NO. 06-

IN THE
Supreme Court of the United States

CHARLES R. RIEGEL and DONNA S. RIEGEL,
Petitioners,

v.

MEDTRONIC, INC.,
Respondent.

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

PETITION FOR A WRIT OF CERTIORARI

WAYNE P. SMITH
157 Barrett Street
Schenectady, NY 12305
(518) 393-1371

ALLISON M. ZIEVE
Counsel of Record
BRIAN WOLFMAN
PUBLIC CITIZEN
LITIGATION GROUP
1600 20th Street, NW
Washington, DC 20009
(202) 588-1000

Counsel for Petitioners
Charles Riegel and Donna Riegel

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QUESTION PRESENTED

Whether the express preemption provision of the Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a), preempts state-law claims seeking damages for injuries caused by medical devices that received premarket approval from the Food and Drug Administration.

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INTRODUCTION

Nine years ago, this Court considered a petition for certiorari that raised the same question presented here: whether state-law damages claims concerning medical devices that received premarket approval ("PMA") from the Food and Drug Administration ("FDA") are preempted by the 1976 Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"). *See Smith Industries Medical Systems, Inc. v. Kernats*, No. 96-1405, *cert. denied*, 522 U.S. 1044 (1998). Responding to the Court's request for advice on the petition, the Solicitor General agreed with the plaintiffs-respondents that PMA does not preempt state-law damages claims. *See* Brief of the United States As Amicus Curiae in *Kernats* at 14-18 (filed Dec. 1997). Although for reasons inapplicable here the Solicitor General recommended against granting certiorari in that case, he noted that "[t]he current division among the lower courts . . . would normally provide a strong justification for this Court to grant review and definitively resolve the conflict." *Id.* at 18.[1]

Today, the division among the lower courts, and thus the need for this Court's guidance, is even more pronounced than when the Solicitor General noted the conflict in his brief in *Kernats*. Today, an injured patient can maintain suit against the manufacturer of a PMA device in the courts of the Eleventh Circuit, for example, but not of the Second Circuit, and in Illinois state courts, for example, but not in Illinois federal

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[1]The Solicitor General argued that the petition should be denied because the Court did not have jurisdiction to review the state appellate court decision (which was not final under 28 U.S.C. § 1257), because the appellate court's holding that PMA did not preempt damages claims was correct, and because of the pendency of a proposed FDA interpretive rule (later withdrawn) regarding preemption.

courts. In fact, three circuit courts have reviewed the same FDA approval with respect to the same medical device, made by the same company, and reached two opposite conclusions. *Compare Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999) (no preemption of state-law damages claims), *with Kemp v. Medtronic, Inc*., 231 F.3d 216 (6th Cir. 2000) (preemption), and *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001) (same). Because the courts' divergent analyses of the pre-emption question focus on the three opinions in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the conflict manifests not only a disagreement over the issue of PMA preemption, but also a disagreement about the obligation of lower courts to follow the holding of a majority opinion of this Court.

Adding to the confusion, the United States, in a letter brief filed in a Third Circuit case, *Horn v. Thoratec*, 376 F.3d 163 (3d Cir. 2004), reversed its position on preemption, making an argument that, by its own admission, contradicts the argument it made to this Court in *Kernats*. *See id*. at 177-78 (describing brief). The government's flip-flop heightens the already "strong justification for this Court to grant review and definitively resolve" the question presented.

In the past several years, this Court has denied review of petitions presenting substantially the same question presented here. *See*, *e.g.*, *Knisley v. Medtronic*, 126 S. Ct. 420 (2005) (denying *cert*.); *Martin v. Medtronic*, 534 U.S. 1078 (2002) (same); *Brooks v. Howmedica*, 535 U.S. 1056 (2002) (same); *Kemp v. Medtronic*, 534 U.S. 818 (2001) (same); *Surgidev Corp. v Niehoff*, 523 U.S. 1005 (1998) (same). For the most part, opponents of review suggested that the courts that found no preemption might change their minds or be overturned en banc. That has not happened. The decisions finding no pre-emption—including the Eleventh Circuit's 1999 decision in

Goodlin v. Medtronic 167 F.2d 1367, the Tenth Circuit's 1997 decision in *Oja v. Howmedica*, 111 F.3d 782, the Illinois Supreme Court's 1999 decision in *Weiland v. Telectronics Pacing Systems*, 721 N.E.2d 1149, and the Kentucky Supreme Court's 1997 decision in *Niehoff v. Surgidev*, 950 S.W.2d 816—remain the law in those jurisdictions. Accordingly, it is now clear that the deep division among the lower courts is firmly established and will not be resolved without this Court's intervention.

