No. 04-0412

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

CHARLES RIEGEL and DONNA RIEGEL,
Plaintiffs-Appellants,

v.

MEDTRONIC, INC.,
Defendant-Appellee.

On Appeal from the United States District Court
for the Northern District of New York

BRIEF OF APPELLANTS
CHARLES AND DONNA RIEGEL

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

Allison M. Zieve
Brian Wolfman
Public Citizen Litigation Group
1600 20th Street, NW
Washington, DC 20009
(202) 588-1000

Counsel for Appellants

March 7, 2005

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES Pages

STATUTES AND LEGISLATIVE MATERIALS

REGULATORY MATERIALS

MISCELLANEOUS

PRELIMINARY STATEMENT

This appeal is from two decisions issued by the Honorable Lawrence Kahn of the United States District Court for the Northern District of New York. The decisions are not reported.

STATEMENT OF SUBJECT MATTER AND APPELLATE JURISDICTION

The district court had jurisdiction over this case under 28 U.S.C. § 1332 based on diversity of citizenship. App. A-15. The district court granted summary judgment on some claims on March 18, 2002, and granted summary judgment on the remaining claims on December 11, 2003. Judgment was entered on December 11, 2003, and disposed of all claims of all parties. App. SPA-1. Plaintiffs filed a notice of appeal on January 6, 2004. App. A-12. This Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

1. Whether 21 U.S.C. § 360k(a), the preemption provision of the 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act, preempts the Riegels' common-law damages claims.

2. Whether the district court erred in holding that there were no genuine issues of material fact precluding summary judgment on the Riegels' negligent manufacturing claim.

STATEMENT OF THE CASE

This appeal involves a suit to recover for injuries suffered by Charles Riegel from a medical device called a balloon catheter sold by defendant Medtronic, Inc. Mr. Riegel's claims, and the derivative claims of his wife Donna Riegel, are based entirely on New York state common law. On Medtronic's first motion for summary judgment, the district court held that section 360k(a) of the 1976 Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA") preempted claims for negligent design, failure to warn, strict liability, breach of implied warranty, and loss of consortium, but not claims for breach of express warranty or negligent manufacturing. App. SPA-2. The following year, the court granted a second motion for summary judgment and dismissed the Riegels' two remaining claims on the merits. App. SPA-20.

Because understanding the structure of the MDA is important to understanding this case, Part A below describes the regulatory structure of the MDA. Part B describes the Supreme Court's decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), in which the Court considered the scope of the MDA's preemption provision. Part C describes the facts concerning Mr. Riegel's injury and briefly summarizes the proceedings below.

A. The Medical Device Amendments

Prior to 1976, the Food and Drug Administration ("FDA") did not have specific authority to regulate the entry of medical devices into the market, as it had had for many years with respect to drugs. H.R. Rep. No. 853, 94th Cong., 2d Sess. 2-3 (1976) ("House Report"). In 1976, Congress enacted the MDA, which created a regulatory structure through which medical devices could enter the market. Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified at 21 U.S.C. § 360c *et seq*.). As the principal Senate sponsor, Senator Edward Kennedy, explained, the law was "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. 10688 (1975). Congress conferred responsibility for implementing and enforcing the MDA on the Department of Health and Human Services, which delegated that responsibility to the FDA. 21 C.F.R. § 5.10(a)(1).

The MDA categorizes devices into three classes based on the potential risk of harm or injury posed by each device. 21 U.S.C. § 360c(a)(1). Class I devices, such as tongue depressors, 21 C.F.R. § 880.6230, are those for which only "general controls" applicable to all devices are sufficient to provide a "reasonable assurance" of safety and effectiveness. 21 U.S.C. § 360c(a)(1)(A). Thus, class I devices are subject to general guidelines concerning recordkeeping, good manufacturing

practices, and the like, which apply to all medical devices. *See* 21 C.F.R. § 860.3(c)(1).

Class II devices, such as certain types of hearing aids, 21 C.F.R. § 874.3300(b)(2), are those for which general controls alone are insufficient to protect public health. *See* 21 U.S.C. § 360c(a)(1)(B). Class II devices are subject, in the FDA's discretion, to "special controls," which may include performance standards, post-market surveillance, patient registries, or other measures. *See* 21 C.F.R. § 860.3(c)(2).

Class III devices are those for which the controls provided for class I and class II devices cannot provide reasonable assurance of safety and effectiveness for human use and which either operate to sustain human life, are of substantial importance in preventing impairment of human health, or pose a potentially unreasonable risk to patients. 21 U.S.C. § 360c(a)(1)(C); 21 C.F.R. § 860.3(c)(3). Before marketing a class III device, a manufacturer must submit a premarket approval ("PMA") application, requesting permission to market the device for uses specified in the application. 21 U.S.C. § 360e(c)(1).

The MDA requires PMA applications for all class III devices but allows two categories of class III devices to be marketed without PMA until such time as the FDA specifically calls for an application. First, any device marketed prior to the

effective date of the MDA—a so-called "grandfathered" device—is not subject to PMA, even if it is a type of device classified in class III. *See*, *e.g.*, 21 U.S.C. §§ 351(f)(2)(B), 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1). Second, under section 510(k) of the FDCA, 21 U.S.C. § 360(k), a device marketed after the MDA's 1976 effective date may also bypass the PMA process if the FDA has not issued a regulation calling for PMA for such a device and its manufacturer can show that the device is "substantially equivalent" to either a "grandfathered" pre-MDA class III device, a class I device, or a class II device. *See* 21 U.S.C. §§ 351(f)(2)(B), 360c(f)(1)(A), 360e(b)(1)(B).

Before submitting a PMA application, a device manufacturer must design and implement an FDA-approved clinical investigation. The PMA application must include the results of that investigation, along with all other relevant studies (such as animal studies and *in vitro* data). *See* 21 U.S.C. § 360e(c)(1); 21 C.F.R. § 814.20; *see also* 21 C.F.R. Part 812 (procedures for establishing clinical investigations). In addition, the PMA application must contain proposed labeling for the device, a sample of the device, and other specified information. *See generally id*. § 814.20.

