NO. 04-

IN THE
Supreme Court of the United States

M. R. KNISLEY, *et al.*,

Petitioners,

v.

MEDTRONIC, INC.,

Respondent.

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

PETITION FOR A WRIT OF CERTIORARI

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June 2005

QUESTION PRESENTED

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

LIST OF PARTIES

PETITIONERS:
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Sarah Knisley
Floy Smith
Jules Barnett
Claire Barnett
Stephen Robbins,
on behalf of the Estate of Margaret Brooks
George Copeland,
as parent and guardian of Scott Copeland
Linda Copeland,
as parent and guardian of Scott Copeland
Theresa Dorsey
Diane Griffin
Thomas Griffin
John Parker
Reuben H. Kulp,
on behalf of himself and of the Estate of Mary Kulp
Thelma Carol Padgett
Jerry Bocock
Patricia Bocock
Donna Maggard
Kenneth Maggard
Richard Zinn
Barbara Shindelman
Lester Shindelman

RESPONDENT:
Medtronic, Inc.

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INTRODUCTION

In the years since the Court's decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the federal and state appellate courts have become deeply divided on the question presented here: whether state-law damages claims concerning medical devices that received premarket approval ("PMA") from the Food and Drug Administration ("FDA") under the 1976 Medical Device Amendments ("MDA") are preempted. 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 the Sixth Circuit, and in Illinois state courts, for example, but not in Illinois federal 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* Pet. App. 1a (preemption), and *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001) (same). The persistent conflict among the lower courts cries out for this Court's review.

Since *Lohr*, this Court has denied review of petitions presenting substantially the same question presented here. *See*, *e.g.*, *Martin v. Medtronic*, 534 U.S. 1078 (2002) (denying *cert.*); *Brooks v. Howmedica*, 535 U.S. 1056 (2002) (same); *Kemp v. Medtronic*, 534 U.S. 818 (2001) (same); *Worthy v. Collagen Corp.*, 524 U.S. 954 (1998) (same); *Surgidev Corp. v Niehoff*, 523 U.S. 1005 (1998) (same). For the most part, opponents of review suggested that the no-preemption decisions might somehow fade away or be overturned en banc. Now, however, nine years after the decision in *Lohr,* it is clear that the deep division among the lower courts will not be resolved without this Court's intervention.

Moreover, a significant number of appellate courts have erroneously reaffirmed broad pre-*Lohr* interpretations of the MDA's preemption provision, 21 U.S.C. § 360k(a). Like the Sixth Circuit, these courts have mistakenly held that the FDA's approval of a PMA application constitutes a specific preemption-triggering federal "requirement" under section 360k(a) and have failed to follow *Lohr*'s holding that claims based either on state-law duties of general applicability or state-law duties that parallel federal requirements are not preempted. *See Lohr*, 470 U.S. at 501-02. Several courts have done so by recasting Justice Breyer's concurring opinion in *Lohr* as the lead opinion and refusing to apply the majority's analysis, in which Justice Breyer himself joined. The Court should grant certiorari to correct this recurring misapplication of its precedent.

OPINIONS BELOW

The decision of the United States Court of Appeals for the Sixth Circuit is reported at 405 F.3d 421, and is reproduced in the Appendix at 1a. The district court decision granting Respondent's motion for summary judgment in part is unreported and is reproduced in the Appendix at 8a. The district court decision denying Petitioners' motion for reconsideration is unreported and is reproduced at 25a. The district court decision granting Respondent summary judgment is unreported and is reproduced at 30a.

JURISDICTION

The judgment of the court of appeals was entered on April 21, 2005. 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 case involves a suit to recover for injuries suffered by 14 individuals from pacemakers manufactured by respondent Medtronic, Inc. The court of appeals held that the MDA preempts Petitioners' 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.

The MDA's principal purpose was to increase consumer protection by preventing the distribution of dangerous medical devices and by providing a process by 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.*). Under the MDA, each medical device falls into one of three classes. In general, as health risks from a device increase, so does regulatory scrutiny under the MDA. H.R. Rep. 853 at 34; 21 U.S.C. § 360c(a).

Class I devices, such as band aids, are the least risky 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 id.* § 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 pacemaker leads at issue here and in *Lohr*—are those that, in general, cannot be marketed until the FDA has found that the device presents a reasonable assurance of safety and effectiveness. 21 U.S.C.