OPINIONS BELOW

The decision of the United States Court of Appeals for the Second Circuit is not yet reported in F.3d and is reproduced in the Appendix at 1a. The district court's March 14, 2003 decision granting Respondent's motion for summary judgment in part is unreported and is reproduced in the Appendix at 55a. The district court's December 2, 2003 decision granting Respondent's subsequent summary judgment motion on the remaining claims is also unreported and is reproduced in the Appendix at 75a.

JURISDICTION

The judgment of the court of appeals was entered on May 16, 2006. Pet. App. 1a. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTES AND REGULATIONS INVOLVED

21 U.S.C. § 360k provides 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 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. There are other State or local requirements that affect

> devices that are not preempted by section 521(a) of the act [21 U.S.C. § 360k(a)] because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:
>
> (1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices. . . .

STATEMENT OF THE CASE

This petition arises from a state-law damages suit by Charles and Donna Riegel to recover for injuries suffered by Mr. Riegel from a balloon catheter manufactured by respondent Medtronic, Inc. The court of appeals held that the MDA preempts the Riegels' claims.

Because an understanding of the structure of the MDA is important to understanding this case, Part A below offers a general description of the MDA. Part B describes the decision in *Medtronic v. Lohr*, in which the Court considered the scope of the MDA's preemption provision. Part C sets forth the facts of this case and the proceedings below.

A. The Medical Device Amendments

Congress enacted the MDA principally to increase consumer protection by preventing the distribution of dangerous medical devices and by providing a process through which devices could reach the market. H.R. Rep. 853, 94th Cong., 2d Sess. 1-12 (1976); *see* P.L. No. 94-295, 90 Stat. 539 (1976) (codified at 21 U.S.C. § 360c *et seq.*). Introducing the bill on the Senate floor, the bill's principal sponsor stated: "The legislation is written so that the benefit of the doubt is always given to the consumer. After all it is the consumer who pays with his health and his life for medical device malfunctions." 121 Cong. Rec. S6140 (Apr. 17, 1975) (Sen. Kennedy).

Under the MDA, each medical device falls into one of three classes. Class I devices, such as band-aids, are the least risky devices and are subject only to "general controls" applicable to all devices, such as general labeling requirements and good manufacturing practices rules promulgated by the FDA, the agency charged by Congress with implementing the MDA. *See* 21 U.S.C. § 360c(a)(1)(A).

Class II devices, such as hearing aids and tampons, are more likely than class I devices to cause harm if they are defective or misused. *Id.* § 360c(a)(1)(B). The FDA may therefore subject them to "special controls," such as the agency's specific warning language for tampon labeling. *See* 21 C.F.R. § 801.430(c), (d) & (e).

Class III devices—such as the devices at issue here and in *Lohr*—are those that, in general, cannot be marketed until the FDA has found that they present a reasonable assurance of safety and effectiveness. 21 U.S.C. § 360c(a)(1)(C). Marketing

permission granted through this process is known as pre-market approval, or PMA. *Id.* § 360e(b)(1)(A).[2]

Three components of the regulatory structure are relevant to this petition. First, when the FDA approves a manufacturer's PMA application, it does not conclude that the device is free of defect in design or labeling. The FDA does not generate the device's design or labeling, and it does not test or conduct studies of the device. Rather, a device's design and labeling originate with the device manufacturer, on whose data the FDA depends in acting on the PMA application. *See* 21 C.F.R. §§ 814.20, 814.44. When granting PMA, the FDA typically sends a form approval letter reminding the manufacturer of generally applicable obligations under federal regulations. There is nothing device-specific in the form approval letter. And although manufacturers of PMA devices must generally conform their products to the approved design and labeling that they devised, they may make design changes with FDA approval. *Id.* § 814.39(a). They may also make labeling changes to enhance safety, such as strengthening contra-indications and warnings, without pre-approval from the FDA. *Id.* §§ 814.39(d)(1) & (2).

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[2]If the FDA finds that a class III device is "substantially equivalent" to a device marketed prior to the MDA's effective date, or to a device that itself was found to be "substantially equivalent" to a pre-MDA device, that device need not obtain PMA until the FDA issues a regulation requiring PMA for that type of device. 21 U.S.C. §§ 360e(b)(1)(B), 360c(f)(1)(A). The FDA's process for giving marketing approval to such a device is sometimes referred to as the "510(k)" process, after the section of the FDCA under which the marketing request is submitted. *See Lohr*, 518 U.S. at 478.

