No. 15-

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

PETITION FOR A WRIT OF CERTIORARI

JAMES W. DOBBS
HOLLADAY & CHILTON, PLLC
204 N. Robinson
Suite 1550
Oklahoma City, OK 73102
405-236-2343

ALLISON M. ZIEVE
Counsel of Record
SCOTT L. NELSON
PUBLIC CITIZEN
LITIGATION GROUP
1600 20th Street NW
Washington, DC 20009
202-588-1000
azieve@citizen.org

Counsel for Petitioner

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QUESTION PRESENTED

Respondent Medtronic, Inc. obtained premarket approval from the Food and Drug Administration (FDA) to market a medical device for a particular use and then marketed that product for an additional use—one never evaluated for safety and effectiveness by the FDA and never approved by the FDA. Medtronic's marketing for the unapproved use succeeded, and hundreds of patients were seriously injured as a result.

This Court held in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), that state-law claims based on injuries caused by a medical device are *not* preempted when the FDA has not evaluated the device for safety and effectiveness. The Court held in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), that state-law claims based on injuries caused by a medical device *are* preempted when the FDA has evaluated the device for safety and effectiveness and granted premarket approval.

The question presented is —

Whether state-law claims based on injuries caused by a medical device are preempted where the device was not granted premarket approval for the particular use that caused the injuries and the manufacturer marketed the device for that unapproved use.

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INTRODUCTION

This Court held in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), that the express preemption provision of the Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a), does not preempt state-law claims based on injuries caused by a medical device when the Food and Drug Administration (FDA) has not evaluated the device for safety and effectiveness. The Court held in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), that § 360k(a) does preempt state-law claims based on injuries caused by a medical device when the FDA has granted premarket approval based on evaluation of the device's safety and effectiveness. This case presents a question on the border of those two cases: whether § 360k(a) preempts state-law claims for injuries caused by a medical device, when the device received premarket approval for one use but the manufacturer sold it for a different use, not evaluated or approved by the FDA, and the patient suffered serious injury as a result of that conduct by the manufacturer.

The reasoning of *Lohr* and *Riegel* dictates the answer to this question: No. Yet the court below, in an opinion acknowledging confusion about how to apply the two decisions, held that state-law claims arising from injuries caused by aggressive marketing for an unapproved use are preempted. The errors in the court's reasoning reflect the appellate courts' broad misapplication of *Lohr* and *Riegel*. As the United States stated last year, "The courts of appeals, in *every* case since *Riegel* involving a device subject to premarket approval, have dispensed with the first step of a proper Section 360k(a) preemption analysis—*i.e.*, asking whether FDA has established device-specific requirements on the same

subject as the relevant state requirement."[1] The court of appeals thus erred by holding petitioner Patricia Caplinger's claims preempted, when the FDA's approval of the device for another use imposed *no* device-specific requirements on the subject of the state-law claims at issue here: namely, the proper design and the necessary warnings when the device is used as it was in this case. The Court should grant the petition to correct the pervasive misunderstanding that led to that error.

In addition, the decision below conflicts with decisions of the Fifth, Sixth, Seventh, and Ninth Circuits. Consistent with *Lohr*, *Riegel*, and *Bates v. Dow Agro-Sciences LLC*, 544 U.S. 431, 447 (2005), those courts recognize that a state-law requirement that parallels a generally applicable federal requirement is not preempted. The Tenth Circuit, however, reached the opposite conclusion here.

The question presented is recurring and important; the decision below is incorrect; and the courts are finding the case law a "real 'struggle'" (Pet. App. 10a) to understand. The Court should grant the petition.

OPINIONS BELOW

The decision of the United States Court of Appeals for the Tenth Circuit is reported at 784 F.3d 1335 and reproduced in the appendix at 1a. The district court's decision granting respondents' motion for summary judgment is unreported and is reproduced in the appendix at 48a. The district court's decision denying peti-

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[1] Brief for United States as Amicus Curiae, *Medtronic, Inc. v. Stengel*, No. 12-1351, at 15 (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 (emphasis added).

tioner's motion for reconsideration is also unreported and is reproduced in the Appendix at 45a.

JURISDICTION

The court of appeals entered its judgment on April 21, 2015. Pet. App. 83a. On May 14, 2015, the court denied petitioner's timely petition for rehearing. *Id.* at 84a. On July 10, 2015, Justice Sotomayor granted an application for an extension of time to file a petition for certiorari to and including September 11, 2015. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTES AND REGULATIONS INVOLVED

The Medical Device Amendments to the Food, Drug, and Cosmetic Act provide in part:

> State and local requirements respecting devices
>
> (a) General rule
>
> Except as provided in subsection (b) of this section, no 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.

21 U.S.C. § 360k.

An FDA regulation found at 21 C.F.R. § 808.1(d) provides in part:

> State or local requirements are preempted only when the Food and Drug Administration has

> established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.

STATEMENT OF THE CASE

This petition arises from a state-law damages suit brought by Patricia Caplinger to recover for severe injuries caused by a spinal bone graft device manufactured by respondent Medtronic, Inc. Ms. Caplinger's injuries were directly attributable to Medtronic's marketing of the device for use in a way that posed threats of serious injury and that had not been approved by the FDA.

