No. 15-321

IN THE
Supreme Court of the United States

PATRICIA CAPLINGER,

Petitioner,

v.

MEDTRONIC, INC., AND
MEDTRONIC SOFAMOR DANEK USA, INC.,

Respondents.

On Petition for a Writ of Certiorari to the
United States Court of Appeals for the Tenth Circuit

REPLY BRIEF FOR PETITIONER

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TABLE OF CONTENTS

TABLE OF AUTHORITIES ii
REPLY BRIEF FOR PETITONER 1
CONCLUSION 12

TABLE OF AUTHORITIES

Cases **Pages**

Bates v. Dow AgroSciences,
544 U.S. 431 (2005).....6, 11

Buckman Co. v. Plaintiffs' Legal Committee,
531 U.S. 341 (2001).....10, 11

Medtronic, Inc. v. Lohr,
518 U.S. 470 (1996).....*passim*

Riegel v. Medtronic, Inc.,
552 U.S. 312 (2008).....*passim*

Statutes

21 U.S.C. § 337(a).....10

21 U.S.C. § 360c(a)(2)(B).....3

21 U.S.C. § 360e 3

21 U.S.C. § 360e(d)(1)(A) 3

21 U.S.C. § 360k(a) .....*passim*

Regulations

21 C.F.R. § 801.39(a)(1).....4

Miscellaneous

FDA, Guidance for Industry: Good Reprint Practices of the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices (Jan. 2009), *available at* www.fda.gov/regulatoryinformation/guidances/ucm125126.htm.....8, 9

Brief for United States as Amicus Curiae, *Medtronic, Inc. v. Stengel*, No. 12-1351 (U.S. filed May 20, 2014), *available at* www.justice.gov/sites/default/files/osg/briefs/2013/01/01/2012-1351.pet.ami.inv.pdf.....6, 9, 10, 12

REPLY BRIEF FOR PETITIONER

Petitioner Patricia Caplinger was seriously injured by respondent Medtronic's Infuse Bone Graft device. Medtronic marketed that device for a use never approved by the Food and Drug Administration (FDA), and Medtronic's marketing for the unapproved use caused Ms. Caplinger's injury. Medtronic's opposition does not contest these facts.

The question here is whether Ms. Caplinger's state-law claims are preempted under these circumstances. The question can be approached in two ways, both raised and preserved below and in the petition for certiorari.

First, premarket approval reflects the FDA's determination that a medical device is safe and effective for the uses described in its labeling if it conforms to the approved design and is accompanied by the approved labeling. Premarket approval involves no determination that the device is safe and effective for other, unapproved uses, and it does not impose requirements for the design and labeling of the device if marketed for other uses, as Medtronic essentially concedes. Because a device is not subject to any device-specific requirements with respect to an unapproved use, § 360k(a) of the Medical Device Amendments (MDA) does not preempt claims arising from injuries caused by the manufacturer's marketing for the unapproved use. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) (no preemption where device not subject to device-specific requirements).

Second, as Medtronic does not dispute, federal law prohibits a manufacturer from introducing a device into commerce with the intention that the device be put to an unapproved use. Doing so renders the product adulterated and misbranded. State-law claims for design

defect and inadequate labeling that arise from a manufacturer's marketing for an unapproved use—regardless of whether the product is approved for a different use—parallel these federal prohibitions.

Because either approach implicates confusion and disagreement among the circuits—as acknowledged by the court below and explained by the Solicitor General in a recent brief—the petition should be granted to resolve the recurring and important issues it presents.

A. Section 360k(a) does not preempt a patient's state-law claims against a medical device manufacturer when the device was not evaluated for safety and effectiveness by the FDA. *Lohr*, 518 U.S. at 493-94, 501. In contrast, § 360k(a) does preempt some such claims when, following evaluation for safety and effectiveness, the FDA has granted premarket approval. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322-23 (2008).

In *Riegel*, the plaintiff made no allegation that the manufacturer had marketed the device for an unapproved use. Thus, the question presented here did not arise. Nonetheless, the reasoning of *Lohr* and *Riegel* answers the question presented—and shows the error in the decision below and many other decisions on this issue.

1. *Riegel* explains that, in contrast to the marketing clearance in *Lohr*, premarket approval "*is* federal safety review." *Id.* at 323. That statement correctly describes premarket approval with respect to the use for which Medtronic marketed the device in *Riegel* and the use for which Medtronic obtained premarket approval of Infuse. It is indisputably *not* true, however, that Medtronic obtained approval—that it underwent "federal safety review"—to market Infuse for

posterior use. Thus, *Riegel*'s underpinning does not support preemption here.

