the device); *id.* at 513 (O'Connor, J., concurring in part) (same). In addition, the Court held that the FDA's generally applicable labeling and manufacturing regulations do not impose device-specific requirements with preemptive effect under § 360k(a). *Id.* at 501 (majority opinion). Those federal requirements, the Court said, reflect "important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect from potentially contradictory state requirements." *Id.*

In the second case, *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the Court held that a so-called "fraud-on-the-FDA" claim was impliedly preempted by the MDA. This unusual claim, the Court explained, was not premised on an underlying state-law duty, but rested solely on a claim that the defendant violated a duty it owed to the FDA under federal law. *Id.* at 352-53. The Court held that the claim was in "conflict" with the FDA's own responsibility to police fraud against it in accordance with its own objectives. *Id.* at 350.

Finally, in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), the Court held that the premarket approval process (PMA) through which some medical devices secure marketing permission from the FDA establishes device-specific requirements that, under § 360k(a), expressly

preempt *different or additional* state-law requirements, but not, the Court reiterated, state-law claims that *parallel* federal requirements. Section 360k(a), the Court stated, "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations." *Id.* at 330. The Court also restated *Lohr*'s conclusion that federal labeling requirements that apply "across the board to almost all medical devices" generally do not preempt state requirements. *Id.* at 322.

Factual and Procedural Background

Medtronic's SynchroMed Pump & Infusion System received premarket approval from the FDA in 1988, and its SynchroMed EL Pump and Catheter received approval through a supplemental PMA in 1999.[1] The device is a system for infusing pain medication into the spine.

Over the next few years, Medtronic became aware that a granuloma (a nodule of inflammatory cells) could form at the tip of the catheter, which had the potential to paralyze the patient. Medtronic did not report this problem to the FDA.

Meanwhile, in October 2000, in Tucson, Arizona, Richard Stengel had the Medtronic infusion pump and catheter system surgically implanted. The catheter was implanted inside the membrane surrounding his spinal cord. The pump delivered pain medication through the catheter tip directly to his spinal cord. In February 2005, Mr. Stengel fell and was taken to the hospital, where, after reporting decreased sensation in his right leg and difficulty urinating, he was admitted for testing.

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[1] All facts are taken from the unanimous en banc decision below, reprinted in the Petition Appendix beginning on page 1a, and from plaintiffs' substitute amended complaint, filed on August 18, 2010.

The first neurosurgeon to treat Mr. Stengel was unaware that the Medtronic infusion pump could cause a granuloma to form at the catheter tip. He therefore failed to diagnose the cause of the symptoms. Several days later, a second physician evaluated Mr. Stengel and noted that he had ascending paralysis in both legs. Because a previous patient of this physician had an infusion pump that had caused formation of a granuloma, the physician's diagnosis included the possibility of a granuloma around the pump's catheter tip, in the spinal canal. Testing revealed that a granuloma caused by the catheter tip had caused complete blockage of spinal fluid and compressed the spinal cord at the T12 level in his spine.

Mr. Stengel underwent surgery to remove the catheter and most of the granuloma in his back. As a result of the granuloma caused by Medtronic's device, he is permanently paralyzed below the T12 level, including in both legs.

More than a year later, between November 2006 and January 2007, during inspections of a Medtronic manufacturing facility, the FDA discovered the problem caused by the infusion pump and catheter system and Medtronic's extensive under-reporting of adverse events. After several months of written discussion with Medtronic, the FDA sent a formal "Warning Letter" to the company, stating, among other deficiencies, that Medtronic had misbranded the infusion pump by concealing known risks, in violation of FDA regulations codified at 21 C.F.R. § 803.50(a)(1) and § 806.10(a)(1). The letter criticized Medtronic's failure to communicate to customers information that it knew as early as 2001 concerning the extent of risk of an inflammatory mass developing at the catheter tip.

In response, Medtronic, in January 2008 sent an "Urgent" Medical Device Correction letter to physicians, which explained the problem and made recommendations to reduce the incidence of the problem and to diagnose it. Two months later, in March 2008, Medtronic altered the warnings provided with the pump and catheter system through a product recall.

