No. 06-179

IN THE
Supreme Court of the United States

CHARLES R. RIEGEL and DONNA S. RIEGEL,
Petitioners,
v.
MEDTRONIC, INC.,
Respondent.

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

BRIEF FOR PETITIONERS

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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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Geier v. American Honda Motor Co.,
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43 Fed. Reg. 18661 (1978) 25, 33

45 Fed. Reg. 67321 (1980) 25

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R. Adler & R. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895 (1994) 16

Boston Scientific, *Boston Scientific to Recall Additional Coronary Stent Systems* (July 16, 2004), *available at* www.fda.gov/cdrh/recalls/recall-071604-pressrelease.html 6

FDA, *FY 2004 Annual Performance Plan* (Jan. 2003), www.fda.gov/ope/fy04plan/2004pp-cdrh.html 5

FDA, *Learn About Medical Devices* (Dec. 19, 2005), www.fda.gov/cdrh/recalls/learn.html#2 6

GAO, *Medical Device Reporting: Improvements Needed in FDA's System for Monitoring Problems With Approved Devices* (Jan. 1997), *available at* www.fda.gov/cdrh/hes9721.pdf 5

P. Hutt, R. Merrill, & L. Grossman, *Food and Drug Law* (3d ed. 2007) 22

B. Meier, *Citing Flaws, Maker Recalls Heart Devices*, N.Y. Times, June 18, 2005 44

86 N.Y. Jur. 2d, Products Liability (2007) 41

Restatement (Third) of Torts: Products Liability (1988) . . 26

St. Jude Medical, *Silzone Coating Advisory* (2007), www.sjm.com/devices/silzoneadvisory.aspx?name=SJM+Regent%26%23174%3B+Valve&location= in&type=18&section=overview 6

World Health Organization, *Medical Device Regulations*: *Global Overview and Guiding Principles* (2003), *available at* www.who.int/medicaldevices/publications/en/MD_Regulations.pdf 5

INTRODUCTION

In *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), Medtronic argued that the Medical Device Amendments of 1976 preempt all damages claims brought by injured patients against medical device manufacturers. This Court unanimously rejected that argument, which four members of the Court described as "not only unpersuasive," but "implausible." *Id*. at 487. Here, Medtronic renews its argument, now limiting it to devices that received premarket approval ("PMA") from the Food and Drug Administration ("FDA"). Under the language of the statute, the FDA's implementing regulations, and *Lohr*'s authoritative construction of 21 U.S.C. § 360k(a), however, that limitation cannot salvage Medtronic's argument. Medtronic's plea for immunity from liability for injuries caused by the most dangerous medical devices should, once again, be rejected.

JURISDICTION

The judgment of the court of appeals was entered on May 16, 2006. Pet. App. 1a. The petition for a writ of certiorari was filed on August 3, 2006, and was granted on June 25, 2007. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTES AND REGULATIONS INVOLVED

The principal statutory and regulatory provisions involved in this case are reproduced in the appendix to this brief.

STATEMENT OF THE CASE

Under federal law, the term "medical device" includes a wide array of products, ranging from common household items such as bandages and toothbrushes, to prosthetic devices such as hip and knee replacements, to cardiac devices such as artificial heart valves and pacemakers. *See* 21 U.S.C. § 321(h). Before 1976, medical devices were largely unregulated. Although for many years the FDA had authority to allow or prevent the entry of new drugs onto the market, the agency lacked such authority over medical devices. *See* H.R. Rep. No.

94-853, at 8-10 (1976); *id*. at 11 (a "serious drawback of the existing authority is that FDA cannot act against a hazardous medical device until after it is on the market"). As a result, the FDA was expending significant resources to seize or enjoin marketing of dangerous devices that never should have been marketed in the first place. *Id*. at 7-8.

By the mid-1970s, the dangers of this regulatory gap were made clear by a series of public health hazards caused by medical devices. Most notably, the defectively designed Dalkon Shield intrauterine device, which had entered the market without prior regulatory scrutiny, had caused many deaths and thousands of serious injuries. *See id.* at 8; S. Rep. No. 94-33, at 1-2, 6-7 (1976), *reprinted in* 1976 U.S.C.C.A.N. 1070-72, 1075-76. The House and Senate reports also recount the hundreds of deaths and injuries caused by heart valves and pacemakers, and severe eye injuries caused by intraocular lenses. H.R. Rep. No. 94-853, at 9; S. Rep. No. 94-33, at 6.

A. The Medical Device Amendments

In response to the harm caused by medical devices, Congress enacted the Medical Device Amendments of 1976 ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"). Pub. L. No. 94-295, 90 Stat. 539 (1976) (chiefly codified at 21 U.S.C. § 360c *et seq*.). The primary purpose of the new law was "to protect the public health" by preventing the distribution of dangerous devices. *See* H.R. Conf. Rep. No. 94-1090, at 1 (1976); H.R. Rep. No. 94-853, at 6-12. Introducing the MDA on the Senate floor, the bill's principal sponsor, Senator Edward Kennedy, 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).

Under the MDA, each medical device falls into one of three classes. Class I devices, such as bandages, 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. *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 promulgate regulations subjecting them to "special controls," such as the agency's specific absorbency testing requirements for tampons and 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*—include life-supporting or life-sustaining devices and devices that pose the greatest risk of serious injury. 21 U.S.C. § 360c(a)(1)(C). In general, class III devices cannot be marketed until the FDA has found a "reasonable assurance" that they are safe and effective. *Id*. Marketing permission granted through this process is called premarket approval, or PMA. *Id.* § 360e(b)(1).

With respect to class III devices already on the market in 1976 when the statute was enacted, the MDA did not require immediate PMA. Rather, such a device can be marketed without PMA until the FDA issues a regulation calling for PMA for that type of device. *Id*. § 360e(b). Likewise, 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. *Id*. §§ 360e(b)(1)(B), 360c(f)(1)(A). The process for giving marketing approval to substantially equivalent devices is sometimes referred to as the "510(k)" process, after the section of the FDCA under which the marketing request is submitted.

Although devices marketed prior to enactment of the MDA are sometimes referred to as having been "grandfathered," the MDA *requires* the FDA to issue regulations calling for PMA

for these older class III devices. *Id*. § 360e(b)(1) ("[T]he Secretary *shall* by regulation . . . require that such device have an approval . . . .") (emphasis added); H.R. Rep. No. 94-853, at 31 ("The requirement to have an approved application for premarket approval with respect to these 'old' devices is subject to provisions delaying the requirement for a statutory period."). Thus, the MDA demands that all class III devices eventually be PMA devices—that is, that no class III devices will be marketed without FDA approval. Because after 14 years the FDA still had not called for PMA for many pre-1976 class III devices, Congress reiterated this requirement in 1990 amendments to the MDA. *See* H.R. Rep. No. 101-808, at 26 (1990), *reprinted in* 1990 U.S.C.C.A.N. 6307, 6319 ("The Committee has serious concerns about FDA's failure to issue regulations under section 515(b) calling for submission of safety and effectiveness data on the great majority of pre-Amendment class III devices and their post-Amendment substantial equivalents.").[1]

Significantly, the FDA does not design PMA devices or draft the labeling, and it does not test or conduct studies of devices. Rather, a device's design and labeling originate with the manufacturer, on whose data the FDA depends when it reviews the PMA application. *See* 21 C.F.R. §§ 814.20, 814.44.

When granting PMA, the FDA typically sends the manufacturer a form approval letter reminding the manufacturer of generally applicable obligations under federal

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[1]The Safe Medical Devices Act of 1990, Pub. L. No. 101-629 (1990) ("SMDA"), required the FDA to issue, before December 1, 1995, a regulation for each grandfathered or 510(k) device, either designating the device as a class I or class II device, or requiring the device to remain in class III. For each device that remained in class III, the SMDA required the FDA to call for PMA applications within 12 months of the regulation requiring that the device remain in class III. 21 U.S.C. § 360e(i). The FDA did not meet these deadlines.

regulations. *See*, *e.g.*, JA 9. Little in the form letter is device-specific. The FDA may establish specific performance standards as a condition of granting PMA, 21 C.F.R. § 861.1(b)(3), but it rarely does so. 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 by submitting a "PMA supplement." *Id*. § 814.39(a). They may also make labeling changes to enhance safety, such as strengthening contraindications and warnings, even before obtaining approval from the FDA. *Id*. §§ 814.39(d)(1) & (2).

If the FDA finds that a PMA application satisfies the "reasonable assurance" standard, 21 U.S.C. § 360c(a)(1)(C), the FDA will grant PMA even if a better, safer product is already on the market. In addition, once approved, a device can be marketed indefinitely. That is, PMAs do not expire, and there is no periodic review process. The MDA calls for manufacturers and user facilities (such as hospitals) to submit to the FDA reports of adverse events associated with their devices. 21 C.F.R. Part 803. However, the "FDA does not systematically act to ensure that the reported problems receive prompt attention and appropriate resolution. As a result, FDA's adverse event reporting system is not providing an early warning about problem medical devices." GAO, *Medical Device Reporting: Improvements Needed in FDA's System for Monitoring Problems With Approved Devices* 2 (Jan. 1997), *available at* www.fda.gov/cdrh/hes9721.pdf. The FDA itself has characterized its post-marketing surveillance system for medical devices as "not working well." FDA, *FY 2004 Annual Performance Plan* 2.6.1 (Jan. 2003), www.fda.gov/ope/fy04 plan/2004pp-cdrh.html.

"No amount of rigour in the pre-marketing review process can predict all possible device failures or incidents arising from device misuse. It is through actual use that unforeseen problems related to safety and performance can occur." World Health Organization, *Medical Device Regulations: Global*

Overview and Guiding Principles 13 (2003), *available at* www.who.int/medical_devices/publications/en/MD_Regulations.pdf. In recognition of this reality, the MDA gives the FDA authority to withdraw approval and, pursuant to amendments passed in 1992, to recall devices. 21 U.S.C. §§ 360e(e), 360h(e). However, the FDA rarely, if ever, invokes this authority, preferring instead to rely on market forces, the tort system, or the threat of agency action to prompt voluntary recalls. *See* FDA, *Learn About Medical Devices* (Dec. 19, 2005), www.fda.gov/cdrh/recalls/learn.html#2 ("Legally, FDA can require a company to recall a device. This could happen if a company refuses to recall a device that is associated with significant health problems or death. However, in practice, FDA has rarely needed to require a medical device recall.").[2]

B. State Regulatory Activity And Preemption Under The MDA

When drafting the MDA, Congress was informed of state regulatory programs that had stepped into the federal regulatory vacuum. Most notably, a California statute required that medical devices undergo premarket approval before commercial distribution in the state and that they comply with state good manufacturing practices regulations. *See* H.R. Rep.