Second, in a few instances, the FDA has issued device-specific requirements for particular types of devices. For instance, the FDA has issued design requirements for certain laser devices, *id*. § 886.4392, and absorbency testing requirements for tampons, *id.* §§ 801.420, 801.430(f). The FDA has never promulgated any such device-specific requirements for balloon catheters, such as the catheter that caused Mr. Riegel's injuries.

Third, the MDA contains a provision, 21 U.S.C. § 360k(a), that preempts certain state-law "requirements" "with respect to a device" that are "different from, or in addition to," MDA "requirements." Under section 360k(b), the FDA may exempt from preemption state requirements that would otherwise be preempted, and FDA regulations implementing this authority reflect section 360k(a)'s narrow reach. *See generally* 21 C.F.R. § 808.1; *see Lohr*, 518 U.S. at 498 n.18 ("FDA's narrow understanding of the scope of § 360k(a) is obvious from the full text of the regulation[.]"). For instance, FDA regulations provide that an FDA requirement has preemptive effect only when it establishes a device-specific "counterpart" to a "divergent" state-law requirement. 21 C.F.R. § 808.1(d). Likewise, to be preempted, state-law requirements must be "specific." Thus, preemption does not extend to state requirements of "general applicability where the purpose of the requirement relates . . . to other products in addition to devices." *Id.* § 808.1(d)(1).

Approximately 15 years after enactment of the MDA, device manufacturers began to argue that section 360k(a) preempts state damages actions. The legislative history of section 360k(a), however, refers solely to the potential for preemption of state and local laws and regulations. *See* H.R. Rep. No. 853 at 4, 45-46.

B. The Decision in *Medtronic v. Lohr*

In *Lohr*, plaintiff Lora Lohr and her husband Michael Lohr filed suit under Florida law for damages resulting from an allegedly defective class III pacemaker lead that the FDA had cleared for marketing under its section 510(k) "substantial equivalence" process. *See supra* note 2. This Court held that none of the Lohrs' claims—based on defective design, defective manufacture, and failure to warn—was preempted by the MDA.

1. *The Majority Opinion*. The majority opinion in *Medtronic* contains three holdings in which all members of the Court concurred: (1) The MDA does not broadly preempt all state-law damages claims against device manufacturers, *see Lohr*, 518 U.S. at 480 (majority); *id.* at 505 (Breyer, J., concurring in part and concurring in the judgment); *id.* at 513 (O'Connor, J., concurring in part and dissenting in part); (2) the Lohrs' design-defect claim was not preempted because the FDA had not issued any design specifications for the device in question, *id.* at 492-94 (majority); *id.* at 513 (O'Connor, J., concurring in part and dissenting in part); and (3) a tort claim premised on state-law duties "equal to, or substantially identical to, requirements" imposed under the MDA or FDA regulations is not preempted. *Id.* at 494-97; *id.* at 513 (O'Connor, J., concurring in part and dissenting in part).

By a 5-4 margin, in Part V of the *Lohr* majority opinion, the Court also held that the Lohrs' failure-to-warn and manufacturing-defect claims were not preempted, even if they did more than seek to enforce the federal requirements. The Court looked to the language of the MDA's preemption provision and the FDA's preemption regulations and noted the "overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal

interest." *Id.* at 500. The generality of the FDA's labeling and manufacturing regulations applicable to the pacemaker lead, the Court held, precluded a finding of preemption. 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.* at 501.

The Court further noted that the Lohrs' damages claims were premised on general state-law duties that did not focus specifically on medical devices. Thus, the Court found that the general state-law duties to use due care in manufacturing and to warn users of potential risks are not the types of requirements that Congress or the FDA feared would impede the FDA's ability to enforce specific federal laws and regulations. Because they were based on general principles of state law, the majority held, such claims were outside of the prohibited category of state-law requirements "with respect to" specific devices within the meaning of section 360k(a). *Id.* at 501-02.[3]

2. *The Concurrence*. Justice Breyer filed a concurring opinion stating that, in his view, section 360k(a)'s reference to state-law "requirements" encompasses state-law damages claims. He did not join Parts IV and VI of the lead opinion (*see supra* note 3) because he was not convinced that MDA

[3]Speaking for a four-Justice plurality, the lead opinion relied on the MDA's language and history to conclude that section 360k(a) was not intended to preempt most, and perhaps any, damages claims. 518 U.S. at 488-91. The plurality found it unnecessary to decide whether section 360k(a) reached any damages claims, however, because, under the majority's more focused analysis, none of the Lohrs' claims was preempted. *Id.* at 502-03.

preemption of damages claims would be "rare." *Id.* at 508. He joined fully, however, in Part V of the majority opinion, discussed immediately above, which demanded specificity on both the state and federal sides of section 360k(a)'s preemption analysis. He stated that the applicable FDA requirements that were related to the Lohrs' claims were not "specific" in any relevant sense and deferred to the FDA's preemption regulation, 21 C.F.R. § 808.1(d), which amplifies the meaning of section 360k(a)'s specificity requirement. 518 U.S. at 505-06. He noted that the language of section 360k(a) reflects principles of conflict preemption, but found no conflict between any federal requirement and any of the Lohrs' claims. *Id.* at 506.