In most cases, before considering a PMA application, the FDA sends the application to an expert panel, 21 U.S.C. § 360e(c)(2), which evaluates the device and the data upon which the application is based and makes a recommendation to the

FDA as to whether, and under what conditions, the device should be approved for marketing. 21 C.F.R. § 814.44(b). In determining whether to grant PMA, the FDA conducts its own review of the PMA application and the details of the proposed device labeling, *id*. § 814.44(d), and reviews the expert panel's recommendation, if any. *Id*. § 814.44(c). A device may be granted PMA for the use specified in the application if the FDA finds that there is "reasonable assurance" that the device is safe and effective for that use. 21 U.S.C. §§ 360e(d)(2)(A) & (B); *see also id*. §§ 360e(d)(2)(C) & (D) (requiring pre-market approval of manufacturing facilities and device labeling). That is, the FDA does not make a finding that the device is, in fact, safe and effective for its intended use, only that there is "reasonable assurance" that it is safe and effective.

Prior to enactment of the MDA in 1976, some states had stepped into the regulatory vacuum and required that devices go through a state premarket approval prior to distribution in that state. House Report at 45 (noting that California required PMA for intrauterine devices). Concluding that state premarket scrutiny was preferable to no premarket scrutiny at all, Congress crafted a provision, section 360k(a), that would permit state regulatory programs to remain in place until the FDA had implemented specific counterpart regulations, but thereafter would preempt conflicting state regulatory measures. *Id*. Thus, section 360k(a) provides that states

and localities may not "establish or continue in effect with respect to a device . . . any requirement" that is "different from or in addition to" certain federal device requirements issued under the MDA. Congress further authorized the FDA to grant to states and localities exemptions from preemption for otherwise preempted requirements. *See* 21 U.S.C. § 360k(b). After notice-and-comment rulemaking, the FDA issued regulations addressing applications for such exemptions, which make clear that the agency understood preemption to apply only to statutes, rules, regulations, or ordinances. *See* 21 C.F.R. § 808.20(c)(1). The regulations also state:

> 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.

Id. § 808.1(d).

B. The Decision In *Medtronic v. Lohr*

The Supreme Court's decision in *Medtronic v. Lohr* is central to resolving this appeal. In *Medtronic*, plaintiffs Lora and Michael Lohr brought suit under Florida law for damages resulting from an allegedly defective class III pacemaker component that the FDA had found "substantially equivalent" to a pre-1976 device and had cleared for marketing under section 510(k). *See supra* p. 5. The complaint alleged

causes of action based on defective design, defective manufacture, and failure to warn. Medtronic moved for summary judgment on the basis of section 360k(a) of the MDA. On review from the United States Court of Appeals for the Eleventh Circuit, the Supreme Court held that none of the Lohrs' claims was preempted by the MDA.

The Majority Opinion. The majority opinion contains three holdings in which all members of the Court concurred: (1) the MDA does not broadly preempt all state-law damages claims against device manufacturers, 518 U.S. at 494, 497, 502 (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, *id*. at 493-94 (majority); *id*. at 513 (O'Connor, J., concurring in part and dissenting in part); and (3) a damages claim premised on state-law duties "equal to, or substantially identical to" requirements imposed under the MDA or FDA regulations is not preempted. *Id*. at 497 (majority); *id*. at 513 (O'Connor, J., concurring in part and dissenting in part).

By a 5-4 margin, the Court held in part V of the majority opinion that the Lohrs' manufacturing-defect and failure-to-warn claims were not preempted, even if they were based on duties that went beyond duties imposed by federal requirements for device manufacturing and labeling. The Court looked to the language of the MDA's preemption provision and the FDA's preemption regulations and noted the

"overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest." *Id*. at 500. The generality of the FDA's manufacturing and labeling regulations applicable to the pacemaker, the Court held, precluded a finding of preemption. Those federal requirements, the Court said, "reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect from potentially contradictory state requirements." *Id*. at 501.

Similarly, the Court stated that the Lohrs' common-law claims were not preempted because they were premised on general state-law duties that do not focus specifically on medical devices. Thus, the Court found, the general duties to use due care in manufacturing and to warn users of potential risks are not the types of requirements that Congress or the FDA feared would impede the FDA's ability to enforce specific federal laws and regulations. Because of their generality, the majority held, such state-law claims are outside the prohibited category of requirements "with respect to" specific devices, within the meaning of section 360k(a). *Id.* at 502.[1]

[1] Speaking for a four-Justice plurality, the lead opinion also relied on the MDA's language and history to conclude that section 360k(a) was not intended to preempt (continued...)

The Concurrence. Justice Breyer filed a concurring opinion stating that, in his view, section 360k(a)'s reference to state-law "requirements" encompasses state-law damages suits. He therefore did not join Parts IV and VI of the plurality opinion (*see supra* note 1) because he was not convinced that MDA preemption of common-law claims would be "rare." *Id*. at 508. He joined fully, however, in the views set forth above and in Part V of the majority opinion, which demanded specificity on both the state and federal sides of section 360k(a)'s preemption analysis. He stated that the applicable FDA requirements related to the Lohrs' claims were not "specific" in any relevant sense and deferred to the FDA's preemption regulation, 21 C.F.R. § 808.1(d), which amplifies the meaning of section 360k(a)'s specificity requirement. 518 U.S. at 505-07. He observed that the language of section 360k(a) reflected basic principles of conflict preemption, but he found no conflict between any federal requirement and any of the Lohrs' claims. *Id*. at 508.

The Partial Dissent. Justice O'Connor dissented in part and concurred in part, joined by the Chief Justice and Justices Scalia and Thomas. She stated that common-law claims can constitute "requirements" under section 360k(a). *Id*. at 509. Although

---

[1](...continued)
most, and perhaps any, damages actions. 518 U.S. at 488-91 (distinguishing *Cipollone v. Liggett Group*, 505 U.S. 504 (1992)). The plurality found it unnecessary to decide whether section 360k(a) reached any damages claims, however, because, under the majority's analysis, none of the Lohrs' claims was preempted. *Id*. at 502.

she agreed with the majority that the Lohrs' design-defect claim was not preempted, Justice O'Connor would have held the manufacturing-defect and failure-to-warn claims preempted to the extent that they sought to impose requirements different from those imposed by the FDA's manufacturing and labeling rules. *Id*. at 513. She agreed with the majority, however, that the Lohrs' state-law manufacturing-defect and failure-to-warn claims were not preempted to the extent that they were based on alleged violations of federal requirements. *Id*.