§ 360c(a)(1)(C). This process is known as pre-market approval, or PMA. *Id.* § 360e(b)(1)(A).[1]

Three components of the regulatory structure are relevant to this petition. First, when the FDA approves a manufacturer's PMA application, it does not warrant that the device is free of defect in design, manufacture, or labeling. The FDA does not generate or specify the device's design, manufacturing process, or labeling, and it does not test or conduct studies of the device. Rather, a device's design, manufacture, 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 its obligations under federal regulations. There is nothing device-specific in the form approval letter.

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

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[1]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 approving such devices is sometimes referred to as the "510(k)" process after the section of the Food, Drug, and Cosmetic Act under which the device application is submitted. *See Lohr*, 518 U.S. at 478.

requirements for tampons, *id.* § 801.420, 801.430(f). The FDA has never promulgated any such device-specific requirements for pacemakers or their component parts, such as the pacemaker lead that caused Petitioners' injuries.

Third, the MDA contains a preemption 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 21 U.S.C. § 360k(b), the FDA may exempt from preemption state requirements that would otherwise be preempted. Implementing this authority, the FDA has issued regulations reflecting section 360k(a)'s narrow reach. *See generally* 21 C.F.R. Part 808; *see Lohr*, 470 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 require that for an FDA requirement to have preemptive effect, it must establish 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).

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 510k "substantial equivalence" process. *See supra* note 1. 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*. Although there was a concurrence and a partial dissent in *Medtronic*, the majority opinion 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*, 470 U.S. at 480; *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; *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' manufacturing-defect and failure-to-warn 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 manufacturing and labeling 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.[2]

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 2) because he was not convinced that MDA 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

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[2]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 (distinguishing *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992)). 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.

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. 470 U.S. at 505-06. He noted that the language of section 360k(a) reflected basic 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 the Chief Justice and Justices Scalia and Thomas. In her view, state-law damages claims can 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 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.

1. This case arose from injuries caused by Medtronic's Model 4004 and 4004M pacemaker leads, among the worst performing leads ever marketed in the United States. A pacemaker lead is a wire that delivers a pacemaker's electrical impulse to the heart. Although the FDA granted PMA to the 4004 and 4004M leads, the FDA later discovered during an inspection that the probability of lead failure was high because a platinum coating intended to prevent degradation of the lead's polyurethane insulation failed to do so. *Goodlin,* 167 F.3d at

1368.[3] The FDA subsequently instructed Medtronic to issue a Health Safety Alert letter informing physicians about the pacemaker's flaw. *Id*. at 1369. In that letter, Medtronic told physicians "to consider whether prophylactic replacement would be appropriate, especially . . . [for] pacemaker-dependent patients." *Id*. The letter said that physicians should replace the pacemaker lead if "the risk of continued use outweigh[ed] the risk associated with implanting a new lead." *Id.*

Petitioners include 14 patients (including the estate of one who later died) who were implanted with 4004 and 4004M leads. Twelve later underwent additional heart surgeries to have their leads replaced, and two had theirs capped. In four separate lawsuits, these Petitioners, along with the spouses of seven of them (also Petitioners here), sued Medtronic in the Southern District of Ohio, alleging claims including strict liability, negligence, negligent misrepresentation, negligence per se, failure to warn, breach of warranty, and misrepresentation. The district court had subject matter jurisdiction based on diversity of citizenship under 28 U.S.C. § 1332(a)(1). The cases were consolidated for pretrial discovery with other cases involving injuries caused by the 4004M lead, and the cases were later stayed during the pendency of the Sixth Circuit's decision in *Kemp v. Medtronic*, 231 F.3d 216 (6th Cir. 2000).

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[3]The 4004 and 4004M leads were approved as "PMA supplements," which allowed Medtronic to change the design of a precursor PMA device, the 4003 lead. The "same procedures and actions" that apply to a PMA apply to a PMA supplement. 21 C.F.R. § 814.39(c). For present purposes, the distinction between approval of an original PMA and a PMA supplement are immaterial.