Medtronic argues that, after a device receives premarket approval, preemption extends to "any" state requirement, not only those concerning the same subjects as applicable federal requirements. Opp. 23-24. That argument contradicts *Lohr*, which found no preemption of design and labeling claims, although the device was subject to an array of federal regulations. *See Lohr*, 518 U.S. at 478-79. Indeed, under Medtronic's expansive view, the company would be immune from liability even if it marketed a device for a use that the FDA had *rejected* for premarket approval, as long as the FDA had granted premarket approval for some other use.

2. Medtronic's assertion that premarket approval is not use-specific, Opp. 27, is misleading. To be sure, premarket approval is approval to market "a Class III device," 21 U.S.C. § 360e, but premarket approval does not allow the manufacturer to market the device for any use it chooses. To the extent Medtronic argues otherwise, its argument is belied by the statute and Medtronic's own conduct.

Medtronic does not contest that the FDA's evaluation of a premarket approval application "rel[ies] on the conditions of use included in the proposed labeling." 21 U.S.C. § 360e(d)(1)(A); *see id.* §§ 360c(a)(2)(B), 360e(d)(2)(A), (B). Here, for example, the FDA approval letter specified that Infuse "is indicated for spinal fusion procedures" in certain patients and is "to be implanted via an anterior open or anterior laparoscopic approach," Tenth Cir. App. 80, and that scope of approval is reflected in the indications listed in the product labeling, *id.* 93.

Additionally, when the FDA grants premarket approval, it specifies conditions, including that the manufacturer submit a supplemental premarket approval application before making changes to the device or its labeling, such as the addition of a new use. *Id.* 84; 21 C.F.R. § 801.39(a)(1) (manufacturer must submit supplement for review and approval before adding new indication). Thus, Medtronic has submitted several supplemental applications, including to expand the approved indication. *See* Tenth Cir. App. 75.

3. Medtronic's defense of off-label promotion is beside the point, as is any debate about the wisdom of physicians' use of devices for indications that have not received FDA approval. Regardless of whether marketing Infuse for the unapproved use was defensible, Medtronic's conduct took this case outside the scope of *Riegel*, because the predicate for the holding in *Riegel*—that the FDA had made a determination of safety and effectiveness—does not apply. *Riegel*, 552 U.S. at 323. Even if Medtronic's conduct had not violated the MDA,[1] the situation here would be similar to that in *Lohr*, where the device was lawfully marketed without premarket approval—and the MDA did not preempt the patient's state-law claims because the FDA had made no determination of safety and effectiveness.

Put simply, under *Lohr* and *Riegel*, the question is not whether the marketing was lawful, but whether the

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[1] *But see* Tenth Cir. App. 13, ¶39 & 14, ¶42 (describing lawsuits against Medtronic for violating False Claims Act by paying illegal kickbacks to physicians for promoting off-label use of Infuse, resulting in submission of false claims to federal health-care programs, and Medtronic's $40 million settlement with the United States).

claims relate to device-specific requirements imposed on the product by the FDA. Where, as in *Lohr*, the manufacturer markets its product for a use as to which the FDA imposed no specific requirements, *Lohr* and *Riegel* dictate that the MDA does not preempt claims arising from injuries that result.

Along the same lines, Medtronic's repeated references to "allegations of off-label use" (*e.g.*, Opp. 13, 15) as opposed to off-label *marketing* are misleading. Ms. Caplinger has not alleged or argued that § 360k(a) does not apply to injuries caused by off-label *use* absent marketing by the manufacturer for that use. The question here is whether a manufacturer receives the protection of § 360k(a) on the ground that the FDA approved the product for one use, when the manufacturer marketed the product for a different use as to which it did not obtain approval. The facts underlying this question are not in dispute. And neither *Lohr* nor *Riegel* supports the result Medtronic advocates.

4. By its own admission, the Tenth Circuit did not understand how to apply *Lohr* and *Riegel*, lamenting that "laying out the rules governing our review is a real struggle in this area," Pet. App. 10a (internal quotation marks omitted), and wondering "How are we to apply all these competing instructions?" *Id.* at 9a. The court suggested that this Court's direction was needed: "One can't help but wonder if perhaps some of those rules warrant revisiting and reconciliation." *Id.* at 10a.