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[2]*See*, *e.g.*, Boston Scientific, *Boston Scientific to Recall Additional Coronary Stent Systems*, July 16, 2004, *available at* www.fda.gov/cdrh/recalls/recall-071604-pressrelease.html (voluntary recall due to design defect in PMA balloon catheter); St. Jude Medical, *Silzone Coating Advisory* (2007), www.sjm.com/devices/silzoneadvisory.aspx?name=SJM+Regent%26%23174%3B+Valve&location=in&type=18&section=overview (January 2000 voluntary recall of defective PMA heart valve replacement and repair products that used Silzone coating); *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1320-21 (3d Cir. 1995) (company voluntarily recalled PMA heart valve, several years after device started to fracture and cause patient death; FDA withdrew approval only after company requested that it do so).

No. 94-853, at 45. To prevent a "substantial number of differing requirements applicable to a medical device," *id*., Congress crafted a provision, 21 U.S.C. § 360k, to address such state regulatory programs.

Section 360k has two parts. Section 360k(a) preempts certain state-law "requirements" "with respect to a device" that are "different from, or in addition to," MDA "requirements." *See infra* 1a. Under § 360k(b), the FDA may exempt from preemption state requirements that would otherwise be pre-empted. *Id*.

FDA regulations implementing § 360k(b) reflect the narrow reach of § 360k(a). *See* 21 C.F.R. §§ 808.1, 808.20, *reprinted infra* 3a-8a; *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 . . . ."). The regulations state, 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.

21 C.F.R. § 808.1(d). In addition, under the regulations' reading of § 360k(a), preemption does not extend to a state requirement of "general applicability where the purpose of the requirement relates . . . to other products in addition to devices." *Id.* § 808.1(d)(1).

More than 10 years after enactment of the MDA, device manufacturers began to argue that § 360k(a) expressly preempts state-law damages actions. The legislative history of § 360k(a), however, refers solely to the potential for preemption of state and local laws and regulations. *See* H.R. Rep. No. 94-853, at 4, 45-46. Damages actions are mentioned elsewhere in the

legislative record to show the extent of the harm caused by the Dalkon Shield, and without any suggestion that Congress was concerned about the lawsuits themselves. *Id*. at 8.

C. The Decision In *Medtronic v. Lohr*

In *Medtronic, Inc. v. Lohr*, 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 § 510(k) "substantial equivalence" process. This Court held that none of the Lohrs' state-law damages claims—based on defective design, defective manufacture, and failure to warn—was preempted by the MDA.

1. *The Majority Opinion*. All members of the Court concurred in three holdings of the *Lohr* majority opinion: (1) The MDA does not broadly preempt all state-law damages claims against device manufacturers, *see* 518 U.S. at 480 (majority); *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 by the MDA, or FDA regulations implementing the MDA, is not preempted. *Id.* at 494-97 (majority); *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 federal standards. 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 federal labeling and

manufacturing regulations applicable to the pacemaker lead, the Court held, precluded a finding of preemption. Those regulations, 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 explained in Part V that the Lohrs' damages claims were premised on general state-law duties that did not focus specifically on medical devices, and that they were not preempted for that reason as well. The Court found that 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. Therefore, the majority held, claims based on these duties are outside the prohibited category of state-law requirements "with respect to" specific devices within the meaning of § 360k(a). *Id.* at 501-02.

In addition, speaking for a four-Justice plurality, Parts IV and VI of the lead opinion relied on the MDA's language and history to conclude that § 360k(a) was not intended to preempt most, and perhaps any, damages claims. *Id*. at 488-91. The plurality found it unnecessary to decide whether § 360k(a) reached any damages claims, however, because, under the majority's analysis, none of the Lohrs' claims was preempted. *Id.* at 502-03.

2. *The Concurrence*. Justice Breyer filed a concurring opinion stating that, in his view, § 360k(a)'s reference to state-law "requirements" encompasses some state-law damages claims. He did not join Parts IV and VI of the lead opinion 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, which demanded

specificity on both the state and federal sides of § 360k(a)'s preemption analysis. He looked to the FDA's preemption regulation, 21 C.F.R. § 808.1(d), which amplifies the meaning of § 360k(a), and stated that, "[i]nsofar as there [were] any applicable FDA requirements" at issue, they were not "'specific' in any relevant sense." 518 U.S. at 505-07. He stated that the language of § 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 concurred in part and dissented in part, joined by Chief Justice Rehnquist and Justices Scalia and Thomas. In her view, state-law damages claims could constitute "requirements" under § 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 in part because, in her view, 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 failure-to-warn and manufacturing-defect claims were not preempted to the extent that they alleged violations of federal requirements. *Id.* at 513.

D. Factual Background And Proceedings Below

This action arose from serious injuries caused by a defective Medtronic percutaneous transluminal coronary angioplasty ("PTCA") catheter. The model at issue 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. Medtronic no longer manufactures the product.

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 lost conscious-

ness and blood pressure. He needed advanced life support and emergency coronary bypass surgery. Pet. App. 4a.

The Riegels sued Medtronic, alleging design and manufacturing defects and inadequate warning, and stating negligence, strict liability, breach of warranty, and loss of consortium claims. The design-defect claim alleges that the product was not designed adequately to function as intended and was unreasonably dangerous. The inadequate warning claim focuses on conflicting information on the label, which, on the one hand, stated not to inflate the catheter's balloon above 8 atmospheres of pressure but, on the other hand, showed test results for inflation up to 13 atmospheres, implying that inflation above 8 atmospheres was acceptable.

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 the negligent manufacturing and express warranty claims could go forward. *See id*. at 55a. Following discovery, Medtronic moved for summary judgment on the two remaining claims, and the court granted the motion. *Id*. at 75a.

The Riegels appealed the district court's decisions with respect to preemption and dismissal of the negligent manufacturing 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 § 360k(a) and that state-law design-defect and inadequate warning claims are sufficiently "device-specific" to warrant preemption. *Id*. at 25a, 32a-33a. The majority suggested that jury verdicts put manufacturers of PMA devices in an untenable position because compliance with both federal requirements and the standards represented by jury verdicts might be "impossible." *Id*. at 34a. The court did not attempt to reconcile that statement with the decades of product liability litigation against device manufacturers or with this Court's recent

decision in *Bates v. Dow AgroSciences LLC*, which noted that "an event, such as a jury verdict, that merely motivates an optional decision is not a requirement." 544 U.S. 431, 445 (2005).[3]

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*, 544 U.S. at 449). 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. She also observed that "the lack of any device-specific federal requirement [for PTCA 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).

SUMMARY OF ARGUMENT

1. Application of the traditional tools of statutory construction demonstrates § 360k(a)'s narrow reach. The language of § 360k(a) does not naturally include state-law damages claims within its preemptive scope. And when Congress enacted the MDA, it said nothing about preempting damages claims. Given the controversial nature of such preemption, Congress's silence

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[3]The Second Circuit also affirmed the holding of the district court dismissing the negligent manufacturing claim on the merits. Pet. App. 43a. That issue is not before the Court.

cannot reasonably be seen as an expression of intent to preempt such claims.

Moreover, Congress included in the MDA two provisions that confirm that § 360k(a) does not preempt damages claims. Section 360k(b), which allows the FDA to exempt state "requirements" from preemption, cannot workably be applied to damages claims. And § 360h(d), entitled "Effect on Other Liability," reveals that, in enacting the MDA, Congress expected that state-law claims would proceed against device manufacturers. The decision below runs contrary to that expectation and should be rejected.

This Court has time and again relied on the presumption that a federal statute may not be construed to preempt the historic police powers of the states absent a finding of Congress's "clear and manifest" intent to do so. The language of § 360k(a) displays no such unambiguous intent. In fact, device manufacturers themselves did not even conceive of the argument that § 360k(a) preempts damages claims until more than a decade after the MDA's enactment.

2. In *Lohr*, the Supreme Court rejected Medtronic's attempt to immunize itself from tort liability in a context similar to this one. Like this case, *Lohr* involved an injury caused by a defective class III medical device. As in this case, Medtronic argued that the MDA preempted the plaintiffs' state-law damages claims. This Court's majority opinion rejected Medtronic's argument. Relying on the language of § 360k(a) and the FDA's longstanding regulation, 21 C.F.R. § 808.1(d), the Court held that for the MDA to preempt a state-law claim, that claim must correspond to some device-specific federal requirement and the state law must have been developed "with respect to" devices. Neither the federal nor the state side of that holding is satisfied here because the PMA process does not impose device-specific design or labeling requirements, and neither a damages verdict nor the common-law duties that

would underlie such a verdict represent device-specific state-law requirements.

3. The Court in *Lohr* unanimously agreed that state-law claims that seek to enforce duties substantially identical to federal requirements are not preempted. That holding applies fully here and compels a finding that the Riegels' claims are not preempted. Even assuming that there are federal requirements applicable to the device within the meaning of § 360k(a), the design defect and inadequate warning claims are based on duties equivalent to the federal standards.

4. The court of appeals erroneously assumed that the effect of its decision finding preemption of state-law damages remedies for people injured by PMA devices was "quite limited." Pet. App. 36a. In fact, PMA devices, which are the riskiest devices, injure a great many patients. Thus, the effect of holding that § 360k(a) preempts damages claims based on injuries caused by PMA devices would not be "quite limited," but quite broad. Federal law provides no alternative remedy for these patients, which, in light of the presumption against pre-emption, further supports a narrow construction of § 360k(a).

ARGUMENT

Medtronic maintains, and the court below held, that because the FDA approved its catheter for marketing, it is entitled to immunity from state-law damages suits, regardless of their merits, the nature of Medtronic's conduct, or the severity of the resulting injuries. Medtronic's position is contradicted by the purpose and language of the MDA and by this Court's preemption jurisprudence.