In January 2010, Mr. Stengel and his wife filed suit against Medtronic in an Arizona state trial court. The complaint alleged state-law claims of strict liability, breach of warranty, and negligence, including negligent design and negligent failure to provide adequate warnings. Medtronic removed the case to federal court on diversity grounds and moved to dismiss based on preemption. Because the motion relied on materials outside the complaint, the Stengels moved for relief under Federal Rule of Civil Procedure 56(d), asking for an opportunity to take discovery, and also moved to amend the complaint to state the claims in terms of parallel FDA requirements.

Specifically, the amended complaint alleged that Medtronic violated federal requirements requiring it to monitor its product, to report to the FDA adverse health consequences associated with the device, and to take corrective action to inform physicians of risks associated with the product. *See* Substituted Amended Complt. ¶¶ 13-24 (citing 21 U.S.C. § 360i & 21 C.F.R. §§ 803.50, 820.198(a)(3)). The complaint cited and attached the FDA letter stating that the device was misbranded. *Id.* ¶ 14. And it alleged that by violating the federal requirements, Medtronic breached its state-law duty to use reasonable care. Had Medtronic complied with the federal requirements, "the danger to [Mr.] Stengel could have been dis-

covered and the injury to [him] would have been avoided." *Id.* ¶ 24.

The court held that the claims initially alleged were expressly preempted and that the claims sought to be alleged in the amended complaint were either expressly or impliedly preempted. The court granted the motion to dismiss with prejudice, denied the motion to amend, and denied the Rule 56(d) motion.

Mr. Stengel appealed. Initially, a divided panel affirmed the district court. But on Mr. Stengel's petition for rehearing en banc, the court of appeals unanimously reversed. The en banc court held that the state-law failure-to-warn claim alleged in the proposed amended complaint is not expressly preempted because it is based on state-law duties that parallel federal requirements and that it is not impliedly preempted under *Buckman* because it is based on an independent state-law duty, not a duty that exists only under federal law. The court remanded to allow the failure-to-warn claim to go forward and potentially to allow the Stengels to file a further amended complaint to re-plead other claims consistent with the en banc court's preemption analysis.

REASONS FOR DENYING THE WRIT

Medtronic argues that the decision below deepens a claimed conflict among the Circuits concerning the scope of express and implied preemption of state-law claims concerning injuries caused by medical devices, and that the decision conflicts with this Court's decisions in *Riegel* and *Buckman*. Its arguments are overblown and incorrect. The petition should be denied.

I. The Express Preemption Question Is Not Cert-Worthy.

Medtronic recognizes that both *Lohr* and *Riegel* hold that § 360k(a) does not expressly preempt state-law requirements that parallel federal requirements. It purports to identify a Circuit split, however, on the question whether a non-preempted state-law duty may be parallel to a federal duty applicable to all medical devices or whether it must parallel a "device-specific" federal requirement. This issue does not warrant review for three reasons: Medtronic did not argue below that a parallel claim could not look to a generally applicable FDA requirement; the Circuits are not divided; and both the text of the MDA and the Court's precedents make clear that a state-law claim need not parallel a device-specific federal regulation to avoid preemption.

A. Medtronic Did Not Preserve an Argument that Only Device-Specific Federal Requirements Can Support a Parallel State-law Claim.

With respect to express preemption, Medtronic is seeking review of an issue that it never raised below: whether a state-law duty that parallels a generally applicable federal requirement, rather than a device-specific federal requirement, is preempted. Because Medtronic is now raising the question for the first time, the question is not properly before the Court. *See* Gressman, Geller, *et al.*, *Supreme Court Practice* § 6.26(b), at 464 (9th ed. 2007) (citing cases including *United States v. United Foods, Inc.*, 533 U.S. 405, 417 (2001); *Penn. Dep't of Corrs. v. Yeskey*, 524 U.S. 206, 212-13 (1998); *Delta Airlines v. August*, 450 U.S. 346, 362 (1981)).