The court's confusion is reflected in the decisions of other courts of appeals. Like the Tenth Circuit, those courts approach preemption in cases involving devices with premarket approval by assuming "that the existence of any device-specific federal requirement has across-the-board preemptive effect, even on a state

requirement addressed to a different subject." Brief for United States as Amicus Curiae at 15, *Medtronic, Inc. v. Stengel*, No. 12-1351 (U.S. filed May 20, 2014).[2] That assumption is "contrary to *Lohr*'s reasoning and FDA's consistent interpretation in its regulations and briefs to this Court." *Id.* The Court should grant this petition to correct the lower courts' repeated error in applying this Court's precedents on MDA preemption.

B. An alternative way to approach the question presented is by asking whether Ms. Caplinger's claims are based on state-law duties that parallel federal requirements. On this point, the Tenth Circuit's approach is inconsistent with that of other courts of appeals and *Bates v. Dow AgroSciences*, 544 U.S. 431 (2005)—a case discussed in the petition (at 23-26) but ignored by Medtronic.

1. Medtronic agrees that the circuits disagree on how to apply this Court's holdings on parallel claims: it could hardly do otherwise because two years ago it represented to the Court that there is "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*." Petition for Writ of Certiorari at 17, *Medtronic, Inc. v. Stengel*, No. 12-1351 (filed May 14, 2013). Medtronic attempts here to dismiss that "pervasive disagreement" by arguing that the particular federal requirements that paralleled state requirements in those cases are different from the particular federal requirements at issue here. Yet in its petition in *Stengel*, Medtronic not only stated the issue more generally but

[2] Available at www.justice.gov/sites/default/files/osg/briefs/2013/01/01/2012-1351.pet.ami.inv.pdf.

also relied on cases addressing different federal requirements. Indeed, Medtronic relied on many of the same cases cited in the petition here. *Id.* at 10-11.

Medtronic's 2013 petition explained that four circuits have found that § 360k(a) does not preempt state-law duties that parallel general federal requirements. The Tenth Circuit's view of parallel claims is inconsistent with the approach of those circuits: The court described the task of stating a parallel claim as "navigating between Scylla and Charybdis," Pet. App. 10a, and an essentially impossible "conundrum." The inconsistent approach taken by the court below establishes the need for review.

Oddly, although the "parallel claim" issue was raised below and in the petition for certiorari, Medtronic argues that it is outside the question presented. That argument is meritless. One way to answer the question whether a device manufacturer is immune from liability for harms caused by a product that it markets for an unapproved use is to hold that the state-law duties on which the patient's claims are based parallel federal requirements. If the Tenth Circuit erred in finding that the duties underlying Ms. Caplinger's failure-to-warn and design-defect claims do not parallel the federal prohibitions on misbranding and adulteration, Ms. Caplinger would prevail on her question presented.

2. Medtronic argues that Ms. Caplinger's position implies that § 360k(a) does not preempt state-law claims against a manufacturer whenever a doctor puts a device to an unapproved use. Opp. 26. To the contrary, where a manufacturer markets its device in compliance with the premarket approval—that is, markets the device for the uses indicated on the approved labeling—a state-law claim premised on the notion that the product should

have been designed or labeled differently, to avoid the possibility that someone *else* might put it to an unapproved use, would place additional requirements on the manufacturer's ability to do what federal law allows. Section 360k(a) would preempt those "additional" requirements. But when the manufacturer exceeds the scope of approval by marketing the device for an unapproved use, state laws requiring that the device be designed and labeled appropriately to that use do not impose additional requirements, because there are no device-specific federal requirements. And, in that circumstance, state-law liability parallels the general federal prohibition on marketing a device with the intent that it be put to uses for which it is not safe, effective, and adequately labeled.

3. Although Medtronic derides the petition for not spending more time arguing the merits, Opp. 30, the argument is outlined in the petition and the briefing below. If the Court grants the petition, both parties will have an opportunity to argue the merits fully. Two of Medtronic's merits arguments warrant a brief response here.

Medtronic argues that a state-law claim based on duties that parallel the FDA prohibition on misbranding must fail to the extent it is premised on the notion that off-label promotion constitutes misbranding, because off-label promotion does not render a product misbranded. Opp. 16. But where off-label promotion shows the manufacturer's intent to market the device for an unapproved use, the FDA considers the device adulterated and misbranded, as Medtronic acknowledges. Opp. 5-6 (citing 1997 FDA Guidance). *See also* FDA, Guidance for Industry—Good Reprint Practices for the Distribution of Medical Journal Articles and

Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices (2009) ("a medical device that is promoted for a use that has not been approved or cleared by FDA is adulterated and misbranded").[3] Thus, where the manufacturer has marketed its device for an unapproved use, state-law prohibitions on marketing a device with an unsafe design or inadequate warnings parallel the federal prohibitions on marketing a misbranded or adulterated product.