I. APPLICATION OF TRADITIONAL TOOLS OF STATUTORY CONSTRUCTION SHOWS THAT CONGRESS DID NOT INTEND TO PREEMPT DAMAGES CLAIMS.

The language of § 360k(a)—preempting state "requirements" "with respect to a device" that are "different from or in

addition to" federal requirements—shows that Congress did not intend the MDA to preempt state damages actions. Section 360k(a) refers once to state-law "requirements" that are candidates for preemption and twice to federal "requirements" that may have preemptive effect. *See infra* 1a. The federal "requirements" flow solely from positive law—the MDA and its regulations. To interpret state-law "requirements" as including actions for damages would thus run counter to the basic rule of statutory construction that multiple uses of the same word in the same statute should be accorded the same meaning. *Commissioner v. Lundy*, 516 U.S. 235, 250 (1996); *Sullivan v. Stroop*, 496 U.S. 478, 484 (1990). In addition, § 360k(a) preempts only state-law requirements "with respect to a device." Unlike state statutory or regulatory requirements for devices, general common-law duties are not requirements "with respect to a device." And if the Riegels prevail at trial, Medtronic will be obligated only to pay damages; it will not be required to do anything with "respect to [the] device." *See Bates*, 544 U.S. at 445.

The starting point for discerning Congress's intent is the text of § 360k(a). *Lohr*, 518 U.S. at 484.[4] But in construing that text, the Court is "not guided by a single sentence or member of a sentence, but look[s] to the provisions of the whole law, and to its object and policy." *Dole v. United Steelworkers of Am.*, 494 U.S. 26, 35 (1990) (citations and internal quotation marks omitted). Like the language of § 360k(a) itself, these traditional tools of statutory construction show that Congress did not intend § 360k(a) to preempt damages claims at all and that, if § 360k(a) is nonetheless read

[4]The part of the *Lohr* opinion quoted above and all other aspects of *Lohr* relied on in this Argument are from the majority opinion, unless otherwise stated.

to encompass damages claims, such preemption would occur only in very narrow circumstances.[5]

A. If Congress had intended to take the significant and controversial step of preempting state-law damages claims for patients injured by the most dangerous medical devices (those that require PMA), one would expect a great deal of discussion and debate about that proposal. Yet "the debate and Congressional record are barren of any indication that Congress intended to preempt court decisions by passing" the MDA. *Haudrich v. Howmedica, Inc.*, 642 N.E.2d 206, 211 (Ill. App. Ct. 1994). Instead, "[a]ny fair reading of the legislative history of the [MDA] will reveal that, except for a few passing references to the need to avoid slowing innovations in medical technology, the critical, and endlessly repeated, focus of congressional attention was to protect consumers from dangerous devices." R. Adler & R. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 922 n.126 (1994) (citation omitted).

Although silent with respect to damages claims, the legislative record is clear that the impetus for Congress's enactment of a preemption provision was the existence of state regulatory programs that potentially could subject device manufacturers to inconsistent requirements once federal requirements were put into place. Addressing the purpose of § 360k(a), the House Report explained: "In the absence of effective federal regulation of medical devices, some States have established their own programs," the most comprehensive of which was California's law requiring premarket approval of new devices and compliance with the state's good manufacturing practices regulations. H.R. Rep. No. 94-853, at

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[5]The majority holding in *Lohr* does not resolve the question whether damages claims can ever be considered "requirements" under § 360k(a). As in *Lohr*, the Court may, but need not, decide this question to hold that the damages claims here are not preempted. *See infra* parts II-III.

45. In contrast to such regulatory schemes, damages claims are not state "programs" "established" in reaction to the "absence of effective federal regulation" of devices. Such claims existed (and exist) apart from federal and state regulation, having developed as part of traditional state tort laws.

Congress's silence on preemption of damages actions is particularly telling because the MDA was motivated by the "increasingly severe injuries that resulted from the failure" of medical devices, particularly the Dalkon Shield intrauterine device. *Lohr*, 518 U.S. at 476. Congress was "acutely aware of ongoing product liability litigation" regarding these incidents, *id*. at 491 (plurality opinion), which makes "its failure even to hint at [preemption of traditional common-law remedies] . . . spectacularly odd." *Id*. The legislative history reveals that Congress focused on "regulat[ing] medical devices *before* they reached consumers, rather than on addressing their consequences once on the market." *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1378 (11th Cir. 1999). The congressional reports and hearings on the MDA show, not simply that Congress "did not focus specifically upon the matter" of preempting damages claims, *Lohr*, 518 U.S. at 504 (Breyer, J., concurring), but that Congress had no concern about ongoing tort suits against device manufacturers.

Moreover, although *Lohr* holds that § 360k(a) does not preempt damages claims brought in connection with 510(k) devices, the MDA requires the FDA eventually to call for PMA for all class III devices. *See supra* pp. 3-4; *Lohr*, 518 U.S. at 479 ("Congress anticipated that the FDA would complete the PMA process for Class III devices relatively swiftly."). Accordingly, to find preemption here would be to conclude that Congress intended to preempt damages claims for *all* class III devices—without a word of discussion.

The conclusion that § 360k(a) was not intended to preempt damages claims is consistent with this Court's decisions recognizing that Congress can, and does, rationally distinguish

state positive law and common law, preempting the former but not the latter. As the Court stated in *Sprietsma v. Mercury Marine*, preemption of state positive law, but not state common law "does not produce anomalous results. It would have been perfectly rational for Congress not to pre-empt common-law claims, which—unlike most administrative and legislative regulations—necessarily perform an important remedial role in compensating accident victims." 537 U.S. 51, 64 (2002) (citing *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984)); *see Cipollone v. Liggett Group, Inc.*, 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.").

In 1976, for Congress to have preempted damages claims without providing an alternative means of compensation would have been unprecedented. Yet "Congress is unlikely to intend any radical departures from past practice without making a point of saying so." *Jones v. United States*, 526 U.S. 227, 234 (1999); *accord Edmonds v. Compagnie Generale Transatlantique*, 443 U.S. 256, 266-67 (1979) (rejecting interpretation of statute that would modify longshoremen's pre-existing rights against negligent vessels where reports and debates leading up to enactment "contain not a word of this concept"). For this reason, "[i]n a case where the construction of legislative language such as this makes so sweeping and so relatively unorthodox a change as that made here, . . . judges . . . may take into consideration the fact that a watchdog did not bark in the night." *Harrison v. PPG Indus., Inc.*, 446 U.S. 578, 602 (1980) (Rehnquist, J., dissenting); *see Chisom v. Roemer*, 501 U.S. 380, 396 (1991) (rejecting proffered statutory construction

because "if Congress had such an intent, Congress would have made it explicit in the statute, or at least some of the Members would have identified or mentioned it at some point in the unusually extensive legislative history").

The glaring absence in the legislative record of any suggestion that consumers would lose their only means of obtaining compensation for injuries caused by poorly designed or inadequately labeled PMA devices counsels against a finding of preemption. "Congress would [not], without comment, remove all means of judicial recourse for those injured by illegal conduct." *Silkwood*, 464 U.S. at 251.

B. Reading § 360k(a) in context reinforces that it does not apply to common-law claims. Section 360k includes not only the preemption provision but also subsection (b), which addresses exemptions from preemption. Subsection (b) authorizes the FDA to exempt a state "requirement" from preemption "[u]pon application of a State or a political subdivision thereof," if the state requirement is "more stringent than a requirement" under the MDA, is "required by compelling local conditions," and would not cause the device to be in violation of any MDA requirement. *See infra* 1a.

In accordance with standard rules of statutory construction, "requirement" should be read to have the same meaning in subsection (a) as in subsection (b). *Commissioner v. Lundy*, 516 U.S. at 250. Yet it is implausible that "requirement" in subsection (b) includes damages claims. A state seeking a blanket exemption for its common law could not show that the law was more stringent than MDA requirements because the common law is typically stated in very general terms. *See*, *e.g*, *infra* p. 41 (describing New York law). And reading § 360k(b) to create a system in which states petitioned the FDA for exemptions *after* each verdict in favor of a plaintiff would be "absurd." *Callan v. G.D. Searle & Co.*, 709 F. Supp. 662, 667 (D. Md. 1989). Not surprisingly, the FDA has interpreted "requirement" in § 360k(b) to apply to a "statute, rule,

regulation, or ordinance," not to common law. *See* 21 C.F.R. § 808.20(c). States have construed it similarly, as they apparently have not applied for exemptions for common-law claims. *See* 21 C.F.R. §§ 808.53-808.101.

Section 360k(b) distinguishes the MDA's preemption provision from the preemption provisions at issue in *Cipollone* and *Bates*. Neither of the statutes at issue in those cases contains a subsection, comparable to § 360k(b), that works in tandem with the preemption provision and thus provides an additional aid to discerning the scope of the preemption intended by Congress. "Language, of course, cannot be interpreted apart from context." *Smith v. United States*, 508 U.S. 223, 229 (1993). In the MDA, reading "requirement" in § 360k(a) together with that same term in § 360k(b) confirms that Congress did not intend that preempted "requirements" would include state common law.

In addition, the MDA refers directly to liability under state law in only one provision, 21 U.S.C. § 360h(d), and that provision indicates that Congress expected that damages actions against device manufacturers would continue after enactment of the MDA. Under § 360h, the FDA has the power to notify health professionals and the public of unreasonable risks associated with devices and to order device manufacturers to repair, replace, or provide refunds and reimbursements with respect to devices that pose such risks. Subsection (d) of § 360h, entitled "Effect on Other Liability," provides:

> Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

Thus, "the only congressional discussion concerning the relationship between the [statute] and state tort remedies

indicates that Congress assumed that such remedies would be available." *Silkwood*, 464 U.S. at 251 (holding no preemption of punitive damages claim under Atomic Energy Act); *see Goodlin*, 167 F.3d at 1379 ("[T]he savings clause [§ 360h(d)] casts real doubt on the idea that Congress intended to preempt state tort liability for all PMA approved devices.").