Neither Medtronic's district court motion nor its appellate brief argued that 21 C.F.R. § 803.50 and § 820.198(a)(3), the federal reporting requirements iden-

tified by the Stengels, could not support a parallel claim because the requirements apply to all devices, not only to Medtronic's infusion pump. *See generally* Medt. App. Br., Ninth Cir. (Apr. 18, 2011); Medt. Motion to Dismiss, App. Excerpt of Record No. 8 (June 4, 2010). In explaining the case law, Medtronic's appellate brief quoted decisions stating that the plaintiff must plead that the state-law duty parallels a "specific federal requirement" or a "specific PMA requirement," Medt. App. Br. 26, but Medtronic did not suggest that the requirement had to be specific *to the particular device*. In fact, while Medtronic stated in passing that a "supposed federal requirement" could be "too indefinite or general to supply a federal duty," *id.* at 27, it never suggested that the FDA reporting requirement on which the Stengels' failure-to-warn claim is based fell into that category. Instead, the appellate brief argued that the state-law duty was not "genuinely equivalent" and that the injury suffered was "attenuated" from the federal violation. *Id.* at 28-29. Neither of these case-specific arguments raises the general versus device-specific issue on which Medtronic now pins its petition for certiorari.

Not surprisingly given Medtronic's argument below, neither the district court opinion nor the appellate panel opinion addressed the question that Medtronic poses here. Indeed, the panel's assumption that the generally applicable federal requirements identified in the Stengels' complaint met the standard for a parallel claim reflects that Medtronic never asserted otherwise. *See* Pet. App. 32a, 35a (holding that state-law claims that parallel requirements set forth in generally applicable provisions of the Code of Federal Regulations are not expressly preempted, and referring to those federal requirements as "detailed reporting requirements").

Again at the rehearing stage, Medtronic's response to the petition for rehearing en banc did not argue that the claims failed for lack of specificity with respect to the parallel federal requirement. The response argued only that the state-law claims were not "genuinely identical." Medt. Reh'g Resp. 9. Rejecting that argument, the unanimous en banc opinion and the concurrence held that the amended complaint properly alleges a parallel claim.

In short, the express preemption issue presented in the petition "was not raised in the Court of Appeals and is not properly before" the Court. *Delta Airlines*, 450 U.S. at 362; *see Decker v. Nw. Envtl. Def. Ctr.*, 133 S. Ct. 1326, 1335 (2013) ("[W]e are a court of review, not of first view.").

B. The Circuits Are Not Divided Over the Scope of Express Preemption.

Medtronic purports to identify a four-to-two disagreement among the federal courts of appeals on the question whether, to escape preemption, a state-law duty must parallel a device-specific, as opposed to a generally applicable, federal requirement. Medtronic is wrong, and the Stengels' claim would survive preemption under the law in each of the six circuits that Medtronic discusses.

To begin with, as Medtronic recognizes, the Fifth, Sixth, and Seventh Circuits have found no preemption where a state-law claim is based on violation of a duty that parallels a generally applicable federal requirement. *See Bass v. Stryker Corp.*, 669 F.3d 501, 510 (5th Cir. 2012) (no preemption of state-law duty that parallels FDA good manufacturing practices regulations); *Bausch v. Stryker Corp.*, 630 F.3d 546, 555 (7th Cir. 2010) (no preemption of state-law duty that parallels FDA good manufacturing practices regulations); *Howard v. Sulzer Othopedics, Inc.*, 382 Fed. App'x 436, 441 (6th Cir. 2010).

For example, in *Hughes v. Boston Scientific Corp.*, 631 F.3d 672, 770-71 (5th Cir. 2011), the Fifth Circuit, like the court below in this case, held that the MDA does not preempt a state-law duty that parallels FDA medical device reporting regulations.