Medtronic also takes a stab at arguing that the Infuse labeling contained an adequate warning concerning the unapproved use. Opp. 9-10. The merit of the failure-to-warn claim is, of course, not before the Court. Even so, Medtronic's defense misunderstands the FDA approval process. The approved labeling, with the warnings it contains, is labeling the FDA considered adequate to allow Medtronic to market the device for the *approved* use, *not* a warning that it considered adequate to allow Medtronic to market the device for an *unapproved* use.

C. Contrary to Medtronic's assertion, the views expressed in the May 2014 invitation brief of the United States in *Stengel* apply directly to the question presented here. There, the United States explained that the courts of appeals are repeatedly misapplying this Court's instruction concerning application of § 360k(a) by holding "that the act of premarket approval itself establishes device-specific requirements on all possible subjects, thus preempting additional or different state requirements whatever their subject." U.S. Br., *Stengel*, *supra* note 2, at 16. That "mistaken belief," *id.* at 15, is

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[3] Available at www.fda.gov/regulatoryinformation/guidances/ucm125126.htm.

exemplified by the decision below. And it leads to incorrect results in cases like this one, "where a plaintiff's claim concerns a subject not addressed in device-specific terms by FDA's premarket approval of the device." *Id.*

None of the reasons why the United States recommended denial of the *Stengel* petition apply here. *See* Pet. 22. Rather, this case presents a clean opportunity to address repeated legal errors in the MDA preemption analysis of the courts of appeals—errors identified by the United States.

D. Medtronic argues that Ms. Caplinger's claims are impliedly preempted under *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). Medtronic's view of implied preemption, with which the United States disagrees, is incorrect.

In *Buckman*, the plaintiffs' theory was that a consultant, working with a device manufacturer, had made misrepresentations to the FDA, absent which the FDA would not have cleared the device for marketing. The claim was not based on state-law duties of care owed by a manufacturer to patients; it rested on alleged duties arising from "the relationship between a federal agency and the entity it regulates." *Id.* at 352. By contrast, Ms. Caplinger alleges traditional state-law claims based on traditional state-law duties of care owed by a manufacturer to customers or patients. As in *Lohr*, her "claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from violation of [statutory] requirements." *Id.*

Medtronic relies primarily on 21 U.S.C. § 337(a), which provides that an action to enforce the Food, Drug, and Cosmetic Act "shall be by and in the name of the United States." That provision is irrelevant here. That

state-law duties underlying common-law claims parallel federal requirements does not convert those claims into ones for noncompliance with federal requirements. Under *Lohr*, *Riegel*, and *Bates*, the existence of parallel federal requirements allows Ms. Caplinger to pursue her state-law claims, but those requirements are not the basis for her claims. Medtronic states that to argue that the claims "'parallel' those federal statutes," Opp. 33, is to concede that the claims seek to enforce federal requirements. If that view were correct, the Court's repeated holding, in *Lohr*, *Riegel*, and *Bates*, that parallel state-law requirements are not expressly preempted would be meaningless. *Buckman* itself recognizes that its holding does not apply in this situation. *See* 531 U.S. at 353.

To the extent that Medtronic argues that state-law claims predicated on its off-label marketing are impliedly preempted, Medtronic misconstrues Ms. Caplinger's claims. *See* Opp. 33. She asserted claims such as failure-to-warn and negligence—indisputably traditional state-law causes of action, unlike the "fraud-on-the-agency" claim in *Buckman*. That Ms. Caplinger's serious injury is attributable to Medtronic's marketing for an unapproved use is important because that conduct disables Medtronic from invoking preemption by relying on premarket approval for a different use and because it shows that Medtronic has violated parallel federal and state requirements. Off-label marketing is not itself a claim.

Medtronic's worry that Ms. Caplinger's suit "would exert an extraneous pull on the FDA's exclusive enforcement discretion," Opp. 33, is unfounded. The brief for the United States in *Stengel* makes clear that the FDA shares no such concern about cases such as this one. To the contrary, the brief expresses concern that "an overly

expansive reading of *Buckman* would extinguish the very parallel claims that § 360k(a) preserves—a result that both *Buckman* itself, 531 U.S. at 352-353, and *Riegel*, 552 U.S. at 330, disclaim." U.S. Br., *Stengel*, *supra* note 2, at 22.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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