C. In addition to the statute's text, purpose, and legislative history, interpretation of § 360k(a) is informed by the well-established presumption against preemption. *Lohr*, 518 U.S. at 485. This strong presumption buttresses the conclusion that § 360k(a) does not preempt state-law damages claims at all (or, at most, that it does so only in narrow circumstances). As the Court has reiterated, "the regulation of health and safety matters is primarily, and historically, a matter of local concern." *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 716, 719 (1985); *see Gonzales v. Oregon*, 546 U.S. 243, 126 S. Ct. 904, 923 (2006); *Lohr*, 518 U.S. at 485. The presumption against preemption instructs that the historic police powers of the states are not superseded by federal law "unless that was the clear and manifest purpose of Congress." *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 814 n.8 (1997) (citation and internal quotation marks omitted); *see Bates*, 544 U.S. at 449; *Lohr*, 518 U.S. at 485; *Hawaiian Airlines, Inc. v. Norris*, 512 U.S. 246, 252 (1994); *Wisconsin Pub. Intervenor v. Mortier*, 501 U.S. 597, 605, 611 (1991); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). This approach "provides assurance that the 'federal-state balance' will not be disturbed unintentionally by Congress or unnecessarily by the courts." *Jones v. Rath Packing Co.,* 430 U.S. 519, 525 (1977) (citation omitted). The presumption applies where a defendant is seeking preemption of state tort remedies for bodily injury because, in that situation, preemption would displace the historic power of the states to protect the health and safety of their citizens. *See*, *e.g.*, *Lohr*, 518 U.S. at 484-86.

Here, § 360k(a)'s plain language preempts only state-law "requirements." Although this Court has held that the word "requirements" *may* include damages claims, *see Bates*, 544 U.S. at 443, as used in § 360k(a), the word certainly does not manifest an unambiguous intent do so. *See* P. Hutt, R. Merrill, & L. Grossman, *The Ambiguous Medical Device Amendments*, *in Food and Drug Law* 1439 (3d ed. 2007) (heading in chapter entitled "Statutory Preemption"); *see also Sprietsma*, 537 U.S. at 63 (statute providing that states "may not establish, continue in effect, or enforce a law or regulation . . . imposing a requirement" does not preempt common-law claims). And in 1976, when Congress drafted the MDA, the Court had not yet recognized that, when used in a preemption provision, the term might refer to a damages claim. *Cf. Bates*, 544 U.S. at 441 (noting "groundswell" of cases about express preemption under 1972 provision of Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") after *Cipollone* was decided in 1992).[6] In 1976, the Court had also never found tort pre-emption in the absence of a federal remedy. In light of the legislative record and the presumption against preemption, even if Medtronic's reading were plausible—indeed, even if it were just as plausible as the Riegels'—the Court "would nevertheless have a duty to accept the reading that disfavors pre-emption." *Bates*, 544 U.S. at 449.

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[6]Similar to the situation described in *Bates*, "the first reported decisions on the industry's attempts to assert federal preemption of state product liability claims for devices subject to the FDA's approval regimes did not appear until 1991, fifteen years after Congress passed the MDA." *Goodlin*, 167 F.3d at 1381; *see* Pet. App. 46a-47a. 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.*

Because the language of § 360k(a), read in conjunction with the statute's purpose, the legislative history, and the MDA as a whole, does not manifest an intent to preempt damages claims, the decision below should be reversed.

II. PREMARKET APPROVAL DOES NOT PREEMPT THE RIEGELS' DAMAGES CLAIMS.

The majority opinion in *Lohr*, while not excluding the possibility that § 360k(a) might preempt some damages claims, adopts a narrow construction of the provision that reflects both the presumption against preemption and the apparent absence of congressional intent to eliminate damages claims against device manufacturers. *Lohr*'s construction of § 360k(a) confirms the conclusion required by the MDA's purpose and the history of device regulation: PMA does not preempt state design-defect and failure-to-warn claims.

In holding that § 360k(a) did not preempt the damages claims at issue in *Lohr*, this Court noted that both the statutory language and FDA regulations reveal an "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. The statute and regulations, the Court held, "require 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*. Although *Lohr* involved a device marketed pursuant to a finding of substantial equivalence under § 510(k), the Court's construction of § 360k(a) yields the same result when applied to cases involving PMA devices. Medtronic's catheter was not subject to a device-specific federal requirement, and the Riegels' damages claims would not impose on the catheter a device-specific state requirement. For each of these reasons, § 360k(a) does not preempt the claims alleged here.

A. Premarket Approval Of Medtronic's Device Did Not Create Any Federal Requirement That Preempts The Riegels' Damages Claims.

1. The PMA Process Does Not Preempt Damages Actions.

Device manufacturers have argued both that the rigor of FDA review makes the PMA process itself a requirement that preempts damages claims, and that the granting of PMA imposes requirements that preempt damages claims. Neither is correct. PMA signifies that the FDA has examined the manufacturer's application and determined that the device satisfies federal criteria for marketing. *See* 21 U.S.C. § 360e(d). The federal criteria for PMAs are generally applicable threshold standards set out in the MDA and the FDA's implementing regulations. *See* 21 C.F.R. § 814.45 (grounds for denying a PMA). The manufacturer is responsible for submitting an application demonstrating that the proposed medical device satisfies those minimum standards. *See*, *e.g.*, *id*. Part 814. Where, as here, the FDA has not set out specific federal requirements for the particular device, the manufacturer may select any design and labeling features that will satisfy the general minimum standards of the MDA and FDA regulations. *See generally supra* pp. 4-5.

Thus, although a PMA application and the FDA's scrutiny of it are more extensive than in the case of a 510(k) device, such as the device at issue in *Lohr*, *see* 518 U.S. at 479 (explaining differences), the approval criteria for PMA are no more "specific" than for the 510(k) process. Both processes apply to class III devices generally, *id.*, and neither specifies how a product is to be designed, labeled, or manufactured. The same labeling regulations, 21 C.F.R. § 801.109, and good manufacturing practices regulations, *id*. § 820.1, apply to both PMA and 510(k) devices. The PMA process demands that all PMA devices provide a "reasonable assurance" of safety and effectiveness, 21 U.S.C. § 360e(d)(2), but it does not

"require"—to use the language of § 360k(a)—any specific design, labeling, or manufacturing. *Lohr*'s observation that the FDA's labeling and manufacturing rules impose no "specific mandate on manufacturers or producers," 518 U.S. at 501, applies fully to the PMA process.

The courts that have found that § 360k(a) preempts damages claims have concluded that, given the degree of FDA scrutiny of PMA applications, PMA must have preemptive effect. *See*, *e.g.*, *Horn v. Thoratec Corp.*, 376 F.3d 163, 169-70 (3d Cir. 2004); *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 226-27 & n.4 (6th Cir. 2000). The Riegels agree that PMA may have a preemptive effect. The question is, what does PMA preempt? That is, what state requirement is the counterpart to a federal requirement mandating PMA for a particular device? The answer is, a state PMA requirement for that same device.

Accordingly, in a 1978 Federal Register notice, the FDA explained that state and local PMA requirements are preempted "on the date the device cannot lawfully be marketed without approval of an application" for federal PMA. 43 Fed. Reg. 18661, 18664 (1978). Consistent with this view, the FDA agreed that California could continue to require a state PMA before allowing any particular device to be marketed in California until the FDA established a "counterpart" requirement for that device—that is, until the date on which the FDA determined either that the device did not require PMA or that the device could not lawfully be marketed without a federal PMA. 45 Fed. Reg. 67321, 67323 (1980).

The principle that preemption under § 360k(a) turns on specific counterpart requirements is both consistent with the congressional purpose, *see supra* pp. 7, 16-17, and expressly stated in *Lohr*'s majority opinion. 518 U.S. at 500. Thus, the existence of one specific federal requirement applicable to a particular device does not preempt *all* state requirements applicable to that device. Rather, the federal requirement preempts only counterpart state requirements. *See id*. To use

the example from Justice Breyer's concurrence, a federal regulation mandating that hearing aids have two-inch wires would preempt a state requirement prescribing one-inch wires, *id*. at 505; but that federal regulation would not preempt state rules regarding packaging of hearing aids.

In short, the federal requirement that a device cannot be marketed without federal PMA preempts a state requirement that the device undergo state PMA but does not preempt state rules regarding other aspects of that device. Product liability claims for design defect or inadequate warning are not counter-part requirements to the requirement that a device receive PMA; such claims simply do not address the same topic (marketing approval). They are therefore not preempted by the federal PMA process.[7]

2. PMA Imposed No Device-Specific Design Requirements On The Device.

Although federal law required Medtronic to obtain PMA before marketing its catheter, the FDA, in granting PMA, did not impose specific requirements concerning the device's design. Like the design of the 510(k) pacemaker lead at issue in *Lohr*, the design of the catheter originated with the company. The FDA "did not 'require' [the device] to take any particular form for any particular reason." *Lohr*, 518 U.S. at 493 (no preemption of design-defect claim where FDA did not require Medtronic's pacemaker lead to adhere to any particular design).

Design specifications result from the manufacturer's decisions about how to design and whether to market the device. The FDA is not involved in device design, does not

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[7]That PMA does not preempt damages claims does not mean that it is irrelevant to the litigation of the claims. Under New York law, compliance with federal law may constitute evidence of due care in defense to negligence claims. *See*, *e.g.*, *Feiner v. Calvin Klein, Ltd.*, 549 N.Y.S.2d 692, 693 (N.Y. App. Div. 1990); *accord* Restatement (Third) of Torts: Prods. Liab. § 4(b) (1988).

compare the relative risks or benefits of possible designs, and does not require a manufacturer to market any product. *Cf. American Airlines, Inc. v. Wolens*, 513 U.S. 219, 228-29 (1995) ("We do not read the [Airline Deregulation Act]'s preemption clause . . . to shelter airlines from suits alleging no violation of state-imposed obligations, but seeking recovery solely for the airline's alleged breach of its own, self-imposed undertakings."). And where a manufacturer has marketing approval for more than one model of its device, nothing in the PMA requires a manufacturer to market one approved design as opposed to another. *See*, *e.g.*, *Blunt v. Medtronic, Inc.*, 2007 WL 2176136, ¶ 20 (Wis. Ct. App. July 31, 2007) (noting that FDA approval of safer defibrillator did not require Medtronic to stop marketing its inferior model).