Each of these decisions recognizes that while the state-law duty must parallel a "specific" federal requirement, nothing in § 360k(a), *Lohr*, or *Riegel* demands that the requirement be specific *to a particular device*. *See Bass*, 669 F.3d at 511-12; *Bausch*, 630 F.3d at 555; *Howard*, 382 Fed. App'x at 440. Although in this case the issue whether generally applicable federal requirements can support parallel claims was not disputed below, the Ninth Circuit's holding that the Stengels' failure-to warn claim is not preempted because it "rests on a state-law duty that parallels a federal duty under the MDA," Pet. App. 20a, is fully consistent with these cases holding that generally applicable requirements can support parallel claims.

On the other side, according to the petition, are decisions from the Eleventh and Eighth Circuits. In each of those cases, however, the plaintiffs failed to tie their claims to the violation of any particular federal requirement, either general or device-specific. And although Medtronic reads the cases to stand for the proposition that a plaintiff must plead the violation of a device-specific federal requirement, neither stands for that proposition.

In *Wolicki-Gables v. Arrow Int'l, Inc.* 634 F.3d 1296 (11th Cir. 2011), where the Eleventh Circuit held that the plaintiff failed to state a parallel claim, the problem was one of pleading: The complaint failed to "set forth any specific problem, or failure to comply with any FDA regulation that can be linked to the injury alleged." *Id.* at

1301-02. The court quoted two district courts that referred to standards specific to a device, but it devoted most of the relevant paragraph to *Parker v. Stryker Corp.*, 584 F. Supp. 2d 198, 1301 (D. Colo. 2008). There, the court explained that, standing alone, general allegations that the manufacturer failed to "satisfy the Food and Drug Administration's Pre-market Approval standards" and was sold "in direct violation of the Code of Federal Regulations" failed to state a claim under *Bell Atlantic Corp. v. Twombly*, 550 U.S. 554 (2007).

The amended complaint in this case, which is clear about the "specific problem" and the "failure to comply with [an] FDA regulation that can be linked to the injury alleged," satisfies the concern of the court in *Wolicki-Gables*. *See Bass*, 689 F.3d at 512 (citing *Wolicki-Gables* for proposition that complaint adequately pleads parallel claim if it "set[s] forth any specific problem, or failure to comply with any FDA regulation that can be linked to the injury alleged"). Indeed, the approving citation to *Wolicki-Gables* in *Bass* refutes Medtronic's suggestion that *Wolicki-Gables* conflicts with the results in *Bass*, *Bausch*, *Howard*, *Hughes*, and the decision below.[2]

The Eighth Circuit's decision in *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, 623 F.3d 1200 (8th Cir. 2010), is similar. There too, the

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[2] *Lohr*, *Riegel*, and *Bates v. Dow AgroSciences*, 544 U.S. 431 (2005), require pleading of conduct that would constitute a violation of a federal requirement, but the cases do not require that the pleading identify the federal requirement to which the state-law duty is parallel. In *Wolicki-Gables* and *In re Medtronic* (discussed *infra*), the complaints failed to allege conduct that would constitute a violation of a federal requirement. Regardless of whether the more specific pleading standard stated in *Wolicki-Gables* is correct, however, the amended complaint in this case satisfies it.

problem was primarily one of pleading. The court explained that the plaintiffs did not allege the violation of *any* particular federal requirement—neither generally applicable nor device-specific. *Id.* at 1207. Rather, they alleged that all of the devices at issue were defectively manufactured because Medtronic used a process called spot welding and that the manufacturing was not "in conformity with applicable requirements." *Id.* at 1206. Further, they "conceded" that the PMA authorized spot welding and expressly "disclaimed the need for discovery" to oppose the motion to dismiss. On those facts, the court held that "*as pleaded and argued*, the manufacturing defect clams are not parallel, they are a frontal assault on the FDA's decision" to approve the product and authorize use of spot welding. *Id.* at 1207 (emphasis in original); *see* Pet. App. 18a ("At no point did [*In re Medtronic*] address a state-law claim based on a state-law duty that paralleled a federal-law duty[.]").