3. *The Partial Dissent*. Justice O'Connor dissented in part and concurred in part, joined by Chief Justice Rehnquist and Justices Scalia and Thomas. In her view, state-law damages claims could constitute "requirements" under section 360k(a). *Id.* at 509-11. Although concurring with the majority that the Lohrs' design-defect claim was not preempted, she would have held that the manufacturing-defect and failure-to-warn claims were preempted to the extent that they sought to impose requirements different from those imposed by the FDA's manufacturing and labeling rules. *Id.* at 513-14. She agreed with the majority, however, that the Lohrs' manufacturing-defect and failure-to-warn claims were not preempted to the extent that they alleged violations of federal requirements. *Id.* at 513.

C. Factual Background and Proceedings Below

This action arose from serious injuries caused by a defective Medtronic balloon catheter. The catheter received marketing approval in 1994 as a supplement to a PMA first

issued in 1988. In 1995 and 1996, Medtronic sought and received approval to make design and labeling changes.

In May 1996, Charles Riegel underwent an angioplasty intended to dilate his coronary artery. His physician used the Medtronic catheter, which burst during the angioplasty. Mr. Riegel developed a complete heart block, and he lost consciousness and blood pressure. Advanced life support was needed to sustain him, and he was rushed to the operating room for emergency coronary bypass surgery. Pet. App. 4a.

The Riegels sued Medtronic, alleging design, labeling, and manufacturing defects and stating negligence, strict liability, and express and implied warranty claims. In January 2002, Medtronic moved for summary judgment based on preemption and to dismiss the express warranty claim for failure to state a claim. In March 2002, the district court granted the summary judgment motion in part, holding that all of the Riegels' claims are preempted except for those based on negligent manufacturing and express warranty. *See id*. at 55a. Following discovery, Medtronic moved for summary judgment on the two remaining claims; the district court granted the motion in a ruling no longer at issue. *Id*. at 75a.

The Riegels appealed the district court's decisions with respect to preemption and the manufacturing defect claim. In a 2-to-1 decision, the Second Circuit affirmed the district court. The majority held that PMA imposes device-specific preemptive "requirements" within the meaning of section 360k(a) and that the Riegels' design and labeling claims are sufficiently "device-specific" to warrant preemption. *Id*. at 25a, 30a. The majority suggested that jury verdicts put manufacturers of PMA devices in an untenable position because compliance with both federal requirements and jury verdicts

might be "impossible." *Id*. at 34a. The court did not attempt to reconcile that statement with the decades of jury verdicts in medical device cases or with this Court's recent decision in *Bates v. DowAgroSciences*, which noted that "an event, such as a jury verdict, that merely motivates an optional decision is not a requirement." 125 S. Ct. 1788, 1799 (2005); *see also Cipollone v. Liggett Group*, 505 U.S. 504, 518 (1992) ("[T]here is no general, inherent conflict between [express] federal preemption of state [regulatory] warning requirements and the continued vitality of state common-law damages actions."); *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 185-86 (1988) ("The effects of direct regulation . . . are significantly more intrusive than the incidental effects of such an award provision. . . . Congress may reasonably determine that incidental regulatory pressure is acceptable, whereas direct regulatory authority is not.").

Judge Pooler dissented from the panel's preemption decision. Explaining that express preemption is a question of congressional intent, she noted the complete lack of evidence that Congress intended to preempt damages claims. Pet. App. 46a. She further observed that the idea that damages claims are "unambiguously preempted is 'particularly dubious' considering that it appears that until relatively recently neither the industry nor the FDA thought that such claims were preempted." *Id*. at 46a (citing *Bates*, 125 S. Ct. at 1801). Judge Pooler explained that the majority opinion overlooked "two critical aspects of the preemption analysis: the presumption against preemption and congressional intent," *id*. at 43a, both of which "weigh against a finding of preemption." *Id.* She also observed that "the lack of any device-specific federal requirement [for balloon catheters] makes it impossible" to conduct "a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state

requirement to determine whether they fall within the intended pre-emptive scope of the statute and regulations." *Id*. at 50a (quoting *Lohr*, 518 U.S. at 500).