PMA "represents only the FDA's judgment that a manufacturer has reasonably assured the FDA of the device's safety and effectiveness." *Webster v. Pacesetter, Inc.*, 171 F. Supp. 2d 1, 11 (D.D.C. 2001). The FDA does not impose through PMA particular design specifications comparable to the hypothetical FDA-required two-inch hearing-aid wire discussed in Justice Breyer's *Lohr* concurrence. 518 U.S. at 504. To be sure, the FDA by regulation *can* impose specific federal requirements with respect to design, labeling, or other characteristics of the device, 21 C.F.R. § 861.1(b)(3), in addition to the general criteria of "reasonable assurance of safety and effectiveness." Such requirements, however, "exist independently" of the PMA process. Br. of U.S. as Amicus Curiae at 15, *Smith Indus. Med. Sys. v. Kernats*, 522 U.S. 1044 (1998) (No. 96-1407) ("U.S. *Kernats* Br."). More importantly, with respect to the device at issue here, the FDA has issued no such requirement.

Here, the impossibility of conducting a "careful comparison" between a federal design requirement and a counterpart state requirement, as *Lohr* requires, 518 U.S. at 500, establishes that § 360k(a) does not preempt the Riegels' claims. If the FDA issued a standard requiring PTCA catheters to meet

certain specifications, *see* 21 C.F.R. § 861.1(b)(3), a design-defect claim that challenged the safety of the device could be analyzed in terms of whether design requirements implied by the claim (if any) were "different from or in addition to" those specifications. *See Lohr*, 518 U.S. at 504 (Breyer, J., concurring); *cf. Cipollone*, 505 U.S. at 524 (failure-to-warn claim preempted where federal law required particular warning); *Boyle v. United Techs. Corp*., 487 U.S. 500, 512 (1988) (state tort claim against government contractor for design defects in equipment designed according to government specifications impliedly preempted).

For example, the FDA has issued specific performance parameters for certain lasers: "Device must emit a laser beam with the following parameters: wavelength = 1064 nanometers; spot size = 50 to 100 microns; pulse width = 3 to 30 nano-seconds . . . ." 21 C.F.R. § 886.4392. In a design-defect case involving this type of laser, one could look at the FDA-mandated performance parameters and evaluate whether state law sought to impose different or additional requirements—whether state law would require a different laser pulse width, for example, than that stated in the device-specific regulation. That scenario would still present the question whether the state-law duties upon which the plaintiff relied were specific enough to trigger preemption under § 360k(a) and whether the common-law design-defect claim reflected a state requirement related to the safety or effectiveness of a medical device. *See Oja v. Howmedica*, 111 F.3d 782, 789 (10th Cir. 1997) (holding damages claim not preempted by tampon-specific labeling requirement). At least, however, a court could compare the federal requirement to the state-law theory underlying the damages claim.

The absence of specific federal requirements for the design (or any other aspect) of Medtronic's device is underscored by the FDA's approval letter in this case. The letter imposes no specific requirements. *See* JA 16-17; *see also* JA 9-11 (approving original application for original model); JA 18-19,

26-27, 34-35 (letters approving later PMA supplements). And the "Conditions of Approval" is an FDA form document that applies to PMA products generally. *See* JA 12-15, 20-25, 28-33. Aside from listing in the November 1986 letter the types of patients for whom use of the product is indicated, none of the letters or Conditions of Approval says anything about catheters or Medtronic's product in particular. As the Eleventh Circuit, holding that PMA does not preempt state-law damages claims, observed:

> The "Conditions of Approval" document enclosed with the letter that noted the FDA's approval of the [device's] PMA application sets forth rules and regulations generally applicable to all devices approved through the PMA process. For example, the "Conditions of Approval" remind Medtronic of its obligation to provide post-approval reports, to refrain from changing the device without FDA approval, and to report adverse reactions and device defects. The document . . . is cast in the most generic of terms and mentions neither the [specific pacemaker lead] nor even pacemaker leads as a class of devices.

Goodlin, 167 F.3d at 1377.

Furthermore, as the Conditions of Approval explain, PMA does not lock the manufacturer into particular design specifications. Rather, FDA regulations allow a device manufacturer to obtain permission to alter the design of a PMA device by filing a PMA supplement. *See* 21 C.F.R. § 814.39. Medtronic itself filed two PMA supplements seeking to make design changes or to market new models of the PTCA catheter, and the FDA allowed both. JA 16, 26. Thus, the notion that PMA "required" a particular design is belied by applicable regulations and the facts of this case.

Moreover, although FDA regulations required Medtronic to obtain FDA authorization before changing the design of its catheter, the same was true with respect to the Medtronic

device at issue in *Lohr*. *Compare* 21 C.F.R. § 814.39 (manufacturer must submit PMA supplement before making change that affects safety or effectiveness of PMA device), *with id*. § 807.81(a)(3)(i) (manufacturer must submit new 510(k) application before making change that affects safety or effectiveness of 510(k) device). In *Lohr*, Medtronic relied on 21 C.F.R. § 807.81(a)(3)(i) to argue for preemption of the design claim, contending that the need to submit a new application before changing the design of its 510(k) device constituted a preemptive "requirement."[8] Yet the Court unanimously rejected the argument that the MDA preempted the design-defect claim. *Lohr*, 518 U.S. at 492-94 (majority); *id.* at 513 (O'Connor, J., concurring in part and dissenting in part).

3. PMA Imposed No Device-Specific Labeling Requirements On The Device.

For preemption purposes, the Riegels' inadequate warning claim is indistinguishable from the warning claim in *Lohr*. The claim is not preempted because, as was true in *Lohr*, Medtronic's device was subject only to the FDA's general labeling regulation. JA 10, 18, 27, 34 (approval letters). The FDA can issue a specific labeling regulation for a particular device. *See*, *e.g.*, 21 C.F.R. § 801.430(c)-(e) (specifying warning and other information for class II tampon labels); *id*. § 1020.30(j) (specifying warning for x-ray equipment). For most PMA and 510(k) devices (and for the catheter here), however, the FDA regulation governing the content of the label is 21 C.F.R. § 801.109—*the same regulation found too general to warrant preemption in Lohr*. *See* 518 U.S. at 497-501.

Like the 510(k) process, PMA does not lock the manufacturer into a particular label. Manufacturers can seek FDA

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[8] *See* Brief for Petitioner Medtronic, *Lohr*, 518 U.S. 470 (Nos. 95-754, 95-886), 1996 WL 88789, at *27-*28; Reply Brief for Petitioner Medtronic, *Lohr*, 518 U.S. 470 (Nos. 95-754, 95-886), 1996 WL 180309, at *13-*14.

permission to alter the labeling of a PMA device by filing a PMA supplement. *See* 21 C.F.R. § 814.39. Labeling changes that enhance the safety of the device by strengthening warnings or instructions or by deleting misleading information can even be made in advance of receiving FDA approval. *Id*. § 814.39(1)(d); *see Lohr*, 518 U.S. at 497 n.16 (suggesting this regulation's relevance to the preemption analysis); *see also infra* p. 42. With respect to the catheter at issue here, Medtronic filed two PMA supplements seeking to revise its label, and the FDA allowed both. JA 18, 34. Thus, PMA did not impose device-specific labeling requirements, and § 360k(a) does not preempt the inadequate warning claim here.

Finally, manufacturers can and do provide updated warning information through non-label means, such as "Dear Doctor" letters, which are not regulated by the FDA. The FDCA defines "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers; or (2) accompanying such article." 21 U.S.C. § 321(m). Similarly, "'label' means a display of written, printed, or graphic matter upon the immediate container of any article." *Id*. § 321(k). Therefore, a post-PMA letter to physicians warning about the risk of over-inflation or clarifying that, although the label shows testing of the device up to 13 atmospheres, the device should not be inflated above 8 atmospheres, would not have constituted "labeling," and Medtronic was free to issue such a letter without approval from the FDA.

4. FDA Regulations Support A Finding Of No Preemption.

Lohr's construction of the statutory language is authoritative and cannot be altered by subsequent changes in the agency's reading of the statute: "Once we have determined a statute's clear meaning, we adhere to that determination under the doctrine of stare decisis, and we judge an agency's later interpretation of the statute against our prior determination of the statute's meaning." *Maislin Indus. v. Primary Steel, Inc*.,

497 U.S. 116, 131 (1990). Nonetheless, to the extent that the FDA's reading of § 360k(a) is entitled to weight in the judicial decisionmaking process, its analysis of the statute strongly supports the *Lohr* construction.

Although Congress did not delegate to the FDA the authority to define the term "requirements" in § 360k(a), the FDA has implemented its authority to grant exemptions from preemption under § 360k(b) through a set of regulations that narrowly construes § 360k(a)'s preemptive scope. The same regulations informed the Court's majority holding in *Lohr*, 518 U.S. at 496-97, 498-99 (majority opinion); *see also id.* at 505-06 (Breyer, J., concurring), and remain in effect, unaltered, today.

FDA regulations reinforce the conclusion that PMA does not impose requirements that preempt the Riegels' damages claims. As discussed above, *see supra* p. 7, the regulation addressing the scope of preemption, 21 C.F.R. § 808.1(d), provides that a state requirement is preempted only when the FDA has "established specific counterpart regulations" or when there are other "specific requirements applicable to the specific device" under the MDA that render a "divergent" state requirement "different from or in addition to" the "specific" FDA requirements. *See infra* 3a. In addition, the regulation addressing procedures for applying for an exemption assumes that a preempted "requirement" will be a "statute, rule, regulation, or ordinance of the State or political subdivision," and instructs the state to include in its exemption application "a reference to the date of enactment, promulgation, or issuance in final form. The application shall also include, where available, copies of any legislative history or background materials pertinent to enactment, promulgation, or issuance of the requirement, including hearing reports or studies concerning development or consideration of the requirement," and any judicial or administrative interpretations of such requirements. *Id*. § 808.20(c)(1) (*infra* 7a).