Like *Wolicki-Gables*, *In re Medtronic* poses no conflict here, where the amended complaint *does* allege facts showing that the defendant violated specific federal requirements—those that required Medtronic to report adverse health consequences associated with the device. *See* Substituted Amended Complt. ¶ 13 (citing 21 U.S.C. § 360i & 21 C.F.R. § 820.198(a)(3)); *id.* ¶ 15 (citing 21 U.S.C. § 360i & 21 C.F.R. § 803.50). Moreover, unlike the situation addressed in *In re Medtronic*, the Stengels' case cannot fairly be characterized as "a frontal assault on the FDA's decision to approve a PMA" application for the device.

C. The Decision Below is Consistent with *Lohr* and *Riegel.*

The understanding that § 360k(a) does not preempt state-law claims that parallel federal requirements,

whether generally applicable or device-specific, follows directly from *Lohr* and *Riegel*—which may be the reason Medtronic did not argue this point below.

Twice this Court has specified that the MDA does not expressly preempt state-law claims seeking damages for injuries caused by medical devices where the state-law duties parallel federal requirements. In *Riegel*, although the Court stated that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations," 552 U.S. at 330, the Court did not consider whether the claims alleged escaped preemption on that basis because the plaintiff had not made the argument below. In *Lohr*, however, the Court did have an opportunity to consider the asserted parallel claims. There, the Court held, unanimously, that the Lohrs' labeling claims were not preempted to the extent that those claims paralleled FDA requirements, although the device was subject to *no* device-specific requirements at all. 518 U.S. 495 (majority), 513 (O'Connor, J., concurring in part and dissenting in part). The Court's majority opinion noted that an FDA regulation, 21 C.F.R. § 808.1(d)(2), "expressly support[s] this conclusion," as it states that § 360k "does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act." *Id.* at 497. *See also Bauch*, 630 F.3d at 555 ("emphasiz[ing] the phrase 'any requirement'" in § 360k(a) and noting that generally applicable manufacturing requirements are "legally binding requirements" under the MDA).

The Court took the same approach in *Bates v. Dow AgroSciences*, 544 U.S. 431. There, the Court considered the "similarly worded pre-emption provision" of the Federal Insecticide, Fungicide, and Rodenticide Act

(FIFRA), and held, again unanimously, that state-law requirements that parallel federal labeling requirements for pesticides are not preempted by the provision. *Id.* at 447 (majority), 456 (Thomas, J., concurring in part and dissenting in part) (agreeing that the claims should be remanded for consideration of whether state law "mirrors the federal standards"). As was true in *Lohr*, no product-specific labeling federal requirements applied to the product. In fact, the plaintiff argued that the state-law duty paralleled the generally applicable statutory requirements "that a pesticide label not contain 'false or misleading' statements, or inadequate instructions or warnings." *Id.* at 447 (citation omitted). Far from holding that a state-law claim that mirrored such generally applicable requirements was preempted, the Court remanded for consideration of whether the common-law duties were "equivalent to FIFRA's misbranding standards." *Id.*

The Court's precedents thus provide the answer to Medtronic's new question. Although Medtronic did not raise the issue below, the court of appeals' decision is wholly consistent with *Lohr*, *Riegel*, and *Bates* on this point. Further review is unwarranted.

II. The Implied Preemption Question is Not Cert-Worthy.

A. This Case Does Not Implicate A Split Over the Scope of Implied Preemption.

Medtronic asserts that the Circuits are divided over whether the MDA impliedly preempts state-law claims alleging failure to warn, even when those claims are based on duties that parallel federal requirements. Medtronic is again wrong. Preemption analysis turns on consideration of the particular claims alleged. *See*, *e.g.*, *Bates*, 544 U.S. at 442, 444-46 & n.15 (undertaking claim-

by-claim analysis); *Lohr*, 518 U.S. at 492-501 (same). The cases cited by Medtronic do not reflect different approaches to preemption but rather different outcomes based on different pleadings.