REASONS FOR GRANTING THE WRIT

A. The Federal And State Appellate Courts Are Deeply Divided Regarding The Application Of *Medtronic v. Lohr* To The Question Presented.

The decision and dissent below reflect the division among the federal and state appellate courts on the question presented: whether the FDA's grant of PMA for a medical device triggers preemption of state-law damages claims alleging that a manufacturer did not properly design the device and failed to warn of the device's risks. The split in authority is particularly problematic in Illinois, Kentucky, and Iowa, where, if the complaint is filed in or removed to federal court, the plaintiff's claims are expressly preempted, but if the complaint is litigated in state court, there is no preemption. *Compare Mitchell*, 126 F.3d 902 (7th Cir.), *Kemp*, 231 F.3d 216 (6th Cir.), *and Brooks v. Howmedica, Inc*., 273 F.3d 785 (8th Cir. 2001), *with Weiland*, 721 N.E.2d 1149 (Ill.), *Niehoff*, 950 S.W.2d 816 (Ky.), *and State ex rel Miller v. New Womyn, Inc.*, 679 N.W.2d 593 (Iowa 2004). Further displaying the division of views on the issue, the decision below and other recent appellate decisions finding preemption have provoked lengthy dissents. *See* Pet. App. 43a (Judge Pooler, dissenting from panel decision); *Horn*, 376 F.3d at 180 (in Third Circuit, Judge Fuentes, dissenting from panel decision); *Brooks v. Howmedica*, 273 F.3d at 799-801 (in Eighth Circuit, Judge Bye, joined by Judge Heaney, dissenting from en banc decision).

As noted above, *Lohr* requires that, before preemption may occur, both the allegedly preemptive federal requirement and the allegedly preempted state-law requirement must be "specific" within the meaning of section 360k(a) and regulations promulgated thereunder. *See* 21 C.F.R. § 808.1(d). As the decision below recognized, Pet App. 23a & n.16, conflicts among the federal and state appellate courts exist with respect to both prongs of *Lohr*'s analytic framework.

1. Looking first to the federal-law side of section 360k(a)'s preemption inquiry, *Lohr* held that, to have preemptive effect under 21 U.S.C. § 360k(a), a federal requirement must be specific. Thus, a specific labeling requirement for a particular type of device might have preemptive effect (*see, e.g.*, 21 C.F.R. § 801.430), in contrast to the comprehensive, but general labeling regulations that the Court held did not have preemptive effect. 518 U.S. at 497-99.

The FDA's criteria for PMA applications are general and do not require devices to be designed or labeled in any particular manner. Accordingly, several courts, including the Eleventh Circuit and the Illinois Supreme Court, have held that PMA does not impose device-specific requirements for purposes of preemption under section 360k(a). *See Goodlin*, 167 F.3d at 1373-77 (11th Cir.); *Weiland*, 721 N.E.2d at 1152-53 (Ill.); *Haidak v. Collagen Corp.*, 67 F. Supp. 2d 21, 23-24 (D. Mass. 1999); *Lakie v. SmithKline Beecham*, 965 F. Supp. 49 (D.D.C. 1997); *Quillen v. American Hosp. Supply Corp.*, 1997 U.S. Dist. Lexis 6974, *14-*15 (N.D. Okla. Mar. 31, 1997); *Sowell v. Bausch & Lomb*, 656 N.Y.S.2d 16, 20-21 (N.Y. App.

Div. 1997); *Walker v. Johnson & Johnson Vision Prods., Inc.*, 552 N.W. 2d 679, 684 (Mich. App. 1996).[4]

Other courts, including the Second Circuit below, have come to the opposite conclusion. *See*, *e.g.*, Pet. App. 25a; *Horn*, 376 F.3d at 169; *Worthy v. Collagen Corp.*, 967 S.W.2d 360, 376 (Tex. 1998), *cert. denied*, 524 U.S. 954 (1998); *Fry*, 695 A.2d at 516; *Green v. Dolsky*, 685 A.2d 110, 117 (Pa. 1996), *cert. denied*, 520 U.S. 1168 (1997); *Steele v. Collagen Corp.*, 63 Cal. Rptr. 2d 879, 887-88 (Cal. App. 1997).

