No. 02-4597

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

BARBARA HORN,

Plaintiff-Appellant,

v.

THORATEC CORP.,

Defendant-Appellee.

On Appeal from the United States District Court
for the Middle District of Pennsylvania

BRIEF OF APPELLANT BARBARA HORN

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STATEMENT OF SUBJECT MATTER AND APPELLATE JURISDICTION

This appeal is from a decision of the district court granting summary judgment to defendant Thoratec Corp. The district court had jurisdiction under 28 U.S.C. § 1332 based on diversity of citizenship. App. A-32. The district court's judgment was entered on November 7, 2002, and disposed of all claims of all parties. App. A-7. Plaintiff Barbara Horn filed her notice of appeal on December 6, 2002. App. A-30. This Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUE

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

This issue was raised in Defendant's motion for summary judgment dated February 22, 2001, which was opposed by Ms. Horn in a memorandum in opposition filed on March 30, 2001. The district court ruled on this issue in a memorandum and order filed on November 7, 2002. App. A-7, A-9.

STATEMENT OF THE CASE

This appeal involves a suit to recover for injuries suffered by Daniel Horn, the deceased husband of plaintiff Barbara Horn, from a medical device called a left

ventricular assist device ("LVAD") sold by defendant Thoratec Corporation, formerly known as Thermo Cardiosystems, Inc. ("TCI").[1] Ms. Horn's claims are based entirely on Pennsylvania common law. On TCI's 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 all of Ms. Horn's claims. App. A-9-10.

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 TCI's LVAD and Mr. Horn'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

[1] Throughout most of the proceedings below, the defendant was known as TCI. For convenience, this brief will refer to the defendant as TCI.

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); *see* 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 its manufacturer can show that the device is "substantially equivalent" to either a "grandfathered" pre-MDA 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* 21 C.F.R. § 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 premarket approval 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, 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 and local regulatory measures. *Id*. Thus, section 360k(a) provides that states 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). 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)(i).

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* pp. 4-5. 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.[2]

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

[2] 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 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.

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 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 injuries caused by a defective TCI heart pump that was implanted into Ms. Horn's deceased husband, Daniel Horn.

The Heart Pump: TCI's HeartMate LVAD is used in patients for temporary circulatory support, as a bridge to heart transplantation. The components of the heart pump are connected to one another in several places by screw rings or other threaded connections. Because of the motion of the device within the body after implantation,

the screw rings, as originally designed, and the threaded connections could (and on occasion during investigational trials did) loosen, causing a disconnection of the blood pathway and, in all likelihood, the death of the patient. To try to address this danger, TCI used sutures, installed either at the factory or by the surgeon during the implant procedure, to tie the screw rings to other parts of the device. App. A-63-64 (¶ 11), A-223 (¶ 6). One of those sutures helped to secure the outlet elbow to the housing of the pump. That suture is tied at one end to an eyelet on a particular conduit and on the other end through a small hole on the screw ring. After the parts are screwed together and tightened, the eyelet and hole for the suture—and thus the suture—can wind up on top of, to the side of, or behind the screw ring. App. A-225.

In March 1992, TCI submitted an application for premarket approval to the FDA. The PMA application included a description of the device and its components, summaries of all pre-clinical testing, results and analyses of clinical studies, a description of the manufacturing process, labeling information, and proposed directions for use. App. A-64 (¶ 13). Because the original submission lacked information necessary to properly evaluate the safety and effectiveness of the device, the FDA, in January 1993 and again in February 1994, notified TCI that the application was not approvable. App. A-149, A-167. The FDA also twice informed TCI that the information provided about the manufacturing process was inadequate.

App. A-204, A-209. TCI provided the necessary information, and the FDA approved the HeartMate LVAD for marketing in September 1994. App. A-213.

TCI altered the design and labeling of the heart pump several times after it received PMA. For example, in August 1995, following reports that a tube component had already broken twice during the short time that TCI had marketed the device, TCI submitted to the FDA a PMA "Supplement," seeking approval for a redesign of that component, which the FDA granted. App. A-235, A-240. In December 1995, following reports of malfunctions involving blood leakage and easy separation of components, TCI submitted a Supplement for a change in the design of certain components used in the inflow and outflow valve conduits and in the outflow graft conduit. App. A-244. In May 1997, TCI submitted a Supplement to redesign the drive line, based on failures that occurred after the 1995 redesign. App. A-249. In March 1999, the company submitted a Supplement regarding the "directions for use," to instruct surgeons to add an additional suture to prevent disconnection of the outflow valve assembly. A- 259. And in November 1999, TCI submitted a Supplement concerning a redesign to incorporate self-locking screw rings that could not loosen after installation and required no sutures. App. A-276.