As Medtronic states, both the decision below and the Fifth Circuit decision in *Hughes* held that a parallel claim, not expressly preempted by the MDA, is also not impliedly preempted under *Buckman*. Pet. App. 20a; *Hughes*, 631 F.3d at 775. The Seventh Circuit, in *Bausch*, reached the same conclusion. *Bausch*, 630 F.3d at 556-58. Those courts understood that where a plaintiff pleads a state-law tort claim that is based on the defendant's violation of *state-law* duties owed to the plaintiff, *Buckman* does not apply. Particularly where the state-law duties parallel federal requirements, such claims in "no way" "conflict with the federal regulations," and thus there is no basis "for them to be impliedly preempted." *Bausch*, 630 F.3d at 557.

To fashion a conflict among the circuits, Medtronic looks to two cases: *In re Medtronic* and *Cupek v. Medtronic, Inc.*, 405 F.3d 421 (6th Cir. 2005). In *Cupek*, which was decided before *Bates* and *Riegel*, the relevant portion of the court of appeals' opinion affirms a district court decision to deny leave to amend a negligence-per-se claim for "failure to comply with the [FDA] conditions of approval." *Id.* at 423. The plaintiff's theory was "that Medtronic's alleged failure to comply with 21 C.F.R. § 814.84 invalidated the FDA's approval of [the device]." District Court Order, Case No. C-1-97-105 (S.D. Ohio Dec. 10, 2001). The Sixth Circuit agreed with the district court that this claim was a "disguised fraud on the FDA claim," impliedly preempted under *Buckman*. *Id.* at 424.

Here, there is no basis to suggest that the Stengels' failure-to-warn claim is a "disguised fraud on the FDA

claim," and the claim in no way second guesses the FDA's approval decision. Moreover, here, the FDA itself initiated enforcement action against Medtronic for misbranding (essentially, failing to warn of a risk that renders the product dangerous to health) two years *before* the Stengels filed their suit. Nothing in *Cupek* suggests that the Sixth Circuit would come out differently than the court below on the facts of this case.

A more recent Sixth Circuit decision, not cited by Medtronic, makes clear that the Sixth Circuit's understanding of *Buckman* is the same as that of the Fifth, Seventh, and Ninth Circuits. In a decision just two months ago, the court held that where the "alleged breach arises from the same act, but the legal basis is different, [t]his is simply not grounds for preemption" under *Buckman*. *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 587 (6th Cir. 2013). Although decided in the context of a case involving drugs, not medical devices, *Fulgenzi* shows that the Sixth Circuit is in agreement with the Fifth, Seventh, and Ninth Circuits on this issue. Indeed, to explain the scope of *Buckman*, *Fulgenzi* cites the en banc decision below. *Id.* at 588.[3]

Medtronic's only other basis for claiming a conflict on the scope of implied preemption is two sentences in the Eighth Circuit's opinion in *In re Medtronic*. The very brief discussion on which Medtronic relies states that the plaintiffs' claims that Medtronic failed to provide the

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[3] *Buckman* is generally applicable to drugs as well as to medical devices because the decision does not turn on the MDA's express preemption clause or other differences in the regulatory schemes. *See, e.g.*, *Lofton v. McNeil Consumer & Specialty Pharm.*, 672 F.3d 372 (5th Cir. 2012); *Lefaivre v. KV Pharm. Co.*, 636 F.3d 935, 943 (8th Cir. 2011).

FDA with information and reports required by federal regulations "are simply an attempt by private parties to enforce the MDA," and that such claims are "foreclosed by [the statute] as construed in *Buckman*." 623 F.3d at 1205-06.

The difference between the outcomes in *In re Medtronic* and in this case follows from differences in the plaintiffs' pleadings. Here, as in *In re Medtronic*, the company failed to submit adverse event reports. But unlike the claims alleged in *In re Medtronic* as understood by the Eighth Circuit, the claim here is not based on a violation of the reporting requirement. It is based on a failure to fulfill a state-law duty. Although Medtronic's violation of federal reporting requirements establishes a parallel between state and federal duties that enables the Stengels' claim to escape express preemption, the federal violation is not the basis for the claim, which does not seek to enforce the MDA.