When it promulgated the regulations, the FDA set forth its interpretation of § 360k(a). Looking first to the words chosen by Congress—dictating that there be a pre-existing federal requirement "applicable to *the device*"—the agency found that device-specific federal rules must be in place before any preemption can occur. 43 Fed. Reg. 18662 (emphasis in original) (quoting § 360k(a)). The FDA further explained:

> Thus, from a plain reading of section [360k] of the act it is clear that the scope of preemption is limited to instances where there are specific FDA requirements applicable to a particular device or class of devices. . . . [A] prime example is the preemption of divergent State or local requirements relating to hearing aid labeling . . . , which occurred when the new FDA hearing aid regulations took effect. . . . [O]nly requirements relating to labeling and conditions for sale were preempted, not all State or local requirements regulating other facets of hearing-aid distribution.

Id; *see also* 42 Fed. Reg. 30383, 30384 (1977) (proposed rule) ("[A] preempting FDA requirement will become applicable to a device within the meaning of section [360k(a)] only after FDA takes a regulatory or administrative action involving the application of a particular requirement of the act to a particular device."). This insistence on specific federal requirements for the same subject matter regulated by the state—which the FDA refers to as the need for "specific counterpart" requirements—is found throughout the FDA's regulations. *See, e.g.*, 21 C.F.R. § 808.1(d)(3).

Although the United States argued in its amicus brief at the petition stage of this case that PMA broadly preempts state-law damages claims, the FDA's longstanding regulation—not the changing positions advocated in its amicus briefs—is entitled to weight. In the preemption context, this Court has given consideration to the views of the agencies to which Congress delegated regulatory authority where those views were

developed through notice-and-comment rulemaking. *See Geier v. American Honda Motor Co.*, 529 U.S. 861, 877-83 (2000) (in conflict preemption case, giving weight to agency's view of the purpose of a particular agency standard, where the view was stated contemporaneously with issuance of the standard and explained "consistently over time"); *Hillsborough County*, 471 U.S. at 714-15 (citing *Chevron U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 842-45 (1984)).

In contrast, statements contained in government amicus briefs are not entitled to substantial weight. *See United States v. Mead Corp*., 533 U.S. 218, 228 (2001); *Christensen v. Harris*, 529 U.S. 576, 587 (2000). This principle is particularly important here, where the government twice filed amicus briefs in this Court arguing against preemption, but then disavowed its own arguments and filed amicus briefs in a court of appeals and in this case taking the opposite position. *Compare* U.S. *Kernats* Br., *supra*, at 14-18, *and* Br. of U.S. as Amicus Curiae, *Lohr*, 518 U.S. 470 (No. 95-754), 1996 WL 118035, *with* Br. of U.S. as Amicus Curiae, *Riegel v. Medtronic, Inc.*, 451 F.3d 104 (2d Cir. 2006) (No. 06-179), *and* Br. of U.S. as Amicus Curiae, *Horn*, 376 F.3d 163 (No. 02-4597).

B. The Riegels' Claims Also Are Not Preempted Because They Are Premised On State-Law Duties Of General Applicability.

Because the federal law's lack of device-specificity with respect to Medtronic's catheter is dispositive under *Lohr*, this Court need not reach the question whether the state-law claims at issue fall within the scope of § 360k(a). However, consideration of the claims independently shows that they would not impose state-law "requirements" that are "with respect to devices" under § 360k(a). Rather, even if damages claims can ever constitute requirements under § 360k(a), the principles of New York law on which the Riegels rely, like the Florida common-law duties on which the Lohrs relied, are

principles of "general applicability," *Lohr*, 518 U.S. at 500 (quoting 21 C.F.R. § 808.1(d)), outside the scope of § 360k(a).

1. Relying on the text of § 360k(a) and guided by the presumption against preemption, the *Lohr* majority held that state laws of general applicability, as opposed to laws specifically applicable to medical devices, are not preempted by the MDA. Accordingly, the Court held that the general duties to warn users of potential risks and to use due care in manufacturing are outside the prohibited category of requirements "with respect to" specific devices, within the meaning of § 360k(a).

The state-law side of the preemption analysis is unaffected by the factual difference between this case and *Lohr*—that is, that this case involves a PMA device and *Lohr* involved a 510(k) device. Because *Lohr*'s discussion of the state-law claims applies fully here, it is worth quoting extensively:

> [T]he general state common-law requirements in this case were not specifically developed "with respect to" medical devices. Accordingly, they are not the kinds of requirements that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements. The legal duty that is the predicate for the Lohrs' negligent manufacturing claim is the general duty of every manufacturer to use due care to avoid foreseeable dangers in its products. Similarly, the predicate for the failure to warn claim is the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use. These general obligations are no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a workforce.

Lohr, 518 U.S. at 501-02.

The agency's regulation takes this same approach, stating that § 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 the 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).

Thus, in *Lohr*, the state common-law claims "escape[d] preemption, not because the source of the duty [was] a judge-made common-law rule, but rather because their generality [left] them outside the category of requirements that § 360k envisioned to be 'with respect to' specific devices such as pacemakers." *Id*. at 502. As in *Lohr*, the general state common law at issue here was not developed "with respect to" medical devices. *See Horn*, 376 F.3d at 182 (Fuentes, J., dissenting). Rather, the claims are "predicated upon . . . general dut[ies] applicable to every manufacturer," such as the duty "to inform users and purchasers of potentially dangerous items of the risks involved in their use." *Lohr*, 518 U.S. at 501, *quoted in Oja,* 111 F.3d at 789 (device-specific federal labeling requirement did not preempt state-law claims based on general common-law duties that did not relate specifically to devices); *accord Niehoff v. Surgidev,* 950 S.W.2d 816, 822 (Ky. 1997) ("Kentucky's strict liability case law and statutes are laws of general applicability to all products and fall beyond the scope of federal preemption under § 360k.").[9]

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[9]*Accord Baird v. American Med. Optics*, 693 A.2d 904, 909-10 (N.J. Super. Ct. App. Div. 1997), *modified and remanded,* 713 A.2d 1019 (N.J. 1997); *Mears v. Marshall*, 944 P.2d 984, 993-95 (Or. Ct. App. 1997); *Wutzke v. Schwagler*, 940 P.2d 1386, 1391-92 (Wash. Ct. App. 1997); *Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763, 771-72 (Cal. Ct. App. 1996)*; Kernats v. Smith Indus. Med. Sys.*, 669 N.E.2d 1300, 1309 (Ill. App. Ct. 1996); *Walker v. Johnson*

(continued...)

2. The United States, in its amicus brief at the petition stage in this case (at 13), tried to convert damages claims based on generally applicable state-law tort duties into device-specific requirements by asserting that a jury verdict would require Medtronic to change the design of its device. This Court has firmly rejected this argument:

> A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement. The proper inquiry calls for an examination of the elements of the common-law duty at issue, see *Cipollone*, 505 U.S. at 524; it does not call for speculation as to whether a jury verdict will prompt the manufacturer to take any particular action (a question, in any event, that will depend on a variety of cost/benefit calculations best left to the manufacturer's accountants).

Bates, 544 U.S. at 445. Thus, here, a jury verdict in favor of the Riegels would require Medtronic only to pay damages; it would not require Medtronic to take any action inconsistent with federal requirements. The possibility that manufacturers will have to pay damages—a possibility present since long before the MDA's enactment in 1976 and unquestioned by medical device manufacturers until the early 1990s—does not implicate § 360k(a). And the common-law duties at issue—the proper focus of inquiry under *Bates*—are not the types of specific requirements that § 360k(a) preempts.

Below, the court analogized a possible verdict against Medtronic to the hearing-aid wire example from Justice Breyer's concurrence in *Lohr*. Pet. App. 33a. That example is inapposite, and, in fact, Justice Breyer's concurrence weighs against preemption here and is consistent with the *Lohr*

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[9](...continued)
& Johnson Vision Prods., Inc., 552 N.W.2d 679, 686 (Mich. Ct. App. 1996).

majority opinion (in which Justice Breyer joined). State damages claims are ordinarily premised on duties of general applicability, such as the duty to warn of risks or to use due care in the design of a product. Here, a verdict awarding damages would be based on Medtronic's dereliction of such duties. *See infra* pp. 41-42 (discussing New York law). That verdict would neither require Medtronic to change the device's design or label (even if Medtronic had not ceased to market this device), nor necessarily or even likely reflect a jury finding regarding a specific design or specific language that Medtronic failed to provide.

To be sure, a state's product liability law could require plaintiffs to prove tort claims with a higher degree of specificity. For instance, a jury instruction could allow the imposition of state-law liability on the ground that a medical device did not meet a particular state design or warning specification different from an FDA specification on the same subject. Or a jury instruction could state that, as a matter of law, the jury should find the manufacturer negligent if its device had one particular design feature rather than another—for instance, a 2-inch wire rather than a 1-inch wire. *See Horn*, 376 F.3d at 183-84 (Fuentes, J., dissenting). These examples reflect the view stated in Justice Breyer's concurrence that a *specific* federal design regulation would preempt a negligence claim based on the theory that the manufacturer should have used a different, *specific* design. *Lohr*, 518 U.S. at 504 (Breyer, J., concurring). Whether or not the state-law side of § 360k(a) would be satisfied in such instances, here, as in *Lohr*, no state requirements "with respect to medical devices" are at issue, and the generality of the state-law damages claims cannot rightly be said to create them. *See Bates*, 544 U.S. 431; *see also* U.S. *Kernats* Br. at 17 (making similar point).

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This Court need go no further than *Lohr* to hold that the Riegels' claims are not preempted. Both because the FDA has issued no device-specific regulations regarding the design or

labeling of PTCA catheters, and because the Riegels' state-law claims are based on laws of general applicability, § 360k(a) does not preempt the Riegels' claims.

III. STATE REQUIREMENTS THAT PARALLEL FEDERAL REQUIREMENTS APPLICABLE TO PMA DEVICES ARE NOT PREEMPTED.

In *Lohr*, the Court held unanimously that § 360k(a) does not preempt state-law claims that parallel federal requirements. 518 U.S. at 495; *id*. at 513 (O'Connor, J., concurring in part and dissenting in part). As the Court explained, "Nothing in §360k denies [states] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Id*. at 495.

> Even if it may be necessary as a matter of [state] law to prove that those violations were the result of negligent conduct, or that they created an unreasonable hazard for users of the product, such additional elements of the state-law cause of action would make the state requirements narrower, not broader than the federal requirement.