2. The decision in *Kemp* dictated the outcome of this case. Three aspects of that decision are pertinent here.

First, *Kemp* held that the FDA's approval of Medtronic's PMA application for the 4004M lead, coupled with the FDA's form approval letter, amounted to a specific preemption-triggering federal requirement within the meaning of 21 U.S.C. § 360k(a) and this Court's decision in *Lohr*. 231 F.3d at 226-27. In particular, it construed the FDA's approval of the 4004M PMA application as transforming the information regarding those topics contained in the application into a specific federal requirement. *Id*. at 228. The court thus held that a state-law damages claim based on a device's defective design or manufacture, or based on a claim that the device was accompanied by inadequate warnings, is preempted because of the perceived conflict between the purported federal requirement and the state-law damages claims. The court acknowledged that its holding was flatly at odds with the Eleventh Circuit's decision in *Goodlin*, 167 F.3d 1367, which also involved the 4004M lead and which held that the FDA's premarket approval does not trigger preemption under section 360k(a). 231 F.3d at 225 (noting that *Goodlin* "addressed this exact issue on largely indistinguishable facts"). In reaching its conclusion, the Sixth Circuit did not mention the *Lohr* majority's holding that state-law duties of general applicability, such as those typically relied on in state-law damages claims, are not preempted by section 360k(a). *See Lohr*, 470 U.S. at 501-02.

Second, the court of appeals provided additional explanation for its holding that the Kemps' failure-to-warn claim was preempted by the MDA. The court stated that, because the plaintiffs alleged that Medtronic failed to warn of the malfunctions of the 4004M's insulation prior to Mrs.

Kemp's injuries, "the claim was premised on the [in]adequacy of the warnings reviewed and approved by the FDA." 231 F.3d at 236. Thus, in the Sixth Circuit's view, this claim was preempted because it would impose a requirement different from that imposed by the FDA. In this regard, the court did not address, or even cite, the FDA regulation permitting a manufacturer to make label changes and provide additional warnings to enhance safety of PMA devices without prior FDA approval. *See* 21 C.F.R. § 814.39(d)(1) & (2) (cited as support for majority holding in *Lohr*, 470 U.S. at 497 n.16).

Third, the Sixth Circuit held that the plaintiffs' negligence per se claim was preempted. That claim was based on plaintiffs' assertion that the FDA required a platinum coating of a specific uniform thickness. Because the Sixth Circuit found that the FDA had not imposed such a requirement, it held that the plaintiffs' claim would impose a requirement "different from and in addition to" the federal requirements for the device. *Kemp*, 231 F.3d at 230-32.

3. After the Sixth Circuit decided *Kemp*, Medtronic moved for summary judgment in each of Petitioners' cases. Petitioners sought to amend their complaints to allege causes of action that would be viable under *Kemp*'s analysis—claims such as (1) post-sale failure to warn, (2) post-sale failure-to-recall, (3) failure to comply with federal requirements that mirrored state requirements; and (4) negligence per se in failing to comply with the FDA's conditions of approval. The amended complaints also included causes of action for strict liability, negligence, and breach of warranty. The district court held that all claims except for (3), above, are preempted. Pet. App. 24a.

The district court gave Petitioners 10 days in which to amend their complaints to include only the one claim that it did not find preempted. The court then consolidated the cases for all purposes under *Cupek v. Medtronic*.[4] Instead of filing a new complaint, Petitioners moved for reconsideration. While that motion was pending, the parties jointly requested a stay pending settlement discussions. After the stay was lifted, the court denied the motion for reconsideration and, then, citing the passage of time since the court's initial order granting leave to amend, denied Petitioners' request for leave to amend their complaint. *Id*. 25a. The court then granted summary judgment to Medtronic. *Id*. 30a.

Relying largely on *Kemp*, the Sixth Circuit affirmed. *Id*. 5a-7a. Further, the court rejected Petitioners' request that the court of appeals revisit *Kemp*. *Id*. 7a.

REASONS FOR GRANTING THE WRIT

Eight years ago, this Court considered a petition for certiorari that raised the same question presented here. *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 in the case that PMA does not preempt state-law damages claims. *See* Brief of the United States As Amicus Curiae in *Kernats* 14-18 (filed Dec. 1997). Although the Solicitor General recommended against granting certiorari in that case—for reasons inapplicable here—he noted that "[t]he

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[4]The case was named for Ethel Cupek, the first-named plaintiff in one of the four original cases, although she was voluntarily dismissed from the case in September 1998.

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.[5]

Since the Solicitor General's filing in *Kernats*, the division among the lower courts, and thus the need for this Court's guidance, has become even more pronounced. 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 the government's position, 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 definitely resolve" the question presented.