Because an understanding of the structure of the Medical Device Amendments (MDA) is important to understanding this case, Part 1 below offers a general description of the MDA. Part 2 describes this Court's decisions addressing the MDA's express preemption provision. Parts 3 through 5 set forth the facts surrounding Medtronic's illegal promotion of the device for an unapproved use, Ms. Caplinger's resulting injuries, and the proceedings below.

1. Federal Medical Device Regulation

Although prescription drugs have been the subject of extensive regulation by the FDA since the enactment of the Food, Drug, and Cosmetic Act in 1938, medical devices, which range in complexity from bandages to artificial hearts, were outside the scope of the FDA's regulatory authority until the enactment of the MDA in 1976. *See Lohr*, 518 U.S. at 475-76. The MDA divided medical devices into three categories—classes I, II, and

III—and established a tripartite scheme for their regulation. *See id.* at 476-77.

Under the MDA, class III devices are those that treat serious medical conditions or pose serious risks of causing injury to patients. 21 U.S.C. § 360c(a)(1)(C).[2] Like new drugs, new class III devices that are not substantially similar to devices already on the market when the MDA was enacted must receive premarket approval (PMA) from the FDA. *See Lohr*, 518 U.S. at 477; *Riegel*, 552 U.S. at 318-19. The PMA process involves a detailed review of a device's safety and effectiveness for particular uses, including all studies and investigations available to the manufacturer, as well as the device's proposed uses, design, and labeling. *See Riegel*, 552 U.S. at 318. PMA represents an FDA finding that the device is safe and effective "under the conditions of use included in the proposed labeling." 21 U.S.C. § 360e(d)(1)(A); *see also id.* § 360e(d)(2)(A), (B) (requiring the FDA to deny approval if a device is not safe and effective for the uses recommended or suggested in the labeling).

In addition, PMA is conditioned on the manufacturer's compliance with ongoing obligations under FDA regulations, including the requirement that the manufacturer report adverse incidents involving the device to the FDA. *Id.* § 360i(a)(1), (3); *see Riegel*, 552 U.S. at 319. A manufacturer must report incidents in which a device "malfunctions" and those in which the device may have caused or contributed to a death or "serious injury." 21

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[2] Class I devices are basic items such as bandages and tongue depressors. Class II devices include items, such as hearing aids, that are more complex and have greater potential to cause harm if defective or misused.

C.F.R. § 803.50(a); *see also id.* § 803.3 (defining "malfunction" and "serious injury"). The FDA makes such reports available to the public. *See id.* § 803.9.

In contrast to new class III devices that are subject to the PMA process, class III devices that were already in existence when the MDA was enacted are subject to less stringent standards. Such devices are grandfathered for uses that existed when the statute was passed. Approval to market devices that are "substantially equivalent" to grandfathered devices may be obtained through a truncated review process generally referred to as the "510(k) process" (so named after the MDA section providing for such review). 21 U.S.C. § 360(k); *see Lohr*, 518 U.S. at 477-79. Section 510(k) review focuses on the question of substantial equivalency and does not entail a thorough examination of the device's safety and effectiveness, or of its design, except to the extent necessary to determine whether it is substantially equivalent to a grandfathered device for the same use. *Riegel*, 551 U.S. at 322. To market a grandfathered or substantially equivalent device for a *new* use, however, a manufacturer must obtain PMA. *See* 21 C.F.R. § 807.92(a)(5); FDA, Guidance for Industry: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications 17 (July 2014), *available at* http://www.fda.gov/downloads/MedicalDevices/.../UCM284443.pdf.

Whether a device is introduced through the PMA or 510(k) process, it can be marketed only for the use(s) approved or cleared by the FDA and specified in the product's labeling. *See* 21 U.S.C. § 360e(d)(1)(A) (in evaluating a PMA application, FDA "shall rely on the conditions of use included in the proposed labeling"); *id.* § 360c(a)(2)(B) (providing that the safety and

effectiveness of a device must be determined "with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device"); FDA, Guidance for Industry: The 510(k) Program, *supra*, at 16-18. Thus, for example, a manufacturer cannot market a device approved as a knee implant for use as a hip implant without first obtaining a supplemental approval or clearance. Although the FDA does not regulate physicians, who may use a device approved for one use for a different use, *see* 21 U.S.C. § 396, a class III device *intended by the manufacturer* for an unapproved, or "off-label," use is adulterated and misbranded. *Id.* §§ 351(f)(1)(B), 352(f).[3] And federal law prohibits manufacturing or marketing an adulterated or misbranded product. *Id.* § 331(a), (b), (c), (g).

2. Preemption Under the MDA

In addition to provisions addressing device classification, approval, and reporting requirements, 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." *Id.* § 360k(a). The FDA has underscored the plain language of the statute by promulgating an implementing regulation that provides that state laws are preempted "only when the [FDA] has established specific counterpart regulations

[3] *See also* 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.

or there are other specific requirements applicable to a particular device under the act," 21 C.F.R. § 808.1(d), and that, even when such specific requirements exist, the MDA "does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act," *id.* § 808.1(d)(2).