Id.

The Court recently reiterated this holding in *Bates*. There, the Court recognized that an express preemption provision "similarly worded" to § 360k(a) did not preempt damages claims based on common-law duties equivalent to the duties imposed under the statute. 544 U.S. at 447. And the Court explained that a state-law duty equivalent to a federal duty "need not be phrased in identical language as its corresponding [federal] requirement." *Id*. at 454. Thus, here, the Riegels' claims are not preempted for the additional reason that they are based on duties that mirror federal design and labeling requirements.

Under New York law, a design-defect claim is premised on obligations equivalent to those imposed by federal law. New York law states these obligations very generally:

> [A] defectively designed product is one which, at the time it leaves the seller's hands, is in a condition not reasonably contemplated by the ultimate consumer and is unreasonably dangerous for its intended use; that is one whose utility does not outweigh the danger inherent in its introduction into the stream of commerce.

Voss v. Black & Decker Mfg. Co., 450 N.E.2d 204, 207 (N.Y. 1983) (citations and internal quotation marks omitted).

Thus, like federal law, state common law prohibits marketing a device where the design is unreasonably dangerous or, to put it another way, requires that devices be designed to provide "reasonable assurance that the device is safe . . . [and] effective under the conditions of use prescribed, recommended, or suggested" in the label. 21 U.S.C. § 360e(d)(2)(A), (B) (standard for PMA); *see also id.* § 352(j) (product is misbranded if, among other things, it "is dangerous to health when used" as prescribed); *id.* § 331 (prohibiting misbranding).

PMA is a determination by the FDA that the device as designed and labeled presents a "reasonable assurance of safety and effectiveness," based on the information provided by the manufacturer in its application. 21 U.S.C. § 360c(a)(1)(C). However, PMA does not preclude a later determination that the device is not in fact safe and effective. Federal law recognizes that approved devices may sometimes prove *not* to be reasonably safe and effective, requiring a recall, alteration of the design or label, or other enforcement action. *Id.* §§ 360e(e) (withdrawal of approval), 360h(e) (recall authority). Accordingly, a state determination, through a damages verdict, that a device was not reasonably safe is consistent with the federal scheme.

Although the remedy under federal law would be for the FDA to withdraw approval of the device or to institute an enforcement action against the manufacturer, *id*. § 360e(e)(1), while the remedy under state law would be damages, the difference in remedies does not mean that state law imposes "different" or "addition[al]" requirements within the meaning of § 360k(a). As Justice O'Connor, concurring in *Lohr*'s unanimous holding, explained, "[s]ection 360k does not preclude States from imposing different or additional *remedies*, but only different or additional *requirements*." 518 U.S. at 513 (opinion concurring in part and dissenting in part).

The Riegels' inadequate warning claim similarly seeks to enforce duties parallel to the MDA's general labeling rules. New York common law requires a manufacturer to provide "adequate warnings regarding use of its product." 86 N.Y. Jur. 2d, Prods. Liab. § 51 (2007). "Liability may be premised upon the complete absence of warnings as to a particular hazard, or upon the inclusion of warnings [that] are insufficient." *El Sheikh v. Chem-Tainer Indus., Inc*., 2006 WL 623464, at *4 (N.Y. Sup. Ct. Mar. 13, 2006); *see Cooley v. Carter -Wallace Inc*., 478 N.Y.S.2d 375, 377 (N.Y. App. Div. 1984) ("warnings must clearly alert the user to avoid certain (unsafe) uses of the product which would appear to be normal and reasonable," and "to be adequate, the warnings must be commensurate with the risk involved in the ordinary use of the product") (citations omitted). A manufacturer may also incur liability for failing to warn of dangers that came to its attention after the product was manufactured or sold, through advancements in the state of the art or through reports of incidents involving dangers that warrant additional warnings. *See Cover v. Cohen*, 461 N.E.2d 864, 871 (N.Y. 1984).

Federal law prohibits the marketing of a misbranded product, 21 U.S.C. § 331(a), and specifies that a device is misbranded if its labeling "is false or misleading in any particular" or if the device "is dangerous to health when used in the . . . manner . . . prescribed, recommended or suggested in

labeling thereof," among other things. *Id*. §§ 352(a), (j). The generally applicable New York state-law duty to warn mirrors this general federal requirement.

In addition, Medtronic's catheter was subject to 21 C.F.R. § 801.109, *see* JA 10, 18, 27, 34, which requires that labels of both PMA and 510(k) devices include certain information, such as a statement that the device is restricted to "sale by or on the order of" a physician, the method of application or use, the date of issuance of the label, and, most significantly here, information about indications, route of administration, hazards, contraindications, precautions, and side effects. 21 C.F.R. § 801.109(b)-(d). The common-law duty and the federal duty in this regard are equivalent. Both call for instructions and warnings that adequately provide for safe use of the device.

Moreover, as explained above, FDA regulations recognize that approved labeling will often prove inadequate and, therefore, allow manufacturers of PMA devices to make certain labeling changes to enhance product safety *without* pre-approval from the FDA. 21 C.F.R. §§ 814.39(d)(1), (2); *see Lohr*, 518 U.S. at 497 n.16 (citing § 814.39(d) as further support for the holding that claims that parallel federal requirements are not preempted). In fact, because it is unlawful to sell a device that has received PMA but is, nonetheless, misbranded, 21 U.S.C. § 331(a), a manufacturer has a continuing obligation to amend labeling when it becomes aware that the approved labeling is false or misleading in any way. *See Bates*, 544 U.S. at 438 (making same point with regard to pesticides).

Here, although the device's label had been approved by the FDA, 21 C.F.R. § 814.39 allowed Medtronic to update the label as soon as it knew that the instructions or warnings were inadequate. To hold Medtronic liable under state law for failing to revise the label once it became aware (for example, through adverse event reports, *see* 2d Cir. App. A-637) that physicians were inflating the balloon catheter above 8

atmospheres and, therefore, that its label was not providing an adequate warning, would provide a remedy for the patient but would not impose any "different" or "additional" requirement on Medtronic. Accordingly, consistent with federal requirements, Medtronic may be held liable for failing to revise the labeling to clarify instructions or strengthen warnings.

Finally, the fact that, in civil cases, juries decide whether parallel state-law duties have been violated is no cause for concern. When a company is prosecuted for violating the FDCA, *e.g.*, *United States v. C.R. Bard, Inc.*, 848 F. Supp. 287, 288 (D. Mass. 1994) (felony prosecution involving PMA device), a jury may render the verdict at the criminal trial. Juries may also decide cases involving alleged violations of injunctions issued in connection with violations of 21 U.S.C. § 331, which includes misbranding. *Id.* § 332. In such a case, the jury makes its own determination about misbranding or adulteration, or whatever the alleged violation may be, and, of course, may disagree with the FDA. Thus, "lay juries are in no sense anathema to [the MDA's] scheme." *Bates*, 544 U.S. at 452 (making same point regarding enforcement of common-law duties that parallel federal standards under FIFRA).

IV. MEDTRONIC'S POSITION WOULD IMPROPERLY FORECLOSE ALL REMEDIES FOR THE MANY PEOPLE INJURED BY PMA DEVICES.

The court of appeals believed that the scope of its decision was "actually quite limited" because most devices enter the market through the 510(k) process, not through PMA. *See* Pet. App. 13a, 36a. That statement was based on an inaccurate assumption that all devices—from bed pans, to bone cement, to heart valves—have an equal propensity for causing serious injury when defective and, therefore, are equally likely to be the subject of damages actions. PMA is required for life-sustaining devices and those that present the greatest risk of causing injury. 21 U.S.C. § 360c(a)(1)(C). Not surprisingly, those devices tend to cause a great many injuries and lawsuits. The

number of reported cases involving PMA devices, many of which are cited in the petition for certiorari and Medtronic's brief in opposition, speaks to the frequency of injuries and litigation attributable to PMA devices. Indeed, another one of Medtronic's PMA devices recently sparked so many cases as to warrant coordination in multidistrict litigation. *See In re Medtronic Implantable Defibrillators*, MDL No. 1726 (D. Minn.) (pending).

Examples of PMA devices that have caused serious injury are numerous:

• In August 2000, the FDA granted PMA to an implantable defibrillator manufactured by Guidant Corporation. In February 2002, Guidant began to receive reports that the device was short-circuiting. Shortly thereafter, in an effort to correct the problem, Guidant revised the design and manufacturing of the device. Nonetheless, it continued to sell the models made before the changes were implemented, and reports of device failures mounted. Guidant also started to receive reports of failures with another line of its implantable defibrillators. In March 2005, a patient died because of the failure of one of the devices. Yet Guidant apparently did not meet with the FDA to discuss the failures until May 2005. *See In re Guidant Corp. Implantable Defibrillators Prod. Liab. Litig.*, MDL No. 05-1708, 2007 WL 1725289, at *1-*3 (D. Minn. June 12, 2007). Guidant issued a public notice about the problem in May 2005, reportedly after hearing that the "problems with the device . . . were going to be publicized in other forums." B. Meier, *Citing Flaws, Maker Recalls Heart Devices*, N.Y. Times, June 18, 2005, at A1. By June 2005, Guidant had determined that the problem was caused by degradation of the insulation material and had replaced that material. Only then did it recall the defective devices. *In re Guidant*, 2007 WL 1725289, at *2. Guidant sold 29,000 of the devices before it recalled them. Meier, *Citing Flaws*, *supra*. After the district court presiding over the multi-district litigation that arose from the injuries caused by the devices

denied Guidant's motion for summary judgment based on preemption, *In re Guidant*, 2007 WL 1725289, at *7-*11, the company agreed to settle the claims against it. *See In re Guidant*, 2007 WL 2071804 (D. Minn. July 16, 2007).

• A Thoratec heart pump was implanted in Daniel Horn in January 1998. The device used sutures to secure several parts that screwed into one another. On May 3, 1998, the pump broke when a factory-installed suture wore through, allowing a connection to loosen. The suture had run across the top of the device, which caused the suture to rub against the underside of Mr. Horn's sternum, which in turn caused the suture to break. As a result, a blood clot or air embolus traveled to Mr. Horn's brain, leaving him brain dead. The company later revised the product design to use self-locking screws, rather than thread, so that the screws would not loosen. The regulatory history of the device showed that the FDA had not required the suture to run along the top of the device and that the placement of the suture in relation to the sternum was not specifically addressed in the PMA application. *See Horn*, 376 F.3d 163 (finding all claims preempted).