Moreover, just as Medtronic's claim that the Sixth and Ninth Circuits are in conflict over the application of *Buckman* is definitively refuted by recent Sixth Circuit authority not cited by Medtronic (*Fulgenzi*), Medtronic's claim that the Eighth and Ninth Circuit are in conflict is undercut by recent Ninth Circuit authority not cited by Medtronic. In *Perez v. Nidek Co.*, 711 F.3d 1109 (9th Cir. 2013), the Ninth Circuit held that claims against a device manufacturer were impliedly preempted where the court, as in *In re Medtronic* but unlike in this case, found that the claims were based "solely" on a violation of federal law. *Id.* at 1119. *Perez* relies on both the en banc decision in this case and *In re Medtronic*, *see id.* at 1118, 1120, and it illustrates that the circuits are not in disagreement about a principle of law, but that the outcomes depend on the facts of each case.

B. The Court of Appeals Correctly Held That The Stengels' Claims Are Not Impliedly Preempted Under the Reasoning of *Buckman*.

In *Buckman*, the plaintiffs claimed that the defendant had violated a duty to the FDA by committing a fraud on the agency. Specifically, the plaintiffs alleged that the defendant "made fraudulent representations to the Food and Drug Administration … in the course of obtaining approval to market" the product and that "[h]ad the representations not been made, the FDA would not have approved the devices, and plaintiffs would not have been injured." 531 U.S. at 343. The Court's opinion repeatedly characterizes the claim before it as a "fraud-on-the-FDA" or "fraud-on-the-agency" claim. *Id.* at 347, 348, 350, 351, 352.

As described by the Court, the critical feature of the *Buckman* "fraud-on-the-FDA" claim was that the claim was not based on anything resembling "traditional state tort law principles of the duty of care owed by" the defendant to the plaintiff, *id.* at 352, but rested entirely on alleged duties arising from "the relationship between a federal agency and the entity it regulates," *id.* at 347. Thus, the sole interest that the claim sought to advance was to "punish and deter fraud against the [FDA]." *Id.* at 348. That objective, the Court stressed, was one in which the states had no independent interest, and it was also one already fully served by the "federal statutory scheme[, which] amply empowers the FDA to punish and deter fraud." *Id.* Allowing state law to "[p]olic[e] fraud against federal agencies," *id.* at 347, would interfere with the federal statutory scheme by "skew[ing]" the "balance sought by the [FDA]" in enforcing prohibitions on fraud in the PMA process. *Id.* at 348. Thus, "[s]tate-law fraud-on-the-FDA claims inevitably conflict with the FDA's

responsibility to police fraud consistently with the Administration's judgment and objectives." *Id.* at 350.

Here, by contrast, the essence of the Stengels' claim is not that Medtronic breached a duty to the FDA, but that it breached a duty to Mr. Stengel—namely, the duty to provide an adequate warning of the dangers of its product. "Under Arizona law, a warning to a third party satisfies a manufacturer's duty if, given the nature of the warning and the relationship of the third party, there is a 'reasonable assurance that the information will reach those whose safety depends on their having it.'" Pet. App. 20a (citation omitted). Thus, Medtronic's violation of the FDA regulations requiring it to report adverse incidents involving the device establishes that it breached the applicable standard of care with respect to its duty to warn the *plaintiffs* of dangers, not (as in a preempted fraud-on-the-FDA claim) that it violated a duty to the agency for which it should be punished. *Buckman*'s reasoning does not extend to actions that rest on "traditional state tort law principles," *id.* at 352, and, as the Court stressed, where an alleged breach of duty does not arise "solely by virtue of [federal] disclosure requirements," *id.* at 353, a plaintiff may maintain a "state-law caus[e] of action that parallel[s] federal safety requirements," *id.*, as the Court had previously held in *Lohr* and later reiterated in *Riegel*.