This Court has considered the MDA's preemptive scope in three cases. First, in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the Court 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 and dissenting 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.*

Further, 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). A state may impose liability for a manufacturer's conduct that violates requirements imposed by federal law, even if the showing required to establish liability requires proof of "additional elements of the state-law cause of action," such as that the

manufacturer engaged in "negligent conduct" or "created an unreasonable hazard for users of the product." *Id.* at 495. Such elements "make the state requirements narrower, not broader, than the federal requirement," and are not "additional or different" requirements for purposes of § 360k(a). *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), as in *Lohr*, the Court stated that express preemption under § 360k(a) requires specific federal requirements applicable to the device, which then operate to preempt different or additional state-law requirements addressing the same subjects. *See* 552 U.S. at 322-23. Applying that framework, the Court held that the PMA process 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. In reaching this conclusion, the Court emphasized that PMA, unlike the 510(k) process considered in *Lohr*, represents an FDA finding that the device is safe and effective for its intended use as designed and labeled. *Id.* at 318, 323.

In addition, *Riegel* reiterates that § 360k(a) does not preempt state-law claims that parallel federal

requirements: § 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.

3. Medtronic's Infuse Bone Graft Device

The InFUSE Bone Graft/L-CAGE Lumbar Tapered Fusion Device (Infuse) consists of two components containing three parts: a cage and bio-engineered bone-filling material with a carrier or scaffold. Infuse is used in spinal fusion surgery as an alternative to grafting a patient's own bone. The bone-filling material, a protein called rhBMP-2, helps fuse vertebrae in the lower (lumbar) spine to treat degenerative disc disease.[4]

As a class III medical device, Infuse could not be marketed until Medtronic obtained PMA from the FDA, which it did in 2002. The FDA approved Infuse for use only in surgery in which the surgeon approaches *from the front* (anterior) of the patient, to treat degenerative disc disease in the lower, or lumbar, region of the spine,[5] as the FDA approval letter expressly stated. Infuse is not approved for use in spinal surgery in which the surgeon proceeds through the patient's *back* (posterior). That use creates an undue risk of unwanted bone growth, intractable pain, weakness, and foot drop, among other things.

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[4] The facts stated herein are taken from plaintiff's first amended complaint, filed on July 23, 2012.

[5] Medtronic later received PMA to market Infuse for use in certain dental surgeries and for repair of certain tibial fractures.

Nonetheless, Medtronic aggressively promoted Infuse for use in posterior-approach surgeries. As the Department of Justice, a Committee of the United States Senate, and a leading journal of spinal medicine have documented, Medtronic's illegal promotion included paying kickbacks and other incentives to physicians to influence clinical studies, prevent publication of adverse events, and encourage the unapproved use.

Medtronic was a defendant in two qui tam lawsuits alleging that it violated the False Claims Act, 31 U.S.C. § 3729, by paying illegal kickbacks to physicians for promoting the off-label use of Infuse, which resulted in the submission of false or fraudulent claims to federal health care programs. In July 2006, Medtronic agreed to pay $40 million to the United States to settle these lawsuits.

Despite the settlement, Medtronic continued to market Infuse for the unapproved use in posterior-approach spinal surgery. In 2008, following a Wall Street Journal article about Medtronic's practices, *see* Armstrong & Burton, *Medtronic linked to surgery problems*, Wall St. J., Sept. 4 2008, members of the Senate expressed serious concerns about continued wrongdoing by Medtronic. For example, Senator Charles Grassley wrote: "[E]arlier this month the [Wall Street Journal] reported on problems with off-label use of Medtronic's Infuse. … Specifically, it was reported that Medtronic gave payments to physicians, in the form of consulting agreements, as a means of increasing sales of Infuse. The allegations that Medtronic has been disguising [as] consulting agreements … inducements or kickbacks for physicians to use Infuse are equally troubling." First Am. Compl. ¶ 53.

In 2011, the Senate Committee on Finance began an investigation into whether Medtronic was continuing to misrepresent the adverse events that resulted from Infuse and rhBMP-2, as well as the possibility that Medtronic used payments to physicians to improperly influence clinical trials and reporting regarding rhBMP-2.

In June 2011, *The Spine Journal*, a leading U.S. medical journal, published a special edition dedicated to addressing serious patient safety and ethical concerns related to the use of Infuse in the spine. The journal reviewed thirteen peer-reviewed articles about rhBMP-2 by industry-sponsored authors, including many sponsored by Medtronic, and found that these articles had inaccurately reported the device's safety by underestimating the risks. In an editorial summarizing the journal's findings, five prominent physicians, including spine surgeons at Stanford University, wrote that the earlier industry-sponsored trials and reports were "remarkable for the complete absence of reported rhBMP-2–related clinical adverse events," including reported instances of adverse back and leg pain events, radiculitis, bone resorption, urinary retention, and implant displacement, as well as sterility and cancer risks.[6] They concluded that the trials and reports suffered from idiosyncratic trial design, reporting bias, and peer-review and publication shortfalls. Carragee, 11 The Spine Journal at 463. According to the editorial and accompanying articles, the thirteen industry-sponsored

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[6] Eugene J. Carragee, et al., *A challenge to integrity in spine publications: years of living dangerously with the promotion of bone growth factors*, 11 The Spine Journal 463 (June 2011), *available at* http://www.researchgate.net/publication/51467883_A_challenge_to_integrity_in_spine_publication_Years_of_living_with_the_promotion_of_bone_growth_factors.

articles reported only successful fusions and low rates of complications with Infuse, "which led to the 'off-label' use of Infuse" and "may have promoted widespread poorly considered on- and off-label use, eventual life-threatening complications and deaths." *Id.*

4. Patricia Caplinger's Injuries

On August 25, 2010, Patricia Caplinger had surgery to correct a degenerative disc condition. The surgeon used the unapproved posterior approach to place the Medtronic Infuse bone graft into the lumbar region of Ms. Caplinger's spine. A Medtronic representative was present during the surgery, and she was actively involved and provided information regarding Infuse as it applied to Ms. Caplinger's particular surgery.