• Medtronic's 4004M pacemaker lead received PMA from the FDA in 1989. Later, an FDA inspector discovered that the lead had a high probability of failure. The FDA subsequently instructed Medtronic to issue a Health Safety Alert letter informing physicians about the lead's flaw. In that letter, Medtronic told physicians to consider whether prophylactic replacement would be appropriate, especially for pacemaker-dependent patients. The letter advised physicians to replace the pacemaker lead if the risk of continued use outweighed the risk associated with implanting a new lead. *Goodlin*, 167 F.3d at 1368-69. Some patients died when the lead failed, and many patients were forced to undergo open-heart surgery to replace Medtronic's faulty lead. *See*, *e.g.*, *Cupek v. Medtronic, Inc*., 405 F.3d 421 (6th Cir. 2005) (finding damages claims preempted); *Goodlin*, 167 F.3d 1367 (finding damages claims not preempted).

Many other PMA devices have caused injuries and deaths that led to significant litigation. *See*, *e.g.*, *In re St. Jude Silzone Heart Valve Prods. Liab. Litig.*, MDL No. 01-1396 (D. Minn.) (pending multi-district litigation for Silzone-coated heart valve products); *In re Sulzer Hip Prosthesis and Knee Prosthesis Liab. Litig.*, 268 F. Supp. 2d 907, 912-13 (S.D. Ohio 2003) (more than 3880 patients required extra surgeries due to two defective PMA devices; more than 1300 lawsuits filed); *Bowling v. Pfizer, Inc.*, 143 F.R.D. 141 (S.D. Ohio 1992) (settlement of class action involving approximately 55,000 patients implanted with defective PMA heart valve).

Neither the MDA nor any other federal law provides any means for patients to obtain compensation for injuries caused by medical devices. Indeed, when Congress enacted the FDCA in 1938, it rejected a proposed federal right of action for damages because a common-law right of action already existed. *See Food, Drugs, and Cosmetics: Hearings Before a Subcomm. of the S. Comm. on Commerce on S. 1944*, 73d Cong. 10, 400, 403 (1933).

Where the federal regulatory scheme does not itself provide a damages remedy, the 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*, 464 U.S. at 251; *see also Sprietsma*, 537 U.S. at 64. No such compelling circumstances are presented here, where, among other things, the legislative history is entirely silent on the topic, the MDA was intended to enhance consumer protection, FDA regulation of PMA devices is inadequate to prevent many serious injuries, and federal regulation and state-law damages remedies co-existed for more than a decade before even the device companies suggested that § 360k(a) preempts damages claims.

CONCLUSION

The decision below should be reversed and the case remanded for a trial on the merits.

Respectfully submitted,

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APPENDIX

PRINCIPAL STATUTORY AND REGULATORY PROVISIONS INVOLVED

21 U.S.C. § 360k provides:

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.

(b) Exempt requirements.—Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

21 U.S.C. § 360h(d) provides:

Effect on other liability.—Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such

liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

21 C.F.R. § 808.1 provides:

(a) This part prescribes procedures for the submission, review, and approval of applications for exemption from Federal preemption of State and local requirements applicable to medical devices under section 521 of the act.

(b) Section 521(a) of the act contains special provisions governing the regulation of devices by States and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.

(c) Section 521(b) of the act contains a provision whereby the Commissioner of Food and Drugs may, upon application by a State or political subdivision, allow imposition of a requirement which is different from, or in addition to, any requirement applicable under the act to the device (and which is thereby preempted) by promulgating a regulation in accordance with this part exempting the State or local requirement from preemption. The granting of an exemption does not affect the applicability to the device of any requirements under the act. The Commissioner may promulgate an exemption regulation for the preempted requirement if he makes either of the following findings:

(1) That the requirement is more stringent than a requirement under the act applicable to the device; or

(2) That the requirement is required by compelling local conditions and compliance with the requirement would not cause the device to be in violation of any applicable requirement under the act.

(d) 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 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.

(2) Section 521(a) does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

(3) Section 521(a) does not preempt State or local permits, licensing, registration, certification, or other requirements relating to the approval or sanction of the practice of medicine, dentistry, optometry, pharmacy, nursing, podiatry, or any other of the healing arts or allied medical sciences or related professions or occupations that administer, dispense, or sell devices. However, regulations issued under section 520(e) or (g) of the act may impose restrictions on the sale, distribution,

or use of a device beyond those prescribed in State or local requirements. If there is a conflict between such restrictions and State or local requirements, the Federal regulations shall prevail.

(4) Section 521(a) does not preempt specifications in contracts entered into by States or localities for procurement of devices.

(5) Section 521(a) does not preempt criteria for payment of State or local obligations under Medicaid and similar Federal, State or local health-care programs.

(6)(i) Section 521(a) does not preempt State or local requirements respecting general enforcement, e.g., requirements that State inspection be permitted of factory records concerning all devices, registration, and licensing requirements for manufacturers and others, and prohibition of manufacture of devices in unlicensed establishments. However, Federal regulations issued under sections 519 and 520(f) of the act may impose requirements for records and reports and good manufacturing practices beyond those prescribed in State or local requirements. If there is a conflict between such regulations and State or local requirements, the Federal regulations shall prevail.

(ii) Generally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices. Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the prohibition will be preempted if the requirement is different from, or in addition to, a Federal requirement established under the act. In determining whether such a requirement is preempted, the determinative factor is how the requirement is interpreted and enforced by the State or local government and not the literal language of the statute, which may be identical to a provision in the act.

(7) Section 521(a) does not preempt State or local provisions respecting delegations of authority and related administrative matters relating to devices.

(8) Section 521(a) does not preempt a State or local requirement whose sole purpose is raising revenue or charging fees for services, registration, or regulatory programs.

(9) Section 521(a) does not preempt State or local requirements of the types that have been developed under the Atomic Energy act of 1954 (42 U.S.C. 2011 note), as amended, the Radiation Control for Health and Safety Act of 1968 (Pub.L. 90-602 (42 U.S.C. 263b et seq.)) and other Federal statutes, until such time as the Food and Drug Administration issues specific requirements under the Federal Food, Drug, and Cosmetic Act applicable to these types of devices.

(10) Part 820 of this chapter (21 CFR part 820) (CGMP requirements) does not preempt remedies created by States or Territories of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(e) It is the responsibility of the Food and Drug Administration, subject to review by Federal courts, to determine whether a State or local requirement is equal to, or substantially identical to, requirements imposed by or under the act, or is different from, or in addition to, such requirements, in accordance with the procedures provided by this part. However, it is the responsibility of States and political subdivisions to determine initially whether to seek exemptions from pre-emption. Any State or political subdivision whose requirements relating to devices are preempted by section 521(a) may petition the Commissioner of Food and Drugs for exemption from preemption, in accordance with the procedures provided by this part.

(f) The Federal requirement with respect to a device applies whether or not a corresponding State or local requirement is preempted or exempted from preemption. As a result, if a State

or local requirement that the Food and Drug Administration has exempted from preemption is not as broad in its application as the Federal requirement, the Federal requirement applies to all circumstances not covered by the State or local requirement.

21 C.F.R. § 808.20 provides:

(a) Any State or political subdivision may apply to the Food and Drug Administration for an exemption from preemption for any requirement that it has enacted and that is preempted. An exemption may only be granted for a requirement that has been enacted, promulgated, or issued in final form by the authorized body or official of the State or political subdivision so as to have the force and effect of law. However, an application for exemption may be submitted before the effective date of the requirement.

(b) An application for exemption shall be in the form of a letter to the Commissioner of Food and Drugs and shall be signed by an individual who is authorized to request the exemption on behalf of the State or political subdivision. An original and two copies of the letter and any accompanying material, as well as any subsequent reports or correspondence concerning an application, shall be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The outside wrapper of any application, report, or correspondence should indicate that it concerns an application for exemption from preemption of device requirements.

(c) For each requirement for which an exemption is sought, the application shall include the following information to the fullest extent possible, or an explanation of why such information has not been included:

(1) Identification and a current copy of any statute, rule, regulation, or ordinance of the State or political subdivision considered by the State or political subdivision to be a requirement which is preempted, with a reference to the date of

enactment, promulgation, or issuance in final form. The application shall also include, where available, copies of any legislative history or background materials pertinent to enactment, promulgation, or issuance of the requirement, including hearing reports or studies concerning development or consideration of the requirement. If the requirement has been subject to any judicial or administrative interpretations, the State or political subdivision shall furnish copies of such judicial or administrative interpretations.

(2) A comparison of the requirement of the State or political subdivision and any applicable Federal requirements to show similarities and differences.

(3) Information on the nature of the problem addressed by the requirement of the State or political subdivision.

(4) Identification of which (or both) of the following bases is relied upon for seeking an exemption from preemption:

(i) The requirement is more stringent than a requirement applicable to a device under the act. If the State or political subdivision relies upon this basis for exemption from preemption, the application shall include information, data, or material showing how and why the requirement of the State or political subdivision is more stringent than requirements under the act.

(ii) The requirement is required by compelling local conditions, and compliance with the requirement would not cause the device to be in violation of any applicable requirement under the act. If the State or political subdivision relies upon this basis for exemption from preemption, the application shall include information, data, or material showing why compliance with the requirement of the State or political subdivision would not cause a device to be in violation of any applicable requirement under the act and why the requirement is required by compelling local conditions. The application

shall also explain in detail the compelling local conditions that justify the requirement.

(5) The title of the chief administrative or legal officers of that State or local agency that has primary responsibility for administration of the requirement.

(6) When requested by the Food and Drug Administration, any records concerning administration of any requirement which is the subject of an exemption or an application for an exemption from preemption.

(7) Information on how the public health may be benefitted and how interstate commerce may be affected, if an exemption is granted.

(8) Any other pertinent information respecting the requirement voluntarily submitted by the applicant.

(d) If litigation regarding applicability of the requirement is pending, the State or political subdivision may so indicate in its application and request expedited action on such application.