2. The split in authority is also profound on the state-law side of *Lohr*'s preemption analysis. The Fifth Circuit, for example, has simply ignored *Lohr*'s holding that damages claims are not preempted if they are premised on general state-law duties that do not focus specifically on medical devices. *See Martin*, 254 F.3d at 582-83. Other post-*Lohr* courts that have found damages claims preempted have dealt with the issue more directly, acknowledging *Lohr*'s majority holding and

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[4]Similarly, two state supreme courts have held that state-law damages claims involving class III devices marketed under the MDA's investigational device approval process (*see* 21 U.S.C. § 360j(g))—which is often a precursor to the PMA process—are not preempted because that process does not establish specific requirements under *Lohr*. *See Connelly v. Iolab Corp.*, 927 S.W.2d 848 (Mo. 1996) (en banc), *cert. dismissed*, 520 U.S. 1260 (1997); *Niehoff v. Surgidev*, 950 S.W.2d at 822. *But see Martin v. Telectronics Pacing Sys., Inc.*, 105 F.3d 1090, 1095 (6th Cir. 1997) (investigational device process does establish preemptive federal requirements), *cert. denied*, 522 U.S. 1075 (1998). *See also Worthy*, 967 S.W.2d at 374 (noting conflict in appellate authority over preemptive effect of MDA's investigational device provisions and stating that PMA and investigational processes are comparable).

noting that it would, if applied in those cases, require a ruling in favor of the plaintiff. *See*, *e.g.*, *Papike v. Tambrands, Inc.*, 107 F.3d 737, 742 (9th Cir. 1997). However, those courts, including the Second Circuit below, have refused to follow this portion of the majority opinion on the ground that it is purportedly incompatible with Justice Breyer's concurrence. *See* Pet. App. 21 n.14 & 30-31; *Horn*, 376 F.3d at 174-75; *Papike*, 107 F.3d at 742; *Mitchell*, 126 F.3d at 912; *see also Steele*, 63 Cal. Rptr. at 887; *Fry*, 695 A.2d at 517.

These rulings are at odds with the decisions of other appellate courts that have held that this Court's majority opinion in *Lohr* meant what it said: State laws of general applicability are not among those laws targeted for preemption by section 360k(a). *See Oja v. Howmedica*, 111 F.3d 782, 789 (10th Cir. 1997) (notwithstanding existence of specific federal label requirement applicable to the device, no preemption of labeling claim because "Howmedica's general duty to warn users of potential dangers in this case does not have 'the effect of establishing a substantive requirement for a specific device'"); *State ex rel Miller*, 679 N.W.2d at 596 (no pre-emption of claim against device manufacturer brought under state consumer fraud statute because statute not limited to devices); *Niehoff*, 950 S.W.2d at 822 (no preemption because "Kentucky's strict liability case law and statutes [on which plaintiff relies] are laws of general applicability to all products and fall beyond the scope of the federal preemption under § 360k"); *Walker*, 552 N.W.2d at 686; *Mears v. Marshall*, 944 P.2d 984, 993-95 (Ore. App. 1997), *review denied*, 961 P.2d 217 (Ore. 1998); *Wutzke v. Schwagler*, 940 P.2d 1386, 1391-92 (Wash. App. 1997), *review denied*, 953 P.2d 96 (Wash. 1998); *Baird v. American Med. Optics*, 693 A.2d 904, 909-10 (N.J. Super., App. Div.), *modified and remanded,* 713 A.2d 1019 (N.J. 1997); *Kernats v. Smith Indus. Med. Sys.*, 669 N.E.2d

1300, 1309 (Ill. App.) ("[P]laintiffs' claims emanate from general common-law duties and are not the sort of state requirements that section 360k was intended to preempt."), *appeal denied*, 675 N.E.2d 634 (Ill. 1996), *cert. denied*, 522 U.S. 1044 (1998); *Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763, 771-72 (Cal. App. 1996), *review denied*, 1997 Cal. LEXIS 833 (Cal. 1997).

This Court should grant the petition to resolve these conflicts among the federal and state appellate courts.

3. Petitioners acknowledge that the decision below is consistent with the decisions of a majority of courts of appeals to have considered preemption of claims involving PMA devices. This point, however, does not lessen the need for this Court to resolve the persistent conflict. In fact, in a series of cases beginning in the early 1990s, this Court has disagreed with a majority of lower courts as to the effect of an express preemption provision on state-law damages claims. Most recently, in *Bates*, the Court rejected a pesticide manufacturer's sweeping preemption argument and the holdings of nine United States courts of appeals, based on a preemption provision "similarly worded" to section 360k(a). 125 S. Ct. at 1800. Likewise, in *Lohr*, the Court rejected the broad preemption holdings of a majority of the appellate courts that had considered the scope of express preemption under the MDA. *See* 518 U.S. at 492-502; *see also Sprietsma v. Mercury Marine,* 537 U.S. 51, 55 n.3, 63-64 (2002) (rejecting unanimous holdings of federal appellate courts on preemption under Boat Safety Act); *Geier v. American Honda Motor Co.*, 529 U.S. 861, 867-68 (2000) (rejecting holdings of a majority of federal appellate courts on express preemption under Motor Vehicle Safety Act); *Cipollone,* 505 U.S. 504 (rejecting broad preemption holdings of a majority of appellate courts and

finding only limited preemption of damages claims under Federal Cigarette Labeling and Advertising Act).