In October and November 2010, Ms. Caplinger's symptoms returned and worsened. She also experienced a foot drop condition in her right leg resulting from exuberant bone growth caused by the use of Infuse. In December 2010, the foot drop condition caused a tear of the anterior cruciate ligament in her right knee, which required surgery in February 2011. MRI and CT imaging of Ms. Caplinger's lumbar spine confirmed exuberant bone in her lumbar spine caused by the use of Infuse and requiring revision surgery on September 9, 2011.

Ms. Caplinger continues to suffer exuberant bone growth and the resulting pain, weakness, and foot drop. A June 2012 CT scan confirmed continuing exuberant bone growth that required additional surgery.

5. Proceedings Below

Ms. Caplinger filed suit against Medtronic on June 4, 2012, seeking to recover for her injuries under state products liability law. The gravamen of the state-law

claims is that Medtronic sold a product that was unreasonably dangerous for the use for which it was intended and failed to provide proper warnings about the dangers associated with that use. Ms. Caplinger's amended complaint states claims for failure to warn, design defect, breach of express and implied warranty, negligence, negligent misrepresentation, fraudulent misrepresentation, fraud in the inducement, and constructive fraud. The complaint also sets forth various FDA regulations violated by Medtronic's conduct but does not allege claims for relief directly under federal law.

Medtronic moved to dismiss, principally on the ground that Ms. Caplinger's claims are foreclosed by the MDA's preemption provision, 21 U.S.C. § 360k(a), which, as explained above, prohibits state laws from imposing "requirements" on devices that are "different from, or in addition to," requirements imposed under the MDA. Ms. Caplinger, relying principally on *Lohr* and *Riegel*, argued that, because federal law prohibited Medtronic's marketing of Infuse for an unapproved use, the MDA does not preempt her state-law claims, which are based on state-law duties that are *not* "different from, or in addition to," those of the MDA.

The district court granted the motion to dismiss. Although the court acknowledged that some state-law claims for injury caused by a PMA medical device are neither expressly nor impliedly preempted, the court held that each of Ms. Caplinger's claims is either expressly or impliedly preempted. The court also held that Ms. Caplinger's fraud claims were not pleaded with adequate specificity under Federal Rule of Civil Procedure 9(b).

Ms. Caplinger appealed. She explained that the FDA does not approve devices in a general sense, but for specific uses, and that the FDA had not approved Infuse for posterior-approach surgery. Accordingly, she explained, the FDA imposed no requirements on Infuse for posterior use (except to the extent that the prohibition against marketing devices for unapproved uses can be said to be a requirement with respect to posterior use), and thus, as in *Lohr*, § 360k(a) does not preempt her state-law claims. She also argued that her claims are not preempted because they are parallel to, not different from or in addition to, federal requirements—in particular, the federal prohibitions against misbranding and against marketing a device without reasonable assurance of safety and effectiveness.

In a 2-1 decision, the Tenth Circuit affirmed. The majority held that all of Ms. Caplinger's claims are expressly preempted by the MDA. The majority made clear its confusion about how to apply this Court's three preemption decisions: Reviewing this Court's holdings in *Lohr*, *Buckman*, and *Riegel*, it stated that "laying out the rules governing our review is a real struggle in this area." Pet. App. 10a (internal quotation marks omitted). "How are we to apply all these competing instructions?" the court asked. *Id.* at 9a. Nonetheless, the majority held that § 360k(a) expressly preempts the underlying state-law duties because those duties would impose different or additional requirements on the Infuse device. In the majority's view, § 360k(a) preempts the claims because the FDA had approved the device for one use, even if not for the use for which Medtronic had marketed the device.

Judge Lucero dissented. As he explained, Ms. Caplinger alleged conduct that was both tortious under state law and violative of federal laws that forbid the

marketing of misbranded or adulterated medical devices. The majority decision that her claims are preempted thus "is compelled neither by binding precedent nor by the plain text and clear purpose of" the MDA. *Id.* at 25a.

REASONS FOR GRANTING THE WRIT

Together, the decisions in *Lohr* and *Riegel* establish, first, that § 360k(a) does not preempt state-law claims in the absence of a relevant federal device requirement and, second, that § 360k(a) does not preempt state-law claims premised on the breach of state-law duties of care that parallel federal regulatory requirements. The decision below is inconsistent with these precedents—an outcome that resulted from the Tenth Circuit's admitted difficulty understanding how to apply them. Notably, as the Solicitor General has stated, the courts of appeals for other circuits to address MDA preemption since *Riegel* have also misunderstood this Court's instruction. In light of the lower courts' confusion and misunderstanding, the Tenth Circuit's suggestion that this area "warrant[s] revisiting" by this Court, Pet. App. 10a, has considerable merit.

Moreover, the decision below is inconsistent with decisions of other federal courts of appeals with respect to non-preempted parallel state-law requirements, and the court reached an incorrect conclusion on a recurring question of exceptional importance.

For each of these reasons, the petition should be granted.