The Stengels' claims also differ from the *Buckman* fraud-on-the-FDA claim in another important respect: They do not require any hypothetical consideration about what regulatory action the agency would have taken if the agency had not been "defrauded." Members of the Court in *Buckman* expressed particular concern about the possibility that fraud-on-the-agency claims would require "speculation as to the FDA's behavior in a counter-

factual situation" and interfere with federal policy by "second-guessing the FDA's decisionmaking." 531 U.S. at 354 (Stevens, J., concurring in the judgment). But unlike the fraud claim in *Buckman*, the Stengels' claims based on Medtronic's violation of FDA reporting requirements do not rest on the theory that Medtronic fraudulently obtained premarket approval by concealing information from the FDA. They therefore do not require a court to explore the issue of reliance by the FDA, to reconstruct what the agency would have done if it had not been misled, or to second-guess its regulatory action or reaction in any way.

Moreover, here, the FDA has already decided that Medtronic had not adequately complied with federal reporting requirements, and that finding is part of the factual predicate for the specifically drawn allegation that Medtronic failed to meet its obligation of reasonable care under Arizona law. And in the trial court, jury instructions can direct the jury's consideration so that it does not apply additional or different requirements. *See Bates*, 544 U.S. at 454.

In short, in this case—where the complaint was filed after the FDA had issued a warning letter to the manufacturer, after the manufacturer had sent physicians an urgent notice with supplemental warnings, and after the warnings provided with the product were augmented through a recall—concern about second-guessing the FDA is particularly inapt.

III. The Lack of Finality Underscores That Review Should Be Denied.

Although this Court has jurisdiction to review interlocutory decisions of federal courts of appeals under 28 U.S.C. § 1254(1), "[o]rdinarily, in the certiorari context, this court should not issue a writ of certiorari to review a

decree of the circuit court of appeals on appeal from an interlocutory order, unless it is necessary to prevent *extraordinary* inconvenience and embarrassment in the conduct of the cause." Gressman, *Supreme Court Practice* § 4.18, at 280 (citation and internal quotation marks omitted, emphasis added). The Court "generally await[s] final judgment in the lower courts before exercising [its] certiorari jurisdiction." *Virginia Military Institute v. United States*, 508 U.S. 946 (1993) (*VMI*) (Scalia, J., concurring).

The posture of this case is far from extraordinary. The Stengels filed a garden-variety state-law tort suit, which the district court dismissed on a Rule 12(b)(6) motion. Aside from preemption, the court considered no other defenses, and it held no trial. On remand, Medtronic will retain any other legal defenses that it may have, and the trier of fact may decide in favor of either party. If Medtronic prevails before the jury or wins the case on any other ground, review on the question presented in the petition would not be necessary (or appropriate).

This case is a less appropriate vehicle for immediate, interlocutory review than was *VMI*. There, the Fourth Circuit had issued a final decision holding that the Commonwealth of Virginia's sponsorship of a military college for men only was unconstitutional, but the district court had yet to rule on the appropriate remedy. The Court denied certiorari on the ground that the decision was not sufficiently final because the remedy phase had not been completed. *See id.* at 946 (Scalia, J., concurring). The Court recognized that there would be time enough to review the decision, if necessary, after the remedial portion of the case had concluded, *id.*, and, in fact, it later did so. *See United States v. Virginia*, 518 U.S. 515 (1996).

Here, there is no decision regarding liability, let alone the appropriate remedy. In fact, the Stengels have been given an opportunity to re-plead other claims, which will allow further fleshing out of and application of the Ninth Circuit's ruling. Should the Stengels ultimately prevail on one or more claims that are determined not to be preempted under the Ninth Circuit's reasoning, the factual record would offer a more appropriate basis on which to render an authoritative judgment as to whether that conduct appropriately stated a non-preempted parallel claim. Moreover, unlike *VMI*, which was sui generis, here, if Medtronic is correct that the question presented is "frequently recurring," Pet. 33, there will be appropriate future vehicles to allow this Court to resolve the issue after entry of a final decision. In the meantime, the Court should allow the Stengels' case to run its course.

Finally, refraining from taking up this case in its interlocutory posture will allow further time for the lower courts to explore the nature of parallel claims under *Riegel* and the relationship of such parallel claims to implied preemption under *Buckman*. Given the absence of disagreement on issues of law and the relatively small number of cases that have reached the appellate courts since *Riegel*, this Court should continue to allow the lower courts to apply its decisions to the specific facts of the cases before them.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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