Daniel Horn's Death and Proceedings Below: A HeartMate LVAD was implanted in Mr. Horn in January 1998. At that time, TCI's device used sutures, not

self-locking rings, to secure the screw rings. The pump implanted in Mr. Horn broke on May 3, 1998, when a factory-installed suture wore through, causing the screw ring that connects the outlet elbow to the body of the pump to loosen. App A-33-35. The complaint alleges that the suture ran across the top of the screw ring because the hole wound up in that position when the screw ring was tightened. App. A-35-36. This placement 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. His organs were donated for transplant, and he was pronounced dead on May 8, 1998. App. A-35.

On April 28, 2000, Barbara Horn brought this action against TCI. The complaint alleges causes of action based on strict liability, negligence, and breach of warranty, for defective design and manufacture and for failure to warn. App. A-32. TCI moved for summary judgment, arguing principally that section 360k(a) of the MDA expressly preempts damages claims related to devices that have received premarket approval from the FDA and, more briefly, that the MDA impliedly preempts such claims. App. A-57. In granting TCI's motion, the district court reviewed the Supreme Court's decision in *Medtronic*. The court held that the outcome should be different here because, unlike the pacemaker lead at issue in *Medtronic*, TCI's LVAD had received premarket approval. The court thus held that premarket

approval preempted all claims based on allegations that the heart pump was defectively designed, manufactured, or labeled, App. A-29; and it entered judgment for TCI. App. A-7.

RELATED CASES AND PROCEEDINGS

This case has not previously been before this Court. Plaintiff is not aware of any related cases or proceedings.

SUMMARY OF ARGUMENT

In *Medtronic v. Lohr*, the Supreme Court rejected an attempt by a medical device manufacturer to immunize itself from tort liability in a context almost identical to that presented here. Like this case, *Medtronic* involved an injury caused by a defective heart device. As in this case, the defendant company argued that the MDA preempted all of the plaintiffs' state-law damages claims. The Supreme Court's majority opinion rejected that 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 state-law claim developed "with respect to" devices is at issue. Rather, Ms. Horn's claims are based on state-law duties of "general applicability." And no federal requirement specific to heart pumps is in effect. Indeed, the company—not the FDA—designed

TCI's heart pump. Accordingly, the Supreme Court's majority opinion requires reversal of the decision below.

In addition, *Medtronic* gave "substantial weight" to the FDA's interpretation of the MDA's preemption provision. Since then, the FDA has reiterated its long-standing view that the statute does not preempt state-law claims like those at issue here. This view, based on sound statutory interpretation and confirmed by *Medtronic*, also reflects the agency's recognition of its own limitations. As the FDA has stated, its general regulatory review and approval processes cannot guarantee the safety of medical devices.

Finally, when it enacted the MDA, Congress said nothing about preemption of damages claims. In fact, Congress included in the MDA a provision that confirms Ms. Horn's 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. TCI's argument runs contrary to that expectation and should be rejected here.

STANDARD OF REVIEW

The district court's decision on summary judgment that Ms. Horn's state-law claims are barred as a matter of law is subject to *de novo* review by this Court. *Michael v. Shiley, Inc*., 46 F.3d 1316, 1321-22 (3d Cir. 1995).

ARGUMENT

The 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 TCI maintains that, because the FDA approved the heart pump 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. TCI's position is contradicted by the Supreme Court's preemption jurisprudence.

Although this Court previously considered the preemptive effect of FDA premarket approval in *Michael v. Shiley*, 46 F.3d 1316 (3d Cir. 1995), that decision was rendered prior to the Supreme Court's decision in *Medtronic*. *Michael* held that PMA preempted claims based on strict liability, negligence, implied warranty, or fraud on the FDA, but not claims based on breach of express warranty or fraud in advertising and promotion. That decision is not binding on this Court to the extent that it is inconsistent with *Medtronic*. *See Sheet Metal Workers Int'l Ass'n v. Department of Veterans Affairs*, 135 F.3d 891, 902 (3d Cir. 1998); *In re Continental Airlines*, 134 F.3d 536, 542 (3d Cir. 1998).

Part I below describes the constitutionally based presumption against preemption and explains how that presumption applies to state-law damages claims in the context of medical devices. Part II explains why Ms. Horn's claims are not

preempted under *Medtronic* on either the state side or the federal side of section 360k(a)'s preemption equation. Part III demonstrates that, in enacting the MDA, Congress did not intend to preempt all common-law claims.

I. THE SUPREME COURT'S PREEMPTION JURISPRUDENCE DICTATES A FINDING OF NO PREEMPTION HERE.

A. 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, 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 & North Western 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); *Green v. Fund Asset Management*, 245 F.3d 214, 224 (3d Cir. 2001); *Witko Corp. v. Beekhuis*, 38 F.3d 682, 687 (3d Cir. 1994). 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* Betsy 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); *see Green*, 245 F.3d at 224. 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., Medtronic*, 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 Electric 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*, 123 S. Ct. 518, 527 (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 TCI'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 Ms. Horn's favor.

B. 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. *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)). Here, the MDA is accompanied by a considerable body of regulations that narrowly construe the MDA's preemptive scope. *See* 21 C.F.R. § 808.1(d); *see also* 21 C.F.R. § 808.20(c)(i). These regulations are entitled to deference. *See Medtronic*, 518 U.S. at 496-97, 498-99 (majority opinion); *see id.* at 505-06 (Breyer, J., concurring).

II. UNDER *MEDTRONIC*, MS. HORN'S DAMAGES CLAIMS ARE NOT PREEMPTED.

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 *Medtronic* 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.[3] 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.

A. Ms. Horn's Claims Are Not Preempted Because They Are Premised On State-Law Duties Of General Applicability.

1. Relying on both the text of 21 U.S.C. § 360k(a) and the presumption against preemption, the *Medtronic* 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 found, 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):

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

> [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.

Medtronic, 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 design defect claims and to claims concerning PMA products. As in *Medtronic*, the general state common-law requirements that Ms. Horn seeks to enforce were not developed "with respect to" medical devices. Instead, Ms. Horn's 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 v. Howmedica,* 111 F.3d 782, 789 (10th Cir. 1997) (even where medical device subject to specific federal requirement, no preemption where state law did not relate specifically to devices). *Accord Niehoff v. Surgidev*, 950 S.W.2d 816, 822 (Ky. 1997) (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 v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763, 771-72 (Cal. App. 1996) (same). Just as nothing about the common-law duties on which the Lohrs relied in *Medtronic* was limited to the medical device at issue, or even medical devices in general, nothing about the common-law duties at issue here is limited to medical devices.

2. 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, Ms. Horn's claims

are indisputably based on product liability theories "of general applicability . . . relat[ing] to other products in addition to devices." *See also Medtronic*, 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").

As the Court recognized in *Medtronic*, 518 U.S. at 496-97, 498-99; *see also id.* at 505-06 (Breyer, J., concurring), deference to the FDA's views is particularly appropriate here because 21 U.S.C. § 360k(b) authorizes the FDA to exempt state laws from preemption. The decision whether to exempt a law from preemption requires the agency first to determine whether that law would be preempted in the first place. 518 U.S. at 496 ("Congress explicitly delegated to the FDA the authority to exempt state regulations from the pre-emptive effect of the MDA—an authority that necessarily requires the FDA to assess the pre-emptive effect that the Act and its own regulations will have on state laws."); *see also* 45 Fed. Reg. 67321, 67322 (1980) (FDA employing that two-step analysis). Thus, the FDA's long-held view that state laws of "general applicability" do not preempt, *see* 21 C.F.R. § 808.1(d), weighs heavily in favor of Ms. Horn.

Furthermore, where, as here, the FDA is acknowledging the states' authority, not claiming power for itself, its position cannot be explained away based on self-interest. And the concern behind the preemption doctrine—protection of federal

interests from inconsistent state or local activity—is not implicated where the federal agency charged with enforcing those interests does not object to, indeed welcomes, state participation. *Cf. Hillsborough County*, 471 U.S. at 714-15 (according dispositive weight to FDA's views of regulatory scheme that ceded power to states and localities). For this reason as well, the agency's views on this issue deserve deference.

Finally, in December 1997, the United States Solicitor General, responding to a request from the Supreme Court, filed an *amicus* brief advising the Court not to grant certiorari in a case that presented the question whether the MDA, and in particular premarket approval, preempts common-law remedies for injuries caused by medical devices. The Solicitor General agreed that the decision in that case, which found no preemption, was correct; and he forcefully reiterated the FDA's position that state-law damages actions premised on general duties, such as those here, are *not* preempted by the MDA. *See* Brief for the United States as *Amicus Curiae* in *Smith Indus. Medical Sys. v. Kernats*, S. Ct. No. 96-1405, at 17-18 (filed Dec. 1997) (Addendum at 6a-7a). The Solicitor General stated: "Section 360k is also inapplicable in the circumstances of this case because [the defendant] has not shown that [state] common law imposes a substantive requirement specifically with respect to the medical device at issue here." *Id.* at 17 (Addendum at 7a). Although a newly minted

government argument without basis in the agency's mandate would not itself be entitled to deference, substantial respect should be accorded when the agency's position is based on its interpretation of its own regulations, *Thomas Jefferson Univ. Hosp. v. Shalala*, 512 U.S. 504, 512 (1994), particularly when the agency's position has been long and consistently held. *United States v. Mead Corp.*, 533 U.S. 218, 228 (2001). Here, where the government's position is based on a 25-year-old regulation, adopted through notice-and-comment rulemaking, addressing the preemptive scope of section 360k(a), the Solicitor General's brief in *Kernats* provides additional support for reversal.

3. The district court concluded that the MDA preempts Ms. Horn's claims in part because it did not properly analyze the state-law side of the preemption equation. When the court reached this point in its discussion, it did not address whether Ms. Horn's damages claims were general or device-specific, but instead stated the issue as whether the claims would impose requirements "different from or in addition to the PMA process." App. A-28. In this way, 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 Niehoff,* 950 S.W.2d at 822; *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. Medical 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,* 57 Cal. Rptr. 2d at 771-72. Having failed to follow the approach prescribed by *Medtronic* and FDA regulations, the district court reached the wrong conclusion. In fact, the principles of Pennsylvania law on which Ms. Horn relies, 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).

Although the district court cited two cases to support its conclusion, the one post-*Medtronic* decision cited by the court simply refused to follow the *Medtronic* majority on the ground that it was incompatible with Justice Breyer's concurrence. *See Mitchell v. Collagen Corp.*, 126 F.3d 902, 912 (7th Cir. 1997) (discussing "tension" between majority opinion and Justice Breyer's concurrence). In so doing, that court effectively elevated the one-Justice concurrence above the five-Justice majority opinion. That approach is fundamentally incorrect. Under basic principles of stare decisis, a separate concurrence, regardless of its content, is not a basis for

disregarding a majority opinion of the Supreme Court of the United States. *See Alexander v. Sandoval*, 532 U.S. 275, 285 n.5 (2001).

In any event, Justice Breyer's concurrence supports Ms. Horn and is consistent with the *Medtronic* majority on this point. 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," *Medtronic*, 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). *See* Brief for the United States as *Amicus Curiae* in *Kernats*, *supra*, at 17 (Addendum at 7a). For instance, under *Medtronic*, 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 *Medtronic* to hold that Ms. Horn's claims are not preempted because those claims are premised on state-law duties of general applicability.

B. The Premarket Approval Of TCI's Device Did Not Create Any Requirement That Preempts Ms. Horn's Damages Claims.

Because the state law's lack of device specificity is dispositive under the *Medtronic* analysis, this Court need not reach the federal side of the preemption analysis. The district court opinion and TCI's argument below, however, both focused on the federal side; and both came to the wrong conclusion. As the United States has explained, "[t]he FDA's decision to grant . . . a PMA for a medical device does not, by itself, create a specific federal requirement." Brief for the United States as *Amicus Curiae* in *Kernats*, *supra*, at 14 (Addendum 6a). Accordingly, the fact that a device receives PMA has no preemptive effect on a plaintiff's common-law claims.

1. Although the criteria for granting PMA are more demanding than the criteria for marketing at issue in *Medtronic*, *see* 518 U.S. at 479 (explaining differences), they are no more "specific." Both processes apply to class III devices generally, *id.*, and neither specifies how a product is to be designed, manufactured, or labeled. Indeed,

the same good manufacturing practices regulations, 21 C.F.R. § 820.1, and prescription device labeling regulations, 21 C.F.R. § 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 *Medtronic* 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 *Medtronic* 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.

In this regard, the Solicitor General of the United States has explained:

> [T]he FDA's grant of a 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 approval of investigational ("IDE") and PMA devices] are important, and the FDA conducts a careful inquiry to ensure compliance. See 21 C.F.R. Pts. 812 (IDE procedures), 814 (PMA procedures). But in the typical case, the federal criteria for IDEs and PMAs are the generally applicable threshold standards set out in the MDA and the FDA regulations. See 21 C.F.R. 812.30(b) (grounds for denying an IDE), 814.45 (grounds for denying a PMA). As in the case of the premarket notification, labeling, and manufacturing requirements in *Medtronic*, those general criteria establish minimum standards that do not displace state law standards of care or common law duties respecting the medical devices.

> The FDA may impose specific federal requirements for a Class III device, above and beyond the general federal criteria, that have preemptive force. For example, if the FDA determines that precise design, manufacturing, or labeling specifications are necessary to protect the public, it may impose such requirements through the promulgation of specific regulations. See, *e.g.*, 21 C.F.R. 861.1(b)(3) (providing for mandatory performance standards for Class III devices). . . . We have been informed by the FDA that it imposes such specific requirements on Class III devices only in extraordinary circumstances, and only after it has considered the preemptive consequences of its action under Section 360k.
>
> . . . . Under the regulatory scheme, a manufacturer is responsible for submitting an application demonstrating that the proposed medical device satisfies federal minimum standards. See, *e.g.*, 21 C.F.R. Pts. 812, 814. If (as in this case) 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 in the Act and regulations, and it may obtain an IDE or PMA on the basis of that selection if the FDA approves the application. Because the FDA has not imposed any specific substantive requirements on [the design of the device] in the course of the review process, that design does not represent a specific federal requirement that preempts state common law requirements.

Brief for the United States as *Amicus Curiae* in *Kernats*, *supra*, at 17 (Addendum 7a).

Other courts have adopted this reasoning. For example, in *Goodlin v. Medtronic*, 167 F.3d 1367 (11th Cir. 1999), the Eleventh Circuit 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 that court noted, one cannot conduct the "careful comparison" between the relevant state and federal requirements, as *Medtronic* 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.") (quoting *Kennedy v. Collagen Corp*., 67 F.3d 1453, 1460 (9th Cir. 1995)).

The FDA agrees that PMA does not impose device-specific requirements sufficient to preempt claims such as Ms. Horn's. Thus, in defining what types of state and local requirements are subject to preemption, the FDA has stated that:

> 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).

2. Although, under the MDA, TCI needed premarket approval before marketing its heart pump, 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 *Medtronic*, the design of the device at issue here originated with the company. The FDA "did not 'require' [the device] to take any particular form for any particular reason." *Medtronic*, 518 U.S. at 493; *accord* Brief for the United States as *Amicus Curiae* in *Kernats*, *supra*, at 15 (Addendum 5a). "[Design] specifications are applicable to a device as a result of the voluntary decision of a private party, the manufacturer, to introduce the device into the market with a design of the manufacturer's choosing. That federal law attaches a consequence to such private decisions does not convert them into federal 'requirements.'" Brief for the United States as *Amicus Curiae* in *Medtronic v. Lohr*, S. Ct. No. 95-754, 1996 WL 118035, at *20-*21 (filed Mar. 15, 1996); *cf. 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 heart pumps to meet certain

specifications, *see* 21 C.F.R. § 861.1(b)(3), a defective design claim that challenged the safety of a heart pump could be analyzed in terms of whether the claim was "different from or in addition to" those specifications. *See Medtronic*, 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 TCI's device is underscored by the FDA's approval letter. That letter imposes no specific conditions, and the attached "Conditions of Approval" is an FDA form document that applies to PMA products generally. *See* App. A-216. The document says nothing specific to heart pumps or to the HeartMate LVAD; 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.

3. Ms. Horn's failure-to-warn claim is based on the theory that Mr. Horn's surgeon should have been warned that a suture on top of the device, facing the bones of the chest, was susceptible to breakage so that the surgeon would know to return the device or take additional precautions. For several reasons in addition to those discussed above, Ms. Horn's failure-to-warn claim is not preempted.

First, the only FDA regulation governing the substance of the heart pump's label is 21 C.F.R. § 801.109—the same regulation found too general to warrant preemption in *Medtronic*. *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)). In accordance with the FDA'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. 18661, 18662 (1978); *see* 21 C.F.R. § 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. 21 C.F.R. § 808.1(d)(6)(ii); *see* 21 C.F.R. § 801.430 (device-specific labeling requirements for tampons).

Second, under 21 C.F.R. sections 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. The Court in *Medtronic* 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), Ms. Horn's failure-to-warn claim is not "different from, or in addition to" the federal requirements within the meaning of section 360k(a).

Third, manufacturers can and do provide updated information through non-label means, such as "Dear Doctor" letters, which are not regulated by the FDA. The FDCA defines "labeling" as "all labels an 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." 21 U.S.C. § 321(k). Thus, a post-PMA letter to physicians warning about the risk of using a HeartMate

LVAD when the suture was tied on top of the device would not constitute labeling, and TCI was free to issue such a letter without prior approval from the FDA.

Because there is no relevant federal requirement, there is no preemption of a state-law product liability claim premised on a duty imposing a non-label warning. This view is reflected in the Solicitor General's amicus brief in *Medtronic*. In that brief, the government maintained that none of the plaintiffs' claims, including the failure-to-warn claims, was preempted by the FDA's medical device regulations. Because non-label information is not labeling, the government noted additionally that "the Lohrs' failure-to-warn claims are not preempted insofar as they allege that warnings should have been made through modes of communications other than labeling." Brief for the United States as Amicus Curiae in *Medtronic*, *supra*, 1996 WL 118035, at *27 (citing *Cipollone*). Likewise here, a claim that TCI should have warned doctors through "Dear Doctor" letters or other non-label communications is not preempted.[4]

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[4] The distinction between warnings provided through a product label or packaging and those provided by non-label means is reflected in *Cipollone*. There, the Court considered a statute that expressly preempts state-law cigarette labeling and packaging requirements "with respect to advertising or promotion." 15 U.S.C. § 1334(b). *Cipollone* held that failure-to-warn claims concerning label-based advertising or promotion of cigarettes are preempted, but specifically noted that a claim that a cigarette manufacturer should have warned through other means would *not* be preempted. 505 U.S. at 524-25 (failure-to-warn claim not preempted if based on (continued...)

* * * * *

Accordingly, because Ms. Horn's state-law claims are based on laws of general applicability, and because the FDA has issued no device-specific regulations regarding the design, manufacturing, or labeling of heart pumps, section 360k(a) does not preempt Ms. Horn's claims.

III. 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 recent decision in *Sprietsma* suggests that the MDA preempts no state-law damages claims at all. *See Sprietsma*, 123 S. Ct. at 526 (no express preemption of common-law damages claims where preemption provision of Federal Boat Safety Act applies to "a [state or local] law or regulation" that establishes a "standard" or imposes a "requirement").

Regardless of whether section 360k(a) preempts any damages claims, the district court's decision finding complete preemption of Ms. Horn's claims is

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[4](...continued)
defendant's "actions unrelated to advertising or promotion").

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 *Medtronic*, 518 U.S. at 475-77). Congress was "acutely aware of ongoing product liability litigation" regarding these incidents, *Medtronic*, 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, which have noted that Congress can, and does, rationally distinguish state positive law and common law, preempting the former but not the latter. *See Sprietsma*, 123 S. Ct. at 527 (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").[5]

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, at best. *Id.*

Moreover, Congress included in the MDA a provision that, consistent with the presumption against preemption, 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

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[5] The Supreme Court's recent decision in *Sprietsma* also demonstrates that the term "requirement" does not always refer to state damages actions and that this term, 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* 123 S. Ct. at 524, 526-27.

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).

As this Court has recognized, Congress "gave indication in 21 U.S.C. § 360h that at least some common law remedies would remain in conjunction with FDA regulation." *Michael,* 46 F.3d at 1326. Yet under TCI's theory, the Horn's would have no remedies at all. In such circumstances, 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; *accord Michael*, 46 F.3d at 1326.

CONCLUSION

For the reasons stated above, the decision of the district court should be reversed and the case remanded for a trial on the merits of Ms. Horn's claims.

Respectfully submitted,

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May 1, 2003

CERTIFICATE OF BAR MEMBERSHIP

I certify that I am a member of the bar of this Court.

_____
Allison M. Zieve

May 1, 2003

CERTIFICATE OF COMPLIANCE

I certify that the foregoing brief was prepared in proportionately spaced, 14-point type and contains 10,605 words.

_____
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Counsel for Appellant

May 1, 2003

RULE 28(f) ADDENDUM

Including
- principal statutory and regulatory provisions involved
- an excerpt from the brief for the United States as *amicus curiae* in opposition to the petition for a writ of certiorari in *Smith Industries Medical Systems v. Kernats*, S. Ct. No. 96-1405 (filed Dec. 1997)

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.

APPENDIX

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CERTIFICATE OF SERVICE

I hereby certify that on this 1st day of May, 2003, I served the foregoing OPENING BRIEF OF APPELLANT BARBARA HORN on the parties listed below by causing two true and correct copies thereof to be placed U.S. mailed, first-class postage prepaid, addressed as follows:

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