I. The Courts of Appeals Widely Misapply *Lohr* and *Riegel*.

The implications of the Tenth Circuit's decision are far-reaching. Under the decision, PMA based on a determination that a medical device is safe and effective

for one use allows a manufacturer to promote the device for any other use and to do so free from liability under state law for injury resulting from its off-label marketing. Nothing in the MDA or this Court's preemption jurisprudence grants a manufacturer such immunity when acting outside the scope of PMA, which allows marketing of the device according to the design and labeling for the particular uses for which the FDA has found the device to be safe and effective.

A. The Decision Below Is Inconsistent with *Lohr* and *Riegel*.

This case involves claims based on a specific use of the Infuse device: its use for posterior spinal fusion surgery. The FDA has never approved the device for that use and, accordingly, has never imposed requirements on the design and labeling of the device for that use. In the absence of device-specific requirements applicable to the use at issue, state-law claims challenging the device's design with respect to that use, the adequacy of Medtronic's warnings concerning that use, and the truthfulness of Medtronic's representations about that use do not seek to impose requirements that are different from or in addition to requirements of federal law within the meaning of § 360k(a). Yet Medtronic argued, and the court below held, that the MDA's preemptive effect protects conduct that the MDA itself condemns.

As explained above, both *Lohr* and *Riegel* hold that the touchstone for preemption under § 360k(a) is the existence of a requirement specifically applicable to a device. Such a federal requirement preempts state requirements that impose different or additional requirements with respect to the subject-matter covered by the federal requirement. *See Riegel*, 552 U.S. at 322-

23; *Lohr*, 518 U.S. at 493-94, 498-502. In *Lohr*, the Court emphasized that preemption under § 360k(a) turns on the existence of specific federal and state requirements on the same subject matter and noted that "it is impossible to ignore [the statute's] overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest." 518 U.S. at 500. Thus, the court concluded that the state-law design defect claims at issue were not preempted because the 510(k) clearance process did not result in imposition by the FDA of specific requirements applicable to the device's design. *Id.* at 492-94.

In *Riegel*, the Court reiterated that preemption under § 360k(a) requires specific federal requirements applicable to the device, which then operate to preempt different or additional state-law requirements addressing the same subjects. *See* 552 U.S. at 322-23. Thus, the Court held that state-law design defect and failure-to-warn claims are preempted to the extent that they would impose requirements different from or in addition to the specific design and labeling requirements imposed through PMA and address the same subject matter as those requirements. *See id.* at 325. The Court's analysis in *Riegel* rests heavily on the notion that the adequacy of the design and labeling of devices for approved uses are matters specifically reviewed and approved by the FDA in the PMA process. *Id.* at 318, 323.[7]

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[7] Below, Medtronic argued that *Riegel* stands for the proposition that § 360k(a) preempts claims for injury arising from off-label marketing of a PMA device because the injury there "arose from an off-label procedure." Tenth Cir. Appellee Br. 23. But although the physician in *Riegel* had used the device in a way contraindicated on the labeling, *see* 552 U.S. at 320, the plaintiffs did *not* allege that Medtronic had marketed the device for an unapproved use. The

(*Footnote continued*)

When a manufacturer markets a device for an unapproved use, it acts outside the scope of the FDA's device-specific design and labeling requirements because, *as to that use*, the FDA has not reviewed and approved the safety and effectiveness of the device and the adequacy of the warnings and instructions contained in the device labeling. The statute specifically provides that, for purposes of PMA, the FDA focuses on the particular uses described in the manufacturer's proposed labeling for the device:

> [T]he safety and effectiveness of a device are to be determined—(A) with respect to the persons *for whose use* the device is represented or intended; (B) with respect to the *conditions of use* prescribed, recommended, or suggested in the labeling of the device; and (C) weighing any probable benefit to health *from the use* of the device against any probable risk of injury or illness *from such use*.

21 U.S.C. § 360c(a)(2) (emphasis added). The FDA's decision to grant or withhold PMA depends on whether it finds a reasonable assurance of safety and effectiveness "under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof," *id.* § 360e(d)(2)(A), (B), and PMA authorizes the manufacturer to market the device only for that use, *id.*; 21 C.F.R. § 801.39(a)(1) (manufacturer must submit PMA supplement for review and approval before adding new indication).

Court in *Riegel* had no occasion to consider and did not consider the preemptive effect of § 360k(a) on claims arising from a manufacturer's off-label marketing of a PMA device.

Here, while PMA for the Infuse device imposes specific design and labeling requirements that Medtronic must meet when marketing Infuse for its approved use in anterior-approach surgery, the PMA imposes no design or labeling requirements on Infuse as a device intended by Medtronic for use in surgery from a posterior approach. The FDA's PMA for another use of Infuse does not require that the device intended for use in posterior spinal surgery "take any particular form for any particular reason," *Lohr*, 518 U.S. at 493, nor does the PMA specify labeling requirements for a device marketed for that unapproved use. When it granted PMA, the FDA neither considered nor approved the safety and effectiveness of Infuse's design for posterior surgery or the adequacy of the device's labeling for that use. The PMA decision thus established no requirements applicable to the Infuse device to the extent that Medtronic intended the device for a posterior-approach surgery.

