

No. 86903

IN THE SUPREME COURT
OF THE STATE OF ILLINOIS

HAROLD WEILAND,

Plaintiff-Appellant,

V.

TELECTRONICS PACING SYSTEMS, INC.,

Defendant-Appellee.

On Appeal from the Appellate Court of Illinois

First District, Fifth Division

No. 1-95-2736

There heard on appeal from the

Circuit Court of Cook County, Illinois

Honorable Gary L. Brownfield, Judge Presiding

BRIEF OF APPELLANT HAROLD WEILAND

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May 4, 1999

ORAL ARGUMENT REQUESTED

TABLE OF CONTENTS

Page

POINTS AND AUTHORITIES i

NATURE OF ACTION

JURISDICTIONAL STATEMENT

STATUTORY PROVISIONS INVOLVED

STATEMENT OF FACTS

 A. The Medical Device Amendments

 B. The Decision In *Medtronic v. Lohr*

 C. The Instant Case

STANDARD OF REVIEW

ARGUMENT

I. APPLICABLE PREEMPTION PRINCIPLES

 A. The Presumption Against Preemption

 B. Preemption And The Federal-State Balance

 C. Deference To Agency Expertise In The Preemption Context

II. UNDER *MEDTRONIC*, MR. WEILAND'S DAMAGES CLAIMS ARE NOT
PREEMPTED.

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

 B. The FDA's Premarket Approval Of Telectronics' Pacemaker
 Does Not Preempt Plaintiff's Claims

III. IN ENACTING THE MDA, CONGRESS RECOGNIZED THE CONTINUING
VALIDITY OF COMMON-LAW CLAIMS

CONCLUSION

APPENDIX

POINTS AND AUTHORITIES

Page

I. APPLICABLE PREEMPTION PRINCIPLES

A. The Presumption Against Preemption

Hillsborough County, Florida v. Automated Medical Laboratories, Inc.,

471 U.S. 707 (1985)

McCulloch v. Maryland, 4 Wheat. 316, 4 L. Ed. 579 (1819)

Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992)

Hawaiian Airlines, Inc. v. Norris, 512 U.S. 246 (1994)

Wisconsin Public Intervenor v. Mortier, 501 U.S. 597 (1991)

Maryland v. Louisiana, 451 U.S. 725 (1981)

Chicago and North Western Transportation Co. v. Kalo Brick & Tile Co.,

450 U.S. 311 (1981)

Rice v. Santa Fe Elevator Corp., 331 U.S. 218 (1947)

Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996)

English v. General Electric Co., 496 U.S. 72 (1990)

Silkwood v. Kerr-McGee Corp., 464 U.S. 238 (1984)

United States Constitution, Article VI, Clause 2

United States Constitution, Tenth Amendment

B. Preemption And The Federal-State Balance

Hillsborough County, Florida v. Automated Medical Laboratories, Inc.,

471 U.S. 707 (1985)

Jones v. Rath Packing Co., 430 U.S. 519 (1977)

Philip H. Corboy & Todd A. Smith, Federal Preemption of Product Liability Law: Federalism and the Theory of Implied Preemption,
15 American Journal of Trial Advocacy 435 (1992)

Gregory v. Ashcroft, 501 U.S. 452 (1991)

Edelman v. Jordan, 415 U.S. 651 (1974)

Fitzpatrick v. Bitzer, 427 U.S. 445 (1976)

Atascadero State Hosp. v. Scanlon, 473 U.S. 234 (1985)

Wisconsin Public Intervenor v. Mortier, 501 U.S. 597 (1991)

Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992)

United States Constitution, Eleventh Amendment

Betsy J. Grey, *Make Congress Speak Clearly: Federal Preemption of State Tort Remedies*,
77 B.U.L. Rev. 559 (1997)

C. Deference To Agency Expertise In The Preemption Context

Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996)

Hillsborough County, Florida v. Automated Medical Laboratories, Inc.,
471 U.S. 707 (1985)

21 C.F.R. § 808.1(d).

**II. UNDER *MEDTRONIC*, MR. WEILAND'S DAMAGES CLAIMS ARE NOT
PREEMPTED.**

Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996)

A. Mr. Weiland's Claims Are Not Preempted Because They Are

<u>Premised On State-Law Duties Of General Applicability.</u>	
<i>Medtronic, Inc. v. Lohr</i> , 518 U.S. 470 (1996)	
<i>Goodlin v. Medtronic, Inc.</i> , 167 F.3d 1367 (11th Cir. 1999)	
<i>Niehoff v. Surgidev</i> , 950 S.W.2d 816 (Ky. 1997)	
<i>Armstrong v. Optical Radiation Corp.</i> , 57 Cal. Rptr. 2d 763 (Cal. App. 1996), <i>review denied</i> , 1997 Cal. Lexis 833 (Feb. 19, 1997)	
<i>Oja v. Howmedica</i> , 111 F.3d 782 (10th Cir. 1997)	
<i>Kernats v. Smith Industries Medical Systems, Inc.</i> , 283 Ill. App. 3d 455, 669 N.E.2d 1300 (1996), <i>appeal denied</i> , 675 N.E.2d 634 (Ill. 1996), <i>cert. denied</i> , 118 S. Ct. 684 (1998)	
<i>Walker v. Johnson & Johnson Vision Prods., Inc.</i> , 552 N.W.2d 679 (Mich. App. 1996)	
<i>Mears v. Marshall</i> , 944 P.2d 984 (Ore. App. 1997)	
<i>Wutzke v. Schwagler</i> , 940 P.2d 1386 (Wash. App. 1997)	
<i>Hillsborough County, Florida v. Automated Medical Laboratories, Inc.</i> , 471 U.S. 707 (1985)	
<i>Auer v. Robbins</i> , 519 U.S. 452 (1997)	
<i>Mitchell v. Collagen Corp.</i> , 126 F.3d 902 (7th Cir. 1997) <i>cert. denied</i> , 118 S. Ct. 1300 (1998)	
<i>Papike v. Tambrands</i> , 107 F.3d 737 (9th Cir. 1997)	
Brief for the United States as <i>Amicus Curiae</i> in <i>Smith Industries Medical Systems v. Kernats</i> , S. Ct. No. 96-1405 (dated Dec. 1997)	
21 U.S.C. § 360k(a)	

21 C.F.R. § 808.1(d)
45 Fed. Reg. 67321 (1980)

B. The FDA's Premarket Approval Of Telectronics' Pacemaker

Does Not Preempt Plaintiff's Claims.

Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996)

Goodlin v. Medtronic, Inc., 167 F.3d 1367 (11th Cir. 1999)

Brief for the United States as *Amicus Curiae* in *Smith Industries Medical*

Systems v. Kernats, S. Ct. No. 96-1405 (dated Dec. 1997)

Brief for the United States as *Amicus Curiae* in *Medtronic v. Lohr*,

S. Ct. No. 95-754, 1996 WL 118035 (filed March 15, 1996).

21 U.S.C. § 360e(d)(2)

21 U.S.C. § 360k(a)

21 C.F.R. § 801.420

21 C.F.R. § 801.430

21 C.F.R. § 808.1(d)

21 C.F.R. § 808.1(d)(3)

21 C.F.R. 861.1(b)(3)

43 Fed. Reg. 18661 (1978)

42 Fed. Reg. 30383 (1977)

**III. IN ENACTING THE MDA, CONGRESS RECOGNIZED THE CONTINUING
VALIDITY OF COMMON-LAW CLAIMS.**

Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996)

Silkwood v. Kerr-McGee Corp., 464 U.S. 238 (1984)

Hawaiian Airlines, Inc. v. Norris, 512 U.S. 246 (1994)

Goodlin v. Medtronic, Inc., 167 F.3d 1367 (11th Cir. 1999)

Mulligan v. Pfizer, Inc., 850 F. Supp. 633 (S.D. Ohio 1994)

Michael v. Shiley, Inc., 46 F.3d 1316 (3d Cir.), *cert. denied*, 516 U.S. 815 (1995)

21 U.S.C. § 360h(d)

H.R. Rep. No. 853, 94th Cong., 2d Sess. (1976)

NATURE OF ACTION

This action was brought to recover damages for breach of warranty and product liability caused by two defective pacemakers implanted in plaintiff-appellant Harold Weiland. On the motion of defendant Telectronics Pacing Systems, Inc. ("Telectronics") for summary judgment, the circuit court dismissed Plaintiff's claims on the ground that they were preempted by 21 U.S.C. § 360k(a), the preemption provision of the 1976 Medical Device Amendments to the federal Food, Drug, and Cosmetic Act. The appellate court affirmed.

ISSUE PRESENTED FOR REVIEW

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.

JURISDICTIONAL STATEMENT

On July 6, 1995, the Honorable Gary L. Brownfield, sitting in the Circuit Court of Cook County, granted Telectronics' motion for summary judgment on Plaintiff Harold Weiland's Third Amended Complaint against Telectronics on the basis that section 360k(a) of the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. §§ 360c *et seq.* (West Supp. 1998), to the federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C.A. §§ 301 *et seq.* (West Supp. 1998), preempted Mr. Weiland's common-law claims for breach of warranty and product liability. On August 3, 1995, Plaintiff filed a timely notice of appeal.

On December 11, 1998, the Appellate Court, First District, Fifth Division, affirmed the summary judgment entered in favor of Telectronics. A true and correct copy of the appellate court's opinion is attached as Appendix A.

On December 30, 1998, within 21 days of the opinion, Plaintiff filed his Affidavit of Intent to File a Petition for Leave to Appeal. A true and correct copy of the affidavit is attached hereto as Appendix B. Plaintiff filed his petition on January 15, 1999, and this Court granted leave to appeal on March 30, 1999. A true and correct copy of the Court's order is attached hereto as Appendix C. Within 14 days thereafter, in accordance with Illinois Supreme Court Rule 315, counsel for Plaintiff filed and served a timely Notice of Election to File Supplemental Brief, in accordance with Illinois Supreme Court Rule 315(g). A true and correct copy of this notice is attached hereto as Appendix D.

STATUTORY PROVISIONS INVOLVED

Section 521(a) of the 1976 Medical Device Amendments to the federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a), entitled "State and local requirements respecting devices," provides:

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

- (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
- (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360h(d), entitled "Effect on Other Liability," provides:

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.

Another relevant statutory provision, 21 U.S.C. § 360k(b), and a relevant regulatory provision, 21 C.F.R. § 808.1(d), are set forth in the appendix to this brief.

STATEMENT OF FACTS

This appeal involves a suit to recover for injuries suffered by plaintiff Harold Weiland from a pacemaker sold by defendant Telectronics. On Telectronics' motion for summary judgment, the circuit court held that section 360k(a) of the MDA preempted all of Mr. Weiland's claims. C001058. The appellate court affirmed. Appendix A.

Because an understanding of 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 sets forth a concise description of the facts of this case and a brief summary of the opinion 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 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 sought to impose 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.*). Congress conferred responsibility for implementing and enforcing the MDA to 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) (definition of class II).

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 because insufficient information exists about the device, 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 PMA 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 prior 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 generic type of device that is later 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 Food, Drug, and Cosmetic Act, 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).

For those devices actually submitted to the PMA process, the manufacturer must design and implement an FDA-approved clinical investigation and must submit to the FDA the results of that investigation, along with all other relevant studies (such as animal 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 to the clinical studies and other data, the manufacturer's 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 some cases, prior to 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 pre-market 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 that 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 certain statutes, rules, regulations, and ordinances. 21 U.S.C. § 360k(b); *see* 21 C.F.R. § 808.20.

B. The Decision In *Medtronic v. Lohr*

The Supreme Court's decision in *Medtronic v. Lohr* is central to resolving the issue presented here. 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. _____. The complaint stated causes of action for defective design, defective manufacture, and failure to warn. Medtronic moved for summary judgment on the basis of section 360k(a) of the MDA, which preempts state-law "requirements" that are "different from or in addition to" federal device requirements and which relate to the safety or effectiveness of medical devices or to device requirements established by 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 were preempted by the MDA.

1. 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 common-law 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 Lohr's manufacturing-defect and failure-to-warn claims were not preempted, even if they did more than seek to enforce the federal requirements on 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 noted that Lohr's 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

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 Part VI of the plurality opinion (*see supra* note 1) because he was not totally 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.

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

He stated that the applicable FDA requirements related to Lohr's 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 noted that the language of section 360k(a) reflected basic principles of conflict preemption, but found no conflict between any federal requirement and any of Lohr's claims. *Id.* at 508.

3. 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 Lohr's 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 further agreed with the majority that Lohr's manufacturing-defect and failure-to-warn claims were not preempted to the extent that they alleged violations of federal requirements. *Id.*

 C. The Instant Case

On July 26, 1993, Harold Weiland filed a Third Amended Complaint at Law against Telectronics and others. C000198. Counts II and V alleged breach of warranty and product liability against Telectronics. C000198. The complaint arose from defective pacemakers that were surgically implanted into Mr. Weiland's body. C000198-203.

Prior to 1991, Mr. Weiland was diagnosed with coronary heart disease and it was determined that a permanent pacemaker should be inserted into the his body. C000199-200. On January 10, 1991, a Model 8222 pacemaker was surgically implanted into his body at Alexian

Brothers Medical Hospital (“Alexian”). C000200. The Model 8222 pacing system was designed and manufactured by Telectronics Proprietary, Ltd. (“TPL”). C000200. The device was then sold or supplied to its American distributor, Telectronics, C000201, which then sold the pacemaker to Alexian. C000201.

Subsequently, Mr. Weiland was admitted to Northwest Community Hospital where it was determined that the pacemaker was malfunctioning. C000201. Mr. Weiland became increasingly ill and disabled as a result of the malfunctioning pacemaker. C000201. On October 17, 1991, he was rushed by ambulance to Alexian to have the malfunctioning pacemaker removed and a new one inserted. C000201. The new pacemaker, Model 1230, was also manufactured by TPL and sold by Telectronics to Alexian. C000201. Later, the Model 1230 pacemaker also malfunctioned and had to be removed. C000202.

Notably, on December 31, 1991, the Department of Health and Human Services Food and Drug Administration issued a recall of all Reflect DDD, Model 8222, Dual Chamber, Multi-programmable Pulse Generators with Telemetry to Telectronics Pacing Systems, Inc. in Englewood, Colorado. C000203. This first model inserted into Plaintiff was this type of pacemaker.

Pursuant to agreement of the parties, TPL was dismissed from the case without prejudice on October 12, 1993. C000399. On May 2, 1994, the Circuit Court of Cook County dismissed Counts VI and VII of the Third Amended Complaint with prejudice. C000679. On August 23, 1994, the Circuit Court dismissed Alexian as a defendant. C000625. A timely appeal was filed, and Mr. Weiland subsequently settled with Alexian.

On July 6, 1995, the Circuit Court granted summary judgment in favor of Teletronics on Counts II and V, the two counts alleged against the company. C001058. The Honorable Judge Brownfield held that Plaintiff's common-law claims for breach of warranty and product liability were preempted by 21 U.S.C. § 360k(a) of the MDA. T000052.

Plaintiff filed a timely Notice of Appeal to the Appellate Court of Illinois for the First District on August 3, 1995. C001063. The matter was held in abeyance pending resolution of *Haudrich v. Howmedica, Inc.*, 267 Ill. App. 3d 630 (1994), by this Court, resolution of *Medtronic v. Lohr*, 518 U.S. 470 (1996), in the Supreme Court of the United States, and resolution of a petition for certiorari in *Kernats v. Smith Industries Medical Systems, Inc.*, 283 Ill. App. 3d 455 (1996), *appeal denied*, 169 Ill. 2d 569 (1996), *cert. denied*, 118 S. Ct. 684 (1998). This Court later decided *Haudrich* without reaching