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

The decision below reflects the division among the federal and state appellate courts on the issue that was determinative in the court below: 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

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[5]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 lower 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.

design and manufacture the device and failed to warn of the device's risks. Some courts, such as the Eleventh Circuit, have held that PMA does not trigger preemption under section 360k(a) and that, therefore, state-law damages actions alleging injuries caused by PMA devices are not preempted. Other courts, such as the Sixth Circuit, have held that PMA does trigger preemption. *Compare, e.g., Goodlin v. Medtronic*, 167 F.3d 1367 (11th Cir. 1999) (no preemption); *Weiland v. Telectronics Pacing Sys., Inc.*, 721 N.E.2d 1149 (Ill. 1999) (same), *with, e.g., Horn v. Thoratec*, 376 F.3d 163 (3d Cir. 2004) (preemption); *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000) (same); *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997) (same), *cert. denied*, 523 U.S. 1020 (1998); *Fry v. Allergan Medical Optics*, 695 A.2d 511 (R.I.) (same), *cert. denied*, 522 U.S. 952 (1997) .

Moreover, 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). Among the federal and state appellate courts, however, conflicts 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, good manufacturing and labeling regulations that the Court held did not have preemptive effect. 470 U.S. at 497-99.

The FDA's criteria for PMA applications are general and do not require devices to be designed, manufactured, or labeled in any particular manner. Accordingly, several courts have held that the PMA process does not constitute a device-specific requirement for purposes of preemption under section 360k(a). *See Goodlin*, 167 F.3d at 1373-77; *Weiland*, 721 N.E.2d at 1152-53; *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); *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).

Several other courts have come to the opposite conclusion. *See*, *e.g.*, *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).[6]

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[6]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 816, 822 (Ky. 1997). *But see Martin v. Telectronics Pacing Sys., Inc.*, 105 F.3d 1090, 1095 (6th Cir. 1997), *cert.*

(continued...)

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 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). Those courts have not followed this portion of the majority opinion, however, on the ground that it is purportedly incompatible with Justice Breyer's concurrence. *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 meant what it said in *Lohr*: 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)*; State ex rel Miller v. New Womyn, Inc.*, 679 N.W.2d 593, 596 (Iowa 2004) (no preemption of claim against device manufacturer brought under state consumer fraud statute because statute not limited

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[6](...continued)
denied, 522 U.S. 1075 (1998) (investigational device process does establish preemptive federal requirements). *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).

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 (same); *Mears v. Marshall*, 944 P.2d 984, 993-95 (Ore. App. 1997) (same), *review denied*, 961 P.2d 217 (Ore. 1998); *Wutzke v. Schwagler*, 940 P.2d 1386, 1391-92 (Wash. App. 1997) (same), *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) (same), *review denied*, 1997 Cal. Lexis 833 (Cal. 1997).

For instance, in *Oja*, the plaintiff claimed that the defendant had failed to warn her about problems with a hip replacement device. The Tenth Circuit agreed with the defendant that there was at least one specific FDA-mandated warning that constituted a federal device "requirement" within the meaning of section 360k(a), but held that the plaintiff's failure-to-warn claim was not preempted because it was not based on a law relating specifically to medical devices:

> Like the failure to warn claim at issue in *Medtronic*, the general state common law requirements imposed by Oja's negligent failure to warn claim were not specifically developed "with respect to" medical devices. Instead,

> Oja's negligent failure to warn claim is predicated upon a general duty applicable to every manufacturer "to inform users and purchasers of potentially dangerous items of the risks involved in their use."

111 F.3d at 789 (quoting *Lohr*, 470 U.S. at 501) (internal citations omitted).

This Court should grant the petition to resolve these conflicts among the federal and state appellate courts.[7]

B. The Sixth Circuit's Holdings Cannot Be Reconciled With *Lohr*.

Review should also be granted because the Sixth Circuit's and other appellate courts' misinterpretation of *Lohr* leaves consumers injured by PMA devices without a damages remedy in many parts of the country. The decisions holding that PMA preempts damages claims err in three fundamental ways.

First, the granting of PMA imposes no device-specific requirement triggering preemption of damages claims under section 360k(a). Although the PMA process is often more

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[7]The split in authority is particularly problematic in Illinois and Kentucky, where, if the complaint is filed in or removed to federal court, the plaintiff's claims are preempted, *see Mitchell*, 126 F.3d 902 (7th Cir.); Pet. App. 1a; *Kemp*, 231 F.3d 216 (6th Cir.), but if the complaint is litigated in state court, there is no preemption. *See Weiland*, 721 N.E.2d 1149 (Ill.); *Niehoff*, 950 S.W.2d 816 (Ky.).

rigorous than the marketing process at issue in *Lohr*, 518 U.S. at 478-79 (explaining differences), 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 at issue" in *Lohr*, the result regarding preemption is the same: "[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 also not preemptive).