Under the reasoning of *Lohr* and *Riegel*, therefore, no federal requirements exist to preempt state requirements applicable to the design or labeling of the device because the FDA has imposed on Infuse no requirements relevant to the asserted claims—all of which are based on marketing of Infuse for a use for which the FDA did *not* grant PMA. Yet in its "struggle," Pet. App. 11a, to understand this Court's preemption precedents—a task that the Tenth Circuit analogized to navigating between Scylla and Charybdis, *id.* at 10a—the court of appeals misunderstood the importance of *relevant* federal requirements to the preemption analysis. As a result, the court reached a decision that cannot be reconciled with this Court's precedents.

B. As the United States Agrees, the Appellate Courts Misunderstand *Riegel*.

Misapprehension of the scope of MDA preemption is widespread. As the United States told the Court last year, decisions of several courts of appeals manifest confusion about application of *Lohr* and *Riegel*. Like the court below, those courts err in addressing preemption in cases involving PMA devices 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." U.S. Br., *Medtronic v. Stengel*, No. 12-1351, *supra* n.1, at 15. That assumption, the government explained, is "contrary to *Lohr*'s reasoning and FDA's consistent interpretation in its regulations and briefs to this Court." *Id.*

"The courts of appeals, in *every* case since *Riegel* involving a device subject to premarket approval, have dispensed with the first step of a proper Section 360k(a) preemption analysis—*i.e.*, asking whether FDA has established device-specific requirements on the same subject as the relevant state requirement," according to the United States. *Id.* (emphasis added) (citing as an example *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 768 (5th Cir. 2011)). The United States suggested that the courts' approach "may reflect a mistaken belief that the act of premarket approval itself establishes device-specific requirements on all possible subjects, thus pre-empting additional or different state requirements whatever their subject." *Id.* at 16 (citing as an example *Bausch v. Stryker Corp.*, 630 F.3d 546, 563 (7th Cir. 2010)).

Although in *Stengel* the United States identified and criticized the courts of appeals' misapplication of *Riegel*, it argued against granting Medtronic's petition because

of what it characterized as the "unnecessarily tortuous theories of causation" advanced there, because a correct preemption analysis would result in a more favorable judgment for the plaintiffs than they had obtained below (and they did not cross-petition), because of the lack of a conflict, and "especially" because of the case's interlocutory posture. U.S. Br., *Medtronic v. Stengel*, No. 12-1351, *supra* n.1, at 7-8. None of those concerns applies here. Moreover, whereas in *Stengel* the United States agreed that the lower court's misunderstanding led to a correct result on the claim at issue in the petition, *id.* at 7, in this case the misunderstanding caused an erroneous outcome that threatens sweeping immunization of conduct directly contrary to the MDA's purposes.

Further, the majority here took precisely the approach criticized by the government in *Stengel*. Like the plaintiff in *Stengel*, Ms. Caplinger attacks conduct that was "governed not by the terms of the [PMA], but rather by FDA's general regulations." *Id.* at 12. Yet the court below focused on the fact that the PMA for Infuse imposed requirements (applicable to the design and disclosures required to market the device for anterior lumbar surgery) and relied on the existence of those requirements as the basis for preemption of state-law claims addressed to a *different* subject (whether the device was designed defectively for posterior lumbar surgery and whether Medtronic's warnings and representations concerning that different use were tortious under state law). The court stated: "[T]he device endured the premarket approval process. So the MDA will preempt all of Ms. Caplinger's claims unless federal requirements impose duties that are at least as broad as those she seeks to vindicate through state law." Pet. App. 11a; *see also id.* at 17a. That rationale—that PMA "itself

establishes device-specific requirements on all possible subjects, thus preempting additional or different state requirements whatever their subject"—encapsulates precisely the belief that the United States characterized as "mistaken." U.S. Br., *Medtronic v. Stengel*, No. 12-1351, *supra* n.1, at 16.

The petition should be granted to correct the lower courts' consistently incorrect approach to preemption of claims involving PMA devices—an approach exemplified by the decision below.

II. The Tenth Circuit's Decision Is Inconsistent with Decisions of Other Federal Courts of Appeals.

Even while sharing in the broad and pervasive confusion over the scope of MDA preemption, the Tenth Circuit's decision is inconsistent with decisions of the Fifth, Sixth, Seventh, and Ninth Circuits finding no preemption of state-law claims that parallel federal requirements. In *Medtronic, Inc. v. Stengel*, Medtronic argued in a petition for certiorari 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*." No. 12-1351, Pet. at 17 (filed May 14, 2013) (stating that "[t]he Circuits are split on whether the MDA expressly preempts state-law claims alleging a violation of a generalized, rather than a device-specific, federal requirement"). Medtronic was incorrect at that time, but the Tenth Circuit's decision creates the conflict that was then lacking.

As this Court stated in *Bates v. Dow AgroSciences LLC*, 544 U.S. 431, 447 (2005), addressing the "similarly worded" preemption provision of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), "a state-law labeling requirement is not pre-empted" if the state

requirement "is equivalent to, and fully consistent with, [the statute's] misbranding provisions." *Accord Riegel*, 552 U.S. at 330; *Lohr*, 518 U.S. at 494-97. Flatly inconsistent with *Bates*, *Lohr*, and *Riegel*, the Tenth Circuit rejected the federal statute's prohibition on misbranding as the basis for a parallel claim.