As these cases indicate, the lower courts have not gotten the message that express preemption provisions are to be narrowly construed. The courts' persistent failure to heed the principles set forth in this Court's recent preemption jurisprudence further demonstrates that the Court's guidance is urgently needed here.

B. The Second Circuit's Holding Cannot Be Reconciled With *Lohr*.

The decisions holding that PMA preempts damages claims are inconsistent with *Lohr* in three fundamental ways. First, the granting of PMA imposes no device-specific requirement triggering preemption of damages claims under section 360k(a). The PMA process is often more rigorous than the 510(k) marketing process at issue in *Lohr*, 518 U.S. at 478-79 (explaining differences), but it is no more "specific." Both processes apply to class III devices generally, and neither specifies how a product must be designed, manufactured, or labeled. As the Eleventh Circuit has explained, although the PMA process "differs in significant ways from the 510k process," the differences do not give rise to preemption under *Lohr*: "[B]ecause the [PMA] approval itself neither reveals nor imposes any ascertainable substantive prerequisite for approval that we could compare to a purportedly conflicting state requirement, the approval itself does not fit within section 360k(a)(1)'s demand for a specific federal requirement." *Goodlin*, 167 F.3d at 1374, 1376; *see id.* at 1376-77 (FDA's "conditions of [PMA] approval" are generic and thus not preemptive).

Thus, the PMA process embodies no rules similar to the FDA's device-specific labeling rules (*see*, *e.g.*, 21 C.F.R. § 801.420), or to the hypothetical FDA-required two-inch hearing aid wire discussed in Justice Breyer's *Lohr* concurrence. *Lohr*, 518 U.S. at 504. Moreover, the PMA process itself does not impose specific federal "requirements," as required by section 360k(a), 21 C.F.R. § 808.1(d), and *Lohr*, because the device's specifications originate with the manufacturer, not with the FDA. *Cf. American Airlines, Inc. v. Wolens*, 513 U.S. 219, 228-29 (1995) (preemption clause of Airline Deregulation Act does not shelter airlines from lawsuits "seeking recovery solely for the airline's alleged breach of its own, self-imposed undertakings").

Second, the decisions finding preemption of traditional damages claims involving PMA devices misapprehend *Lohr* because such claims are, without dispute, premised on state-law duties of general applicability. *See Lohr*, 518 U.S. at 501-02. The FDA's long-standing preemption regulation, 21 C.F.R. § 808.1, provides that section 360k(a) "does not preempt State or local requirements of general applicability where the purpose of the requirement relates . . . to other products in addition to devices." 21 C.F.R. § 808.1(d)(1). The FDA's regulation encompasses the Riegels' traditional state-law claims, which are based on generally applicable tort duties. Notably, although the panel majority recognized that *Lohr* "relied upon 21 C.F.R. § 808.1(d)," Pet. App. 19a n.11, the panel failed to consider or apply the regulation.

Third, the court below, like several other courts of appeals, have held that PMA preempts traditional damages claims only by disregarding the *Lohr* majority's analysis and focusing on Justice Breyer's concurrence. *See*, *e.g.*, Pet. App. 22a n.14 ("There is, undeniably, a certain degree of tension

between Justice Breyer's joining of Part V of the opinion and his separate concurrence. We resolve that tension in favor of the latter."); *Horn*, 376 F.3d at 174-76; *Mitchell*, 126 F.3d at 912. However, even assuming that Justice Breyer's concurrence represents *Lohr*'s holding, the holdings of those courts are inconsistent with the concurrence. Justice Breyer explained that a specific federal regulation demanding a two-inch hearing aid wire would preempt a common-law claim premised on a specific state-law requirement for a one-inch wire. *Lohr*, 518 U.S. at 504 (Breyer, J., concurring). Yet damages claims such as the Riegels', which are based on general state-law duties to design a safe product and to warn of its risks do not involve a specific state-law requirement of this kind. Moreover, they have no counterpart in specific federal requirements. Thus, such claims do not present the kind of direct conflict that concerned Justice Breyer.