Thus, the PMA process contains 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*, 470 U.S. at 504. Moreover, the PMA process itself does not impose specific federal "requirements" 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*, 470 U.S. at 501-02. Of particular importance, the court of appeals did not mention,

in either the decision below or the *Kemp* decision, the FDA's longstanding preemption regulation, 21 C.F.R. § 808.1, although that regulation is directly applicable here. Section 808.1, which was accorded substantial weight in *Lohr*, 470 U.S. at 496; *see id.* at 505-06 (Breyer, J., concurring), provides that section 360k(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 Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices . . . ." 21 C.F.R. § 808.1(d)(1). The FDA's regulation encompasses Petitioners' traditional state-law claims.

Third, many of the 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.*, *Horn*, 376 F.3d at 174-76; *Mitchell*, 126 F.3d at 912. Yet the holdings of those courts are in fact 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*, 470 U.S. at 504 (Breyer, J., concurring). Petitioners' state-law damages claims, however, based on general state-law duties to properly design and manufacture a product and to warn of its risks, do not involve a specific state-law requirement of this kind, and thus their claims do not present the kind of direct conflict that concerned Justice Breyer.

In any event, even if the concurrence offered a different analytical approach to assessing the scope of section 360k(a), a lower court has no warrant to disregard a majority holding of this Court. Federal circuit courts are bound to adhere to the

controlling decisions of the Supreme Court. *Hutto v. Davis*, 454 U.S. 370, 375 (1982). As Justice Rehnquist has stated: "[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." *Id.; see also Thurston Motor Lines v. Jordan K. Rand, Ltd.*, 460 U.S. 533, 535 (1983) ("Needless to say, only this Court may overrule one of its precedents."). Under basic principles of stare decisis, 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).

By elevating Justice Breyer's concurrence above the majority opinion, decisions such as *Horn*, *Mitchell*, and the cases cited *supra* at p. 17, flout the Court's instruction concerning the weight to be given to concurring opinions, and indeed with the hierarchy of our federal court system. To take one of the more glaring examples, in *Horn*, the majority opinion conceded that the plaintiff's state-law claims were based on "general requirements stemming from state common law," 376 F.3d at 173, that "are not specific 'with respect to'" the particular model of heart pump at issue or even heart pumps generally. *Id*. at 174. Further, it recognized that the *Lohr* plaintiffs had sued "for essentially the same claims Horn has brought," *id*., and that "*Lohr* concluded that these claims 'escape[] pre-emption, not because the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that

§ 360k envisioned to be "with respect to" specific devices such as pacemakers.'" *Id*. (quoting *Lohr*, 518 U.S. at 502).

Nonetheless, the *Horn* majority declined to follow the majority opinion of the Court in *Lohr* because it read Justice Breyer's concurrence to mean something different from the majority's holding. *Id*. In fact, the Third Circuit went so far as to say that Justice Breyer's concurrence effectively negates the fact that he expressly joined in this aspect of the majority holding. *Id*. It then recast Justice Breyer's vote in *Lohr* to transform the four-Justice dissent into a five-Justice majority on this point. *Id*. at 176. Indeed, the opinion repeatedly refers to the holdings of the *Lohr* **majority** as the statements of a **plurality**. *See*, *e.g.*, *id*. at 174, 175, 176; *see also id.* at 184 (Fuentes, J., dissenting) (highlighting error of majority's approach). Although Justice Breyer provided the "fifth vote" for the holding that state-law claims based on duties of general applicability are outside the scope of preemption, the *Horn* majority declared that vote a nullity: "This was not a principle that received Justice Breyer's agreement." *Id*. at 175.

Because Justice Breyer joined in the holding of *Lohr*, thereby forming a majority, the Third, Seventh, and Ninth Circuits, in *Horn*, *Mitchell*, and *Papike*, have overstepped their authority and "ignored, consciously or unconsciously, the hierarchy of the federal court system created by the Constitution and Congress." *Hutto*, 454 U.S. at 375. 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 petition should be granted for this reason as well.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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