The allegation was clearly made: Ms. Caplinger alleged an extensive program of off-label marketing, explained that off-label marketing renders a product misbranded and adulterated in violation of federal law, and explained that these federal prohibitions parallel the state-law duties on which the claims for failure-to-warn, fraudulent misrepresentation, and design defect are based. Yet the court of appeals overlooked adulteration entirely, and it held that Ms. Caplinger's claims did not parallel the prohibition on misbranding because it thought that misbranding is limited to mislabeling, whereas Ms. Caplinger's claims look to conduct beyond labeling. Pet. App. 12a. That reasoning ignores that marketing for an unapproved use renders the labeling false and misleading because the labeling no longer accurately describes the use for which the manufacturer intends the product, no longer provides warnings for using the product safely and effectively for that use, and no longer meets other requirements of an adequate label. The Tenth Circuit's view thus contradicts the FDA's determination that a device is misbranded (that is, its labeling is false and misleading) when the product is marketed for an unapproved use. It contradicts as well this Court's decisions holding that a state-law duty to

warn may parallel the federal prohibition against misbranding.[8]

Consistent with *Bates*, *Lohr*, and *Riegel*—but in stark contrast to the Tenth Circuit—the Fifth, Sixth, Seventh, and Ninth Circuits have found no preemption in cases concerning PMA devices where a state-law claim is based on violation of a duty that parallels a generally applicable federal requirement, including duties comparable to the misbranding provisions and marketing restrictions on which Ms. Caplinger relies. *See Stengel v. Medtronic*, 704 F.3d 1224, 1233 (9th Cir. 2013) (no preemption of state-law duty to warn that parallels FDA reporting requirement); *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); *Hughes*, 631 F.3d at 770-71 (5th Cir.) (no preemption of state-law duty to warn that parallels FDA reporting requirement); *Bausch*, 630 F.3d at 555 (7th Cir.) (no preemption of state-law duty that parallels FDA good manufacturing practices regulations); *Howard v. Sulzer Orthopedics, Inc.*, 382 Fed. App'x 436, 441 (6th Cir. 2010) (same); *cf. Walker v. Medtronic*, 670 F.3d 569, 571 (4th Cir. 2012) ("In light of Walker's concession that the device was designed, manufactured, and distributed

[8] The court of appeal's erroneous understanding of this Court's case law was compounded by its assumption that device labeling is fixed in time at the point of FDA approval—that federal law "precludes" a manufacturer from revising labeling. Pet. App. 12a. In fact, the FDA permits device manufacturers to revise labeling to "enhance the safety of the device" prior to FDA approval of the revision, much as drug manufacturers are able to do. 21 C.F.R. § 814.39(d)(1); *see also Wyeth v. Levine*, 555 U.S. 555 (2009) (no preemption of failure-to-warn claim against drug manufacturer where FDA regulations allow revision without prior approval); Tenth Cir. Reply Br. at 15.

in compliance with the terms of its premarket approval, given by the [FDA] as required under the MDA, however, we are compelled to affirm [the finding of preemption].").[9]

In reaching its contrary conclusion, the Tenth Circuit suggested that, to state a parallel state-law claim, Ms. Caplinger would face the "conundrum" of "requir[ing] more label warnings that federal law seems to prohibit." Pet. App. 12a. In so doing, the court—contrary to other federal courts of appeals—defined the task of stating a parallel claim for failure to warn as an impossibility. The petition should be granted to resolve the conflict among the Circuits regarding the nature of a "parallel" federal requirement.

III. The Court Below Incorrectly Decided A Recurring Question Of Importance.

Finally, the majority below reached an incorrect conclusion on a question of exceptional importance: whether a medical device manufacturer is immune from liability for harms caused by a product that it markets for a use never approved by the FDA. Medtronic's extensive marketing of Infuse for an unapproved use has led to a large number of injuries and lawsuits, and the

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[9] Medtronic incorrectly argued below that the violation for which Ms. Caplinger seeks to hold it accountable is its off-label marketing—that is, its violation of federal law. *Cf. Buckman*, 531 U.S. 341. Ms. Caplinger's suit, however, does not seek to state a claim for off-label marketing itself, but asserts state-law claims that parallel the prohibitions against misbranding and adulteration that Medtronic violated through its marketing scheme. Both the state-law duties and federal law prohibit the marketing of a device for a use for which it is not properly designed and is unreasonably dangerous, and for which adequate warnings have not been provided.

question whether federal law preempts state-law remedies for injuries caused by that unapproved use arises frequently.[10] Furthermore, the issue is likely to arise with respect to other products as well, given the interest of medical device companies in marketing for unapproved uses to increase revenues while avoiding the time and expense of demonstrating a reasonable assurance of safety and effectiveness through the PMA process.[11]

The regulatory regime, developed to protect patients from unsafe or ineffective medical devices, appropriately puts the burden on the manufacturer to prove safety and effectiveness; the manufacturer must make this showing for each use for which it intends to sell a device. This

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[10] *E.g.*, *Otis-Wisher v. Medtronic, Inc.*, 2015 WL 3557011 (2d Cir. June 9, 2015) (unpublished) (affirming dismissal on preemption grounds); *Hafer v. Medtronic, Inc.*, 2015 WL 1648978 (W.D. Tenn. Apr. 13, 2015) (consolidation of 141 individual cases; preemption of several claims); *Garross v. Medtronic, Inc.*, 77 F. Supp. 3d 809 (E.D. Wis. 2015) (no preemption); *Martin v. Medtronic, Inc.*, 32 F. Supp. 3d 1026 (D. Ariz. 2014) (preemption); *Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166 (C.D. Cal. 2013) (preemption); *Ramirez v. Medtronic Inc.*, 961 F. Supp. 2d 977 (D. Ariz. 2013) (no preemption of most claims); *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413 (Cal. Ct. App. 2014) (preemption in part); *McCormick v. Medtronic, Inc.*, 101 A.3d 467 (Md. Ct. Spec. App. 2013) (no preemption).