More fundamentally, even if the concurrence could be read to favor preemption of generally applicable state-law duties, a lower court has no authority to disregard a majority holding of this Court. Federal courts of appeals are bound to adhere to the controlling decisions of the Supreme Court. *See Hutto v. Davis*, 454 U.S. 370, 375 (1982) ("[U]nless we wish anarchy to prevail within the federal judicial system, a precedent of this Court must be followed by the lower federal courts no matter how misguided the judges of those courts may think it to be."). A separate concurrence, regardless of its content, is not a basis for disregarding a majority opinion of the Supreme Court of the United States. *See Alexander v. Sandoval*, 532 U.S. 275, 285 n.5 (2001) (concurrence does not alter meaning of majority opinion); *Maryland v. Wilson*, 519 U.S. 408, 413 (1997) (concurring opinion does not establish precedent); *see also Agostini v. Felton*, 521 U.S. 203, 217 (1997) (case law not affected by views of five Justices in

concurring opinions). As the Tenth Circuit recognized in *Oja*, 111 F.3d at 788 n.3, the five-justice majority opinion is the binding precedent established in *Lohr*. The appellate courts' misapplication of rules of precedent underscores the need for review here.

C. The Decision Below Leaves Patients Injured By The Most Risky Devices With No Remedy—A Result Inconsistent With The History Of The MDA.

Review should also be granted because the Second Circuit's and other courts' misinterpretation of *Lohr* and section 360k(a) leaves consumers injured by PMA devices without any remedy in many parts of the country. Where, as here, the federal regulatory scheme does not itself provide a damages remedy, this Court has ascribed preemptive intent to Congress only in the most compelling circumstances. *See English v. General Elec. Co.*, 496 U.S. 72, 87-90 (1990); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984); *see also Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002) ("perfectly rational for Congress not to pre-empt common-law claims" when preempting state regulatory law because common-law claims "perform an important remedial role in compensating accident victims"). Such circumstances are not present here.

Congress, when enacting the MDA, made no mention of a desire to preempt common-law claims. Pet. App. 45a-46a (dissent); *see also Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984) ("Congress would [not], without comment, remove all means of judicial recourse for those injured by illegal conduct."). Congress' silence on this point is particularly telling because a major impetus for the MDA was the highly publicized injuries caused by the Dalkon Shield

intrauterine device, which resulted in "well-known, ongoing litigation." Pet. App. 45a (dissent); *Goodlin*, 167 F.3d at 1378 (citing *Lohr*, 518 U.S. at 475-77); *Lohr*, 518 U.S. at 491 (plurality) (Congress was "acutely aware of ongoing product liability litigation" regarding Dalkon Shield). In crafting the MDA, Congress focused on "regulat[ing] medical devices *before* they reached consumers, rather than on addressing their consequences once on the market." *Goodlin*, 167 F.3d at 1378 (emphasis in original). "It would have been inconsistent for the same Congress that enacted these sweeping reforms, intending to make a potentially dangerous industry safer for patients by blocking the admission of defective devices to the market, then to preempt product liability suits when those devices caused injury." *Id*.

Moreover, the notion that section 360k(a) unambiguously preempts state damages claims "is 'particularly dubious' considering it appears that until relatively recently neither the industry nor the FDA thought such claims were preempted." Pet. App. 46a (dissent) (quoting *Bates*, 125 S. Ct. at 1801). More specifically, in 1997, 20 years after enactment of the MDA, the FDA argued to this Court that claims such as the Riegels' were not preempted. *See supra* p.1; *Bates*, 125 S. Ct. at 1801 ("The notion that FIFRA contains a nonambiguous command to pre-empt the types of tort claims that parallel FIFRA's misbranding requirements is particularly dubious given that just five years ago the United States advocated the interpretation that we adopt today."). And the first reported decisions on the medical device industry's attempts to argue that section 360k(a) preempts product liability claims are from 1991, 15 years after enactment. Pet. App. 47a (dissent); *Goodlin*, 167 F.3d at 1381. The notion "that the industry would have ignored its immunity under the MDA for so long after the statute's enactment if Congress, in fact, had intended to provide

immunity in 1976" is far-fetched, *id.*, and further shows the Second Circuit's misunderstanding of the scope of section 360k(a).

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

Wayne P. Smith
157 Barrett Street
Schenectady, NY 12305
(518) 393-1371

Allison M. Zieve
Counsel of Record
Brian Wolfman
PUBLIC CITIZEN
LITIGATION GROUP
1600 20th Street, NW
Washington, DC 20009
(202) 588-1000

Counsel for Petitioners
Charles Riegel and Donna Riegel

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