C. Statement of Facts and Proceedings Below

This action arose from serious injuries caused by a defective Medtronic Evergreen Balloon Catheter. The catheter received marketing approval in 1994 as a supplement to a PMA first approved in 1988. A-109, A-112. Medtronic subsequently sought and received approval to make design changes, A-120, and to revise the product's labeling. A-114, A-126.

In May 1996, Charles Riegel underwent an angioplasty intended to dilate his coronary artery. His physician used the Medtronic catheter, which burst during the angioplasty. Mr. Riegel developed a complete heart block, and he lost consciousness and blood pressure. Advanced life support was needed to sustain him, and he was rushed to the operating room for emergency coronary bypass surgery. A-107.

The Riegels later sued Medtronic, alleging design, labeling, and manufacturing defects and stating causes of action under negligence, strict liability, and express and implied warranty. In January 2002, Medtronic moved for summary judgment on the ground of preemption and to dismiss the express warranty claim for failure to state a claim. In March 2002, the district court granted the summary judgment motion in part, holding that all of the Riegels' claims are preempted except for those based on negligent manufacturing and express warranty. *See* SPA-2.

Following discovery, Medtronic moved for summary judgment on the negligent manufacturing and express warranty claims. The court granted the motion. *See* SPA-20. With respect to the negligent manufacturing claim, the court agreed with the Riegels that, under New York law, the claim could be proved by circumstantial evidence where the actual product at issue is not available as evidence. Here, Mr. Riegel's doctors threw away the balloon after it burst, and therefore the Riegels could not present direct evidence that the balloon had burst due to a manufacturing defect. Medtronic argued that the balloon may have burst because it was inflated beyond its rated burst pressure, or because it was punctured by a spicule of calcium in Mr. Riegel's artery or by the metal stents used during the angioplasty procedure. The Riegels responded that Medtronic's own literature warns that one in each thousand balloons will burst, that inflating the balloon beyond the rated burst pressure was

routine, that the doctor removed any calcium spicules with a rotablator before using the balloon catheter, that his doctor testified in deposition that a stent could not have ruptured the balloon, and that the balloon did not burst longitudinally (which would have been consistent with its design) but radially. Nonetheless, rather than leaving it to a jury to decide whether the Riegels had carried their burden of excluding the causes of the burst not attributable to a manufacturing defect, the court stated that the evidence was insufficient to rule out the possibility that the balloon burst because of a calcium spicule. The court, therefore, granted summary judgment to Medtronic on this claim.

SUMMARY OF ARGUMENT

1. In *Medtronic v. Lohr*, the Supreme Court rejected an attempt by Medtronic to immunize itself from tort liability in a context almost identical to that presented here. Like this case, *Lohr* involved an injury caused by a defective medical device. As in this case, Medtronic argued that the MDA preempted the plaintiffs' state-law damages claims. The Supreme Court's majority opinion rejected Medtronic's argument. Instead, the Court held that for the MDA to preempt a common-law claim, that claim must be developed "with respect to" devices and must correspond to some device-specific federal requirement.

Here, no federal requirement specific to balloon catheters is in effect. Indeed, the company—not the FDA—designed the device. In addition, no state-law claim developed "with respect to" devices is at issue. Rather, the Riegels' claims are based on state-law duties of "general applicability." Accordingly, the Supreme Court's majority opinion in *Lohr* requires reversal of the decision below.

When it enacted the MDA, Congress said nothing about preemption of damages claims. In fact, Congress included in the MDA a provision that confirms the Riegels' view of the scope of MDA preemption. That provision, section 360h(d), entitled "Effect on Other Liability," reveals that, in enacting the MDA, Congress expected that state-law claims would proceed against medical device manufacturers. Medtronic's argument runs contrary to that expectation and should be rejected here.

2. The parties' experts disagreed about why the catheter balloon used during Mr. Riegel's angioplasty burst. This disagreement creates a genuine issue of material fact with respect to the negligent manufacturing claim. The district court thus erred in granting summary judgment on that claim.

STANDARD OF REVIEW

The district court's decision granting summary judgment is subject to *de novo* review by this Court. *HMI Mechanical Sys., Inc. v. McGowan,* 266 F.3d 142, 148 (2d Cir. 2001).

ARGUMENT

I. THE RIEGELS' DAMAGES CLAIMS ARE NOT PREEMPTED.

The main issue in this appeal is whether 21 U.S.C. § 360k(a) preempts common-law damages claims brought against the manufacturer of a defective medical device. Defendant Medtronic maintains that, because the FDA approved its balloon catheter for marketing, it is entitled to sweeping immunity from state-law damages suits, regardless of the merits of the lawsuit or the severity of the injuries. Medtronic's position is contradicted by the Supreme Court's preemption jurisprudence.

Part A below describes the constitutionally based presumption against preemption and explains how that presumption applies to state-law damages claims regarding medical devices. Part B explains why the Riegels' claims are not preempted under *Lohr* on either the federal side or the state side of section 360k(a)'s preemption equation. Part C demonstrates that, in enacting the MDA, Congress did not intend to preempt all common-law claims for PMA devices.[2]

---

[2]This Court has not previously considered the preemptive effect of FDA premarket approval. However, the Court has twice before considered the effect of section 360k(a) on damages claims involving non-PMA devices. Neither decision determines the outcome here because each was rendered prior to the Supreme Court's decision in *Lohr* and is not binding on this Court to the extent that it is inconsistent with *Lohr*. *See Zervos v. Verizon New York, Inc*., 252 F.3d 163, 172 (2d Cir. 2003) ("[W]e have (continued...)

A. The Supreme Court's Preemption Jurisprudence Dictates A Finding Of No Preemption Here.

1. The Presumption Against Preemption

The federal preemption doctrine has its origin in the Supremacy Clause, article VI, clause 2 of the Constitution of the United States, which states:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby,

---

[2](...continued)
often noted that one panel of this court is not bound by a prior panel decision whose 'rationale is overruled, implicitly or expressly, by the Supreme Court.'" (citation omitted)). Nonetheless, both decisions support the Riegels.

First, in *Becker v. Optical Radiation Corp.*, 66 F.3d 18 (2d Cir. 1995), the Court held that the general requirements applicable to experimental devices preempted common-law claims seeking damages of injuries caused by such a device. The decision in *Becker* was based on the experimental nature of the device at issue and on fact that the MDA and FDA regulations specifically about that device "specifically exempt [the device] from the safety and effectiveness standards usually imposed on medical devices" 66 F.3d at 21. In contrast, the balloon catheter at issue here was not experimental and was not exempt from safety and effectiveness standards.

Second, in *LaMontagne v. E.I. Du Pont De Nemours & Co.*, 41 F.3d 846 (2d Cir. 1994), the Court held that section 360k(a) did not preempt damages claims where the device at issue was subject only to the "general controls" of the MDA. *Id*. at 855. This Court agreed with the district court, which had looked to the FDA's regulation, 21 C.F.R. § 808.1(d), and held that a *"state law tort claim is preempted only if . . . the FDA has established regulation specific to the medical device at issue in the particular case. . . ."* *Id*. at 853 (emphasis in original). Although the device in *LaMontagne* was a class II device, the opinion's analysis and its reliance on section 808.1(d) reflect the approach later adopted by the Supreme Court in *Lohr*.

> any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

The Supremacy Clause provides the constitutional authority for the proposition that conflicts between federal and state law are resolved in favor of federal law. *See McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 316, 427 (1819); *Cipollone v. Liggett Group,* 505 U.S. 504, 516 (1992). Preemption is said to be "express" if a federal statute explicitly addresses the domain of state law that is or is not preempted, and "implied" if the structure and purpose of federal law, but not its actual words, preempt state law. *See id*.

The Supremacy Clause is restricted by principles implicit and explicit in the constitutional plan. In particular, the Tenth Amendment provides:

> The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.

In light of this constitutional imperative of federalism, "[c]onsideration under the Supremacy Clause starts with the basic assumption that Congress did not intend to displace state law." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981). A party seeking preemption of state law thus bears a heavy burden, for "[p]reemption of state law by federal . . . regulation is not favored 'in the absence of persuasive reasons—either that the nature of the regulated subject matter permits no other

conclusion, or that Congress has unmistakably so ordained.'" *Chicago & N. W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 317 (1981) (quoting *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142 (1963)). The strong presumption *against* preemption may be overcome only by "clear and manifest" congressional intent to the contrary. *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 715 (1985); *see Hawaiian Airlines, Inc. v. Norris*, 512 U.S. 246, 252 (1994); *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 605, 611 (1991). 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) (quoting *United States v. Bass*, 404 U.S. 336, 349 (1971)); *see also* Grey, *Make Congress Speak Clearly: Federal Preemption of State Tort Remedies*, 77 B.U. L. Rev. 559, 627 (1997) ("Our system of federalism demands that interference with states' policy decisions to give their citizens tort remedies should be the product of judgment and careful balancing, rather than an unintended result of congressional inattention or imprecision."); *cf. Atascadero State Hosp. v. Scanlon*, 473 U.S. 234, 238-46 (1985) (demanding unambiguous statement to abrogate state authority in analogous Eleventh Amendment federalism jurisprudence).

Moreover, the presumption against preemption is even stronger where "Congress [has] legislated . . . in a field which the States have traditionally occupied, [involving] the historic police powers of the States." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). In other words, the presumption is "that state and local regulation of health and safety matters can constitutionally coexist with federal regulation" because "the regulation of health and safety matters is primarily, and historically, a matter of local concern." *Hillsborough County*, 471 U.S. at 716, 719. This presumption applies where a defendant is seeking preemption of state tort remedies 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.

Where, as here, the federal regulatory scheme does not itself provide a damages remedy, the Supreme Court has ascribed preemptive intent to Congress only in the most compelling circumstances. *See English v. General Elec. Co.*, 496 U.S. 72, 87-90 (1990); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984); *see also Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002) ("perfectly rational for Congress not to pre-empt common-law claims" when preempting state regulatory law because common-law claims "perform an important remedial role in compensating accident victims"). This interpretive principle is important here because Medtronic's broad

reasoning, if accepted by the Court, would leave injured patients without any means of redress for injuries caused by a wide array of medical devices.

The foregoing anti-preemption precepts are not mere precedential idiosyncrasies. Rather, they are deeply embedded in the "federal-state balance" that is fundamental to the constitutional plan. *Hillsborough County*, 471 U.S. 707; *Jones*, 430 U.S. at 525. Thus, the Supreme Court's Supremacy Clause jurisprudence is "an acknowledgment that the States retain substantial sovereign powers under our constitutional scheme, powers with which Congress does not readily interfere." *Gregory v. Ashcroft*, 501 U.S. 452, 461 (1991).

Accordingly, to the extent that the answer to the question whether 21 U.S.C. § 360k(a) preempts the common-law claims at issue here is ambiguous, that ambiguity must be resolved in the Riegels' favor.

2. Deference To Agency Expertise In The Preemption Context

One additional principal is important to the resolution of this case. In the preemption context, as in others, the views of an agency to which Congress has delegated regulatory authority are entitled to substantial deference where those views have been developed through notice-and-comment rulemaking. *Hillsborough County*, 471 U.S. at 714-15 (citing *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 842-45 (1984)); *see United States v. Mead Corp.*, 533 U.S.

218, 228 (2001). Here, the MDA has been implemented through a considerable body of regulations that narrowly construe the MDA's preemptive scope. *See* 21 C.F.R. § 808.1(d); *see also id*. § 808.20(c)(1). These regulations are entitled to deference. *See Lohr*, 518 U.S. at 496-97, 498-99 (majority opinion); *see id.* at 505-06 (Breyer, J., concurring).[3]

B. Under *Lohr*, The Riegels' Damages Claims Are Not Preempted.

---

[3]In contrast, statements contained in amicus briefs are not entitled to deference. *See Mead Corp*., 533 U.S. at 228; *Christensen v. Harris*, 529 U.S. 576, 587 (2000). This principle is particularly important here, where the government twice filed amicus briefs in the United States Supreme Court arguing against preemption, but then disavowed its own arguments and filed a court of appeals amicus brief taking the opposite position. *Compare* Br. of U.S. as Amicus Curiae in *Smith Industries Medical Systems v. Kernats*, S. Ct. No. 96-1407, at 14-18 (filed Dec. 1997), *and* Br. of U.S. as Amicus Curiae in *Medtronic v. Lohr*, S. Ct. No. 95-754, 1996 WL 118035 (filed Mar. 15, 1996), *with* Br. of U.S. as Amicus Curiae in *Horn v. Tharatec, Inc*., 3d Cir. No. 02-4597 (filed May 14, 2004).

The government's position in the *Horn* amicus brief contradicts not only the argument made in its two Supreme Court briefs, but also the FDA's previous construction of its own regulation, 21 C.F.R. § 808.1(d), to which the Supreme Court majority gave substantial weight in *Lohr*. *See* 518 U.S. 470, 496-97, 498-99 (1996); *id.* at 505-06 (Breyer, J., concurring). For this reason, "[a]lthough generally 'an agency's construction of its own regulations is entitled to substantial deference,' *Lyng v. Payne,* 476 U.S. 926, 939 (1986), no such deference is appropriate here." *Norfolk S. Ry. Co. v. Shanklin*, 529 U.S. 344, 356 (2000); *see Mead Corp*., 533 U.S. at 228 (degree of deference due to government depends on, among other things, consistency and formality of government's position); *cf. Maislin Indus. v. Primary Steel, Inc.,* 497 U.S. 116, 131 (1990) ("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.").

In holding that section 360k(a) did not preempt the plaintiffs' damages claims in *Medtronic v. Lohr*, the Supreme 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 section 510(k), the Court's analysis applies as well to PMA devices. Here, the absence of both a device-specific federal requirement and a counterpart state requirement shows that section 360k(a) does not preempt the claims alleged here.[4]

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

a. Although the criteria for granting PMA are more demanding than the marketing approval criteria at issue in *Lohr*, *see* 518 U.S. at 479 (explaining differences), they are no more "specific." Both processes apply to class III devices

[4] Although part of the *Lohr* decision was joined only by a four-Justice plurality, the portion quoted above and all other aspects of *Lohr* relied on in this Argument are from the Court's *majority* opinion, unless otherwise stated.

generally, *id.*, and neither specifies how a product is to be designed, manufactured, or labeled. The same good manufacturing practices regulations, 21 C.F.R. § 820.1, and prescription device labeling regulations, *id.* § 801.109, are applicable to both PMA and 510(k) devices. And the PMA process contains no rules similar to the hypothetical FDA-required two-inch hearing-aid wire discussed in Justice Breyer's *Lohr* concurrence. *See* 518 U.S. at 504. It demands that *all* PMA devices have a "reasonable assurance" of safety and effectiveness, 21 U.S.C. § 360e(d)(2), but it does not "require"—to use the language of section 360k(a)—any *specific* design. Thus, as *Lohr* noted in referring to the FDA's labeling and manufacturing rules, the PMA process imposes no "specific mandate on manufacturers or producers." 518 U.S. at 501.

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). 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 Medtronic device at issue in *Lohr*, *see* 21 C.F.R. Part 814 (PMA procedures), the federal criteria for PMAs are typically the generally applicable threshold standards set out in the MDA and FDA regulations. *See id.* § 814.45 (grounds for denying a PMA). The manufacturer is responsible for submitting an application demonstrating that the proposed medical

device satisfies federal minimum standards. *See*, *e.g.*, *id*. at Part 814. And where, as here, the FDA has not set out specific federal requirements for the particular device, the manufacturer may select any design, manufacturing, and labeling features that will satisfy the general minimum standards of the MDA and regulations. Unless the FDA imposes specific substantive requirements on the device in the course of the review process, the PMA does not represent a specific federal requirement that preempts state common law requirements.

To be sure, the FDA can impose specific federal requirements for a class III device in addition to the general federal criteria. *See id*. § 861.1(b)(3) (providing that FDA may issue performance standards as condition of granting PMA); *see*, *e.g.*, *id.* § 801.430 (specific labeling and testing requirements for tampons), *id*. § 886.4392 (design specifications for laser devices). With respect to the device at issue here, however, it has not done so.

Likewise, the FDA had imposed no device-specific requirements on the PMA device at issue in *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999), and the Eleventh Circuit accordingly found no preemption. The court focused on the "ordinary construction of the language of section 360k, as well as the use of the term 'requirement' in the broader statutory context and its interpretation in the FDA's regulation," to explain that preemption under § 360k(a) required "imposition of some

identifiable precondition that applies to the device in question." *Id.* at 1374. As the Eleventh Circuit noted, one cannot conduct the "careful comparison" between the relevant state and federal requirements, as *Lohr* instructs, unless one can first identify the precise federal requirement at issue. The court, however, was "[unable] to ascertain any such identifiable requirement from the FDA's approval of" the device at issue in that case. *Id*. at 1374-75; *accord Weiland v. Telectronics Pacing Sys.*, 721 N.E.2d 1149, 1152-53 (Ill. 1999); *Haidak v. Collagen Corp*., 67 F. Supp. 2d 21, 24 (D. Mass. 1999); *see also Lakie v. SmithKline Beecham*, 965 F. Supp. 49, 54 (D.D.C.1997) ("Premarket approval is supposed to benefit consumers, not create a rose garden, free from liability, for manufacturers.") (citation omitted); *but see*, *e.g.*, *Horn v. Thoratec Corp*., 376 F.3d 163, 169 (3d Cir. 2004) (PMA preempts damages claims); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 911 (7th Cir. 1997) (same).

FDA regulations reinforce the conclusion that PMA does not impose device-specific requirements sufficient to preempt the Riegels' claims. In defining what types of state and local requirements are subject to preemption, FDA regulations state:

> 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) (emphasis added). When it promulgated this regulation, the FDA set forth its interpretation of section 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. 18661, 18662 (1978) (quoting § 360k(a), emphasis in Fed. Reg.). 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, 30385 (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 upon device-specific 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).

b. Although federal law required Medtronic to obtain PMA before marketing its balloon catheter, neither the FDA nor the MDA imposed any specific requirement on 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. Design specifications are applicable to a device as a result of the decision of the manufacturer to introduce the device into the market with a design of the manufacturer's choosing. *Cf. American Airlines v. Wolens*, 513 U.S. 219, 228-29 (1995) (preemption clause of Airline Deregulation Act does not shelter airlines from lawsuits "seeking recovery solely for the airline's alleged breach of its own, self-imposed undertakings"); *Cipollone*, 505 U.S. at 526 (plurality opinion) ("a common law remedy for a contractual commitment voluntarily undertaken should not be regarded as a 'requirement . . . *imposed under State law*' within the meaning of the" Cigarette Labeling Act) (ellipsis and emphasis in original).

The impossibility of comparing a federal requirement and a counterpart state requirement shows that section 360k(a) does not preempt the claims alleged here. If the FDA issued a performance standard requiring balloon catheters to meet certain

specifications, *see* 21 C.F.R. § 861.1(b)(3), a defective design claim that challenged the safety of the device could be analyzed in terms of whether the claim was "different from or in addition to" those specifications. *See Lohr*, 518 U.S. at 504 (Breyer, J., concurring); *compare* 21 C.F.R. § 801.430 (specific warning requirements for tampons). That scenario would still present a question as to whether the state-law duties upon which the plaintiff relied were sufficiently specific to trigger preemption under section 360k(a) and whether the common-law design defect claim constituted a state requirement related to the safety or effectiveness of a medical device. At least there, however, a court could compare the federal design requirement to the state-law theory underlying the damages claim.

The lack of specific federal requirements as to the design (or any other aspect) of Medtronic's device is underscored by the FDA's approval letter. That letter imposes no specific requirements, *see* App. A-109, *see also* App. A-112, A-114, A-120, A-126, and the attached "Conditions of Approval" is an FDA form document that applies to PMA products generally. *See* App. A-110; *see also* App. A-116, A-122. The document says nothing specific to balloon catheters or to Medtronic's product in particular. It does not even mention them. As the Eleventh Circuit observed in *Goodlin*:

> The "Conditions of Approval" document enclosed with the letter that noted the FDA's approval of the [specific pacemaker lead] 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.

167 F.3d at 1377.

Moreover, although FDA regulations required Medtronic to obtain FDA authorization before changing the design of its balloon 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 at issue there, contending that the need to submit a new application before changing the design of its 510(k) device constituted a preemptive "requirement."[5] Yet the Supreme Court unanimously rejected the

[5] *See* Brief for Petitioner Medtronic in *Medtronic v. Lohr*, S. Ct. Nos. 95-754, 95-886, 1996 WL 88789 at *27-*28 (Mar. 1, 1996); Reply Brief for Petitioner Medtronic in *Medtronic v. Lohr*, S. Ct. Nos. 95-754, 95-886, 1996 WL 180309, *13-*14 (Apr. 16, 1996).

argument that the design-defect claim was preempted. *Lohr*, 518 U.S. at 492-94 (majority); *id.* at 513 (O'Connor, J., concurring in part and dissenting in part).

c. The Riegels' failure-to-warn claim is indistinguishable from the failure-to-warn claim in *Lohr*. For two reasons in addition to those discussed above, that claim is not preempted.

First, the only FDA regulation governing the substance of the catheter's 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. And as the Supreme Court noted, the FDA's preemption regulations strongly support the view that general federal labeling requirements cannot preempt state-law failure-to-warn claims. 518 U.S. at 498-99 (citing 21 C.F.R. § 808.1(d)). Consistent with the Reigels' (and the Supreme Court's) view that general labeling regulations do not themselves have preemptive effect, the agency deemed state hearing aid regulations preempted only after it promulgated regulations specifically addressing labeling of hearing aids. 43 Fed. Reg. 18662; *see id*. § 801.420. Similarly, FDA regulations provide that states and localities may prohibit the manufacture of mislabeled devices unless the FDA has established a "specific labeling requirement for a specific device" that conflicts with the state or local requirement. *Id*. § 808.1(d)(6)(ii); *see id*. § 801.430 (device-specific labeling requirements for tampons).

Second, under 21 C.F.R. §§ 814.39(d)(1) and (2), manufacturers of PMA devices may make certain labeling, quality control, and manufacturing changes to enhance product safety, *without* pre-approval from the FDA. For example, manufacturers may add or strengthen contraindications, warnings, precautions, or information about adverse reactions. *Id*. § 814.39(d)(2)(i). The Supreme Court in *Lohr* specifically cited those regulations as further support for the holding that claims that parallel federal requirements are not preempted. *See* 518 U.S. at 497 n.16. In light of section 814.39(d), the Riegels' failure-to-warn claim—which seeks to enforce a state-law duty that obligated Medtronic to provide adequate warnings about use of its catheter—is not "different from, or in addition to" the federal requirements within the meaning of section 360k(a).

2. The Riegels' Claims 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 balloon catheter is dispositive under the *Lohr* analysis, this Court need not reach the state side of the preemption analysis. The district court, however, held that the MDA preempts the Riegels' claims in part because, after concluding that PMA imposes preemptive requirements, the court did not address whether the Riegels' damages claims are general or device-specific. Instead, the court simply stated that allowing

the device "to be subjected to state-law tort claims would impose state law requirements on the Defendant that would conflict with the federal requirements already applicable to the device." App. SPA-13. Thus, the district court skipped an essential step in the analysis, for consideration of whether the claims are based on state-law requirements of general applicability is necessary to determining whether the claims would impose requirements "different from or in addition to the PMA process." *See Lohr*, 518 U.S. at 502; *Oja v. Howmedica*, 111 F.3d 782, 789 (10th Cir. 1997); *Niehoff v. Surgidev,* 950 S.W.2d 816, 822 (Ky. 1997); *Walker v. Johnson & Johnson Vision Prods., Inc.*, 552 N.W.2d 679, 686 (Mich. App. 1996); *Mears v. Marshall*, 944 P.2d 984, 993-95 (Ore. App. 1997); *Wutzke v. Schwagler*, 940 P.2d 1386, 1391-92 (Wash. App. 1997); *Baird v. American Med. Optics*, 693 A.2d 904, 909-10 (N.J. Super., App. Div. 1997), *modified and remanded,* 713 A.2d 1019 (N.J. 1997); *Kernats v. Smith Indus. Med. Sys.*, 669 N.E.2d 1300, 1309 (Ill. App. 1996) ("plaintiffs' claims emanate from general common-law duties and are not the sort of state requirements that section 360k was intended to preempt"); *Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763, 771-72 (Cal. App. 1996).

Having failed to follow the approach prescribed by *Lohr* and FDA regulations, the district court reached the wrong conclusion. In fact, the principles of New York law on which the Riegels rely, like the common-law duties of Florida law on which

the Lohrs relied, are those of general applicability, outside the reach of section 360k(a). *See Barban v. Rheem Textile Sys., Inc*., 2005 WL 387660, *7-*9 (E.D.N.Y. 2005) (reviewing negligence and strict liability standards for design defect and failure-to-warn claims under NY law).

a. Relying on the text of 21 U.S.C. § 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 the kinds of laws targeted for preemption by the MDA. Thus, the Court held that the general duties to use due care in manufacturing and to warn users of potential risks are outside the prohibited category of requirements "with respect to" specific devices, within the meaning of section 360k(a):

> [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. These state requirements therefore escape pre-emption, not because the source of the duty is a judge-made common-law rule, but rather because their

> generality leaves them outside the category of requirements that § 360k envisioned to be "with respect to" specific devices such as pacemakers. As a result, none of the Lohrs' claims based on allegedly defective manufacturing or labeling are pre-empted by the MDA.

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

Although the above-quoted paragraph addresses manufacturing and duty-to-warn claims for non-PMA devices, its rationale—that the state-law duties are general duties to use due care or to inform—applies fully to claims concerning PMA products. As in *Lohr*, the general state common-law requirements that the Riegels' seek to enforce were not developed "with respect to" medical devices. Rather, their claims are "predicated upon . . . general dut[ies] applicable to every manufacturer," such as the duty to use due care and the duty "to inform users and purchasers of potentially dangerous items of the risks involved in their use." *Oja,* 111 F.3d at 789 (even where medical device was subject to specific federal requirement, no preemption where state-law duty on which plaintiff relied was general and did not relate specifically to devices); *accord Niehoff*, 950 S.W.2d at 822 (no preemption of claims regarding PMA device because "strict liability case law and statutes [on which plaintiff relies] are laws of general applicability to all products and fall beyond the scope of federal preemption under § 360k"); *Armstrong,* 57 Cal. Rptr. 2d at 771-72 (same). As was true of the common-law duties on which the Lohrs relied, nothing

about the common-law duties at issue here is limited to the specific device at issue or even to medical devices generally.

b. The FDA's views on the preemptive scope of section 360k(a)—established in a formal rulemaking over 20 years ago—are flatly at odds with the result reached by the court below. The agency's regulations provide that section 360k(a) "does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (*e.g.*, requirements such as general electrical codes, and 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). In this case, as noted above, the Riegels' negligence and strict liability claims are indisputably based on product liability theories "of general applicability . . . relat[ing] to other products in addition to devices." *See also Lohr*, 518 U.S. at 498 n.18 (quoting 21 C.F.R. § 808.1(d), and noting that "FDA's narrow understanding of the scope of § 360k(a) is obvious from the full text of the regulation").

c. The district court referred to an example from Justice Breyer's concurrence, which posited a situation in which an FDA regulation required a two-inch hearing aid wire, but a jury found state-law liability based on a manufacturer's failure to use a one-inch wire. App. SPA-13. However, Justice Breyer's example is inapposite here

because, again, the balloon catheter was not subject to any such specific federal design requirement, nor, at this stage of the litigation, is there reason to assume that a jury verdict would impose a device-specific state requirement.

Like the district court, several other courts have misconstrued Justice Breyer's concurrence to support decisions finding preemption of state-law claims. *See*, *e.g.*, *Horn*, 376 F.3d at 174. In fact, however, the concurrence supports the Riegels and is consistent with the *Lohr* majority on this point. *See id.* at 183-84 (dissent). State damages claims are ordinarily premised on duties of general applicability, 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 2258, or to use "reasonable care" in the design or manufacture of a product. Nonetheless, a state's product liability law could, in some instances, require plaintiffs to prove tort claims with the kind of specificity demanded by section 360k(a). For instance, under *Lohr*, a jury instruction allowing the imposition of state-law liability on the ground that a medical device did not meet a particular state-created design, manufacturing, or warning specification might meet section 360k(a)'s specificity requirement. Similarly, a negligence per se claim premised on violation of a state statutory requirement specifically applicable to medical devices—for instance, a state labeling requirement for hearing aids—might be preempted if it imposed a duty different from that imposed by an FDA requirement

on the same subject. Indeed, this analysis of section 360k(a) mirrors that of Justice Breyer's concurrence, where he said that a *specific* federal regulation demanding a two-inch hearing-aid wire would preempt a common-law claim premised on a *specific* state-law requirement for a one-inch wire. *Id*. at 504 (Breyer, J., concurring). Thus, this Court need go no further than *Lohr* to hold that the Riegels' claims are not preempted because those claims are premised on state-law duties of general applicability.

* * * * *

Because the FDA has issued no device-specific regulations regarding the design, manufacturing, or labeling of balloon catheters, and because the Riegels' state-law claims are based on laws of general applicability, section 360k(a) does not preempt the Riegels' claims.

C. In Enacting The MDA, Congress Recognized The Continuing Validity Of Common-Law Claims.

This Court need not reach the issue whether section 360k(a) ever preempts common-law claims because, as discussed above, the need under section 360k(a) for specificity—identified by both the Supreme Court majority and the FDA—on both the federal and the state sides of the preemption equation is not satisfied here. Nonetheless, the Supreme Court's decision in *Sprietsma* suggests that the MDA

preempts no state-law damages claims at all and demonstrates that the term "requirement" in a preemption provision does not always encompass state damages actions, but rather, like all statutory language, derives its meaning from context. In *Sprietsma*, the Court held that the preemption provision of the Federal Boat Safety Act, 46 U.S.C. § 4306, which preempts certain state laws, regulations, or standards "imposing a *requirement*," does *not* reach common-law claims. *See* 537 U.S. at 59, 63.

The district court's decision finding preemption of the Riegels' claims is inconsistent with the Supreme Court's repeated admonition that "a federal statute will be read to supersede a State's historic powers only if this is 'the clear and manifest purpose of Congress.'" *Hawaiian Airlines*, 512 U.S. at 252. In enacting the MDA, Congress made no mention whatsoever of a desire to preempt common-law claims. *See* House Report 4, 45-46 (referring only to potential for preemption of state and local laws and regulations); *see also Silkwood*, 464 U.S. at 251 ("Congress would [not], without comment, remove all means of judicial recourse for those injured by illegal conduct.").

Congress' silence on the topic of preemption of common law is particularly telling because the impetus for the MDA was "several highly publicized incidents involving defective medical devices, particularly the Dalkon Shield intrauterine

device." *Goodlin*, 167 F.3d at 1378 (citing *Lohr*, 518 U.S. at 475-77). Congress was "acutely aware of ongoing product liability litigation" regarding these incidents, *Lohr*, 518 U.S. at 491 (plurality opinion), which makes "its failure even to hint at [preemption of traditional common-law remedies] . . . spectacularly odd." *Id.* Thus, 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*, 167 F.3d at 1378 (emphasis in original). "It would have been inconsistent for the same Congress that enacted these sweeping reforms, intending to make a potentially dangerous industry safer for patients by blocking the admission of defective devices to the market, then to preempt product liability suits when those devices caused injury." *Id.*

This conclusion is consistent with other decisions of the Supreme Court noting that Congress can, and does, rationally distinguish state positive law and common law, preempting the former but not the latter. *See Sprietsma*, 537 U.S. at 64 (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.") (citing *Silkwood v. Kerr-McGee Corp.*, 464 U.S. at 251);

Cipollone, 505 U.S. at 518 ("there 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."); *Silkwood*, 464 U.S. at 256 (despite federal preemption of state regulatory authority, state-law punitive damages awards not preempted even though "regulatory in the sense that a nuclear plant will be threatened with damages liability if it does not conform to state standards").

The Court should also be "loath to infer a tacit trade-off between regulation and liability [because] it appears that even the regulated industry was unaware of the purported bargain until relatively late in the day." *Goodlin*, 167 F.3d at 1381. More specifically, "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." *Id.* 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.*

Moreover, Congress included in the MDA a provision that assumes that state-law damages actions would co-exist with federal regulation of devices. Under section 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 unreasonable risks. "Of vast significance" to the preemption analysis, *Mulligan v. Pfizer, Inc.*, 850 F. Supp. 633, 636 (S.D. Ohio 1994), is subsection (d) of section 360h, entitled "Effect on Other Liability." Subsection (d) 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, section 360h(d) "specifically contemplates state law liability and damages" against manufacturers of medical devices, and "unambiguously prohibits a finding of liability pursuant to section [360h](b) and (c) from shielding a defendant from state liability and damages. . . ." *Mulligan*, 850 F. Supp. at 636. Considered in conjunction with the language of section 360k, the FDA's regulations, and the strong presumption against preemption, section 360h(d) is powerful evidence that the statute contemplated that state-law damages actions would co-exist with MDA regulation. *See Goodlin*, 167 F.3d at 1379 (section 360h(d) "casts real doubt on the idea that

Congress intended to preempt state tort liability for all PMA approved devices"); *Mulligan*, 850 F. Supp. at 636 & n.1 (denying motion for summary judgment on preemption grounds).

Under Medtronic's theory, the Riegels have no remedies at all. Consistent with the presumption against preemption, the Court should be especially "reluctant to conclude that Congress sought to remove all remedies available to the very class of persons that it sought to protect when it enacted the MDA." *Goodlin*, 167 F.3d at 1379.

II. GENUINE ISSUES OF MATERIAL FACT EXIST AS TO WHY THE BALLOON CATHETER BURST.

Addressing Medtronic's motion for summary judgment on the negligent manufacturing claim, the parties advanced different arguments about why the Medtronic balloon may have burst. Medtronic's experts blamed the inflation pressure, calcium spicules, and stents. Mr. Riegels' doctor disputed these theories, and his expert blamed a defect in the balloon. Given the disagreement, the district court erred by denying summary judgment, rather than allowing a jury to decide the factual issues.

As the district court recognized, when the actual product used is not available for examination, a manufacturing defect can be proven by circumstantial evidence.

Speller v. Sears, Roebuck & Co., 760 N.Y.S.2d 79, 81 (2003), *cited at* SPA-25. In such a case, the plaintiff must show that the product did not perform as intended and must exclude all causes for the product's failure that are not attributable to the defendant. *Id*. at 81-82. Here, as the district court stated, "[t]here is no question that the balloon failed." SPA-26. The question is why it failed.

The Riegels' expert Dr. Milo stated in an affidavit his conclusion that the balloon burst *radially*. App. A-635, A-637-38. If his conclusion is correct, then causes of the balloon's failure not attributable to Medtronic would be excluded because Medtronic's theories all assume a *longitudinal* failure. Moreover, Mr. Riegel's doctor addressed and refuted each one of Medtronic's arguments about proper use of the product, removal of calcium spicules, and stents, App. A-639-44, and Dr. Milo's report addressed and disagreed with Medtronic about inflation of the balloon and removal of calcium. App. A-637-38.

The district court decided that Medtronic's theories were more persuasive than the Riegels', but that decision was not his to make. It was a decision for a jury. Because the parties' dispute on this issue was one of fact, not of law, the court erred in granting summary judgment on the negligent manufacturing claim. *Anderson v. Liberty Lobby*, 477 U.S. 242, 248 (1986) ("[S]ummary judgment will not lie if the

dispute about a material fact is genuine, that is, if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.").[6]

CONCLUSION

For the reasons stated above, the decisions of the district court holding that the Riegels' design and labeling claims are preempted and that the factual disputes regarding the Riegels' negligent manufacturing claim should not be submitted to a jury should be reversed.

Respectfully submitted,

Allison M. Zieve
Brian Wolfman
Public Citizen Litigation Group
1600 20th Street, NW
Washington, DC 20009
(202) 588-1000

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

Counsel for Appellants

March 7, 2005

[6]Citing *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993), the district court disregarded Dr. Milo's conclusions. Although the court may properly act as a gatekeeper in deciding whether proferred expert testimony is presented to a jury, *Daubert* was not a proper basis for the court's decision here because the court did not hold a *Daubert* hearing or otherwise consider the four *Daubert* factors.

RULE 32(a)(7)(C) CERTIFICATION

Using the word count provided on our word processing system, I hereby certify that the above brief contains 10,261 words.

_____

Allison M. Zieve

March 7, 2005

RULE 28(f) ADDENDUM

of principal statutory and regulatory provisions involved

PRINCIPAL STATUTORY 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 [requiring a manufacturer to repair, replace, or provide reimbursement for expenses relating to an unsafe device] 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.

PRINCIPAL REGULATORY PROVISION INVOLVED

21 C.F.R. § 808.1(d) provides in part:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act [21 U.S.C. § 360k(a)] because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:
>
> (1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices. ...
>
> (6)...(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.

CERTIFICATE OF SERVICE

I hereby certify that on this 7th day of March, 2005, I served the foregoing BRIEF OF APPELLANTS CHARLES AND DONNA RIEGEL on appellee Medtronic, Inc. by causing two true and correct copies thereof to be placed in the United States mail, first-class postage prepaid, addressed as follows:

Richard Bakalor
Quirk and Bakalor
845 Third Avenue, 15th floor
New York, New York 10022

_____
Allison M. Zieve