[11] Examples of recent federal indictments and civil complaints against medical device manufacturers for off-label marketing are available on the Department of Justice website at http://www.justice.gov/opa/pr/vascular-solutions-inc-and-its-ceo-charged-selling-unapproved-medical-devices-and-conspiring (announcing November 2014 indictment and discussing related civil action brought by Dep't of Justice), and http://www.justice.gov/opa/pr/united-states-files-enforcement-action-against-south-dakota-laser-medical-device-distributor (announcing October 2014 civil complaint filed by Dep't of Justice).

regime developed in response to real-world situations that highlighted the need for an objective decision-maker to assess the safety and effectiveness of drugs and devices for particular uses before they are marketed to patients.[12] As this case illustrates, manufacturers' assurances that claims of safety and effectiveness are well-supported are no substitute for FDA evaluation of the evidence.[13] *See supra* pp. 12-13 (discussing *The Spine Journal*'s criticism of Medtronic's promotion of Infuse).

Under the reasoning of *Lohr* and *Riegel*, "[i]t would make little sense to allow [a company] to receive the protection of preemption when it is actively promoting

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[12] *See generally* Henry A. Waxman, *A History of Adverse Drug Experiences: Congress Had Ample Evidence to Support Restrictions on the Promotion of Prescription Drugs*, 58 Food & Drug L.J. 299, 301-06 (2003) (detailing history of harms resulting from marketing of drugs for uses for which they had not been shown to be safe and effective).

[13] Extensive evidence shows that companies use marketing techniques that mislead doctors about the safety and effectiveness of unapproved uses. Mark A. Ford, *Another Use of OxyContin: The Case for Enhancing Liability for Off-Label Drug Marketing*, 83 B.U. L. Rev. 429, 434 (2003); *see also Washington Legal Found'n v. Friedman*, 13 F. Supp. 2d 51, 65 (D.D.C. 1998) (noting that "manufacturers will likely only seek to disseminate information that presents their product in a favorable light"), *vacated on other grounds*, 202 F.3d 331 (D.C. Cir. 2000). For example, companies may lead doctors "to believe that a certain [product] is safe and effective because a manufacturer has found, and aggressively promoted, 'the one' article that supports use of their [product], even if there exists considerable evidence to the contrary." *Friedman*, 13 F. Supp. 2d at 65. These marketing techniques are particularly pernicious because studies are overwhelmingly funded by the companies themselves and thus may lack the objectivity of reliable medical research. Editorial, *Sponsorship, Authorship, and Accountability*, 345 New Eng. J. Med. 825 (Sept. 13, 2001).

off-label uses that have not been reviewed by the FDA." *Ramirez*, 961 F. Supp. 2d at 992. "When the device is not being used in the manner the FDA preapproved and the manufacturer is actually promoting such use, there is no law or policy basis on which to pre-empt the application of state law designed to provide … protection" to patients. *Id.* at 991.

Device-specific requirements imposed via PMA apply to a device marketed for its approved use. Medtronic, when it acted affirmatively to subvert those requirements by marketing its device for a different use, acted outside the requirements imposed by the FDA. To hold otherwise would turn the law upside down and allow manufacturers to claim that, by telling them *not* to do something, the FDA has given them protection when they do it. Medtronic should not be permitted to "cite[] the existence of federal regulations it is allegedly circumventing to justify" preemption. *Id.*

Thus, the court of appeals erred by looking to the general holding of *Riegel*—that PMA may form the basis for preemption—without appreciating its factual premise: PMA is based on the FDA's determination, based on the information set forth in the PMA application for the stated "conditions of use," that the product "provides a reasonable assurance of safety and effectiveness." *Riegel*, 552 U.S. at 322. The MDA does not preempt state requirements "absent a specific federal requirement that reflects the FDA's weighing of competing considerations on the same subject and specific to the device." U.S. Br., *Medtronic v. Stengel*, No. 12-1351, *supra* n.1, at 11; *see Riegel*, 552 U.S. at 322 (federal labeling requirements that apply "across the board to almost all medical devices" generally do not preempt state requirements).

Here, Medtronic marketed its product for a use never evaluated by the FDA for safety and effectiveness and never determined by the FDA to provide a reasonable assurance of safety and effectiveness. *Riegel* no more applies to this situation than to the non-PMA device at issue in *Lohr* or to a device marketed with no approval at all.

Whether this situation is viewed as presenting an absence of relevant federal requirements or as presenting parallel federal requirements, § 360k(a) cannot rationally preempt Ms. Caplinger's state-law claims under this Court's precedents. Review should be granted to address this important issue of federal law.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

JAMES W. DOBBS
HOLLADAY & CHILTON, PLLC
204 N. Robinson
Suite 1550
Oklahoma City, OK 73102
405-236-2343

ALLISON M. ZIEVE
Counsel of Record
SCOTT L. NELSON
PUBLIC CITIZEN
LITIGATION GROUP
1600 20th Street NW
Washington, DC 20009
202-588-1000
azieve@citizen.org

Counsel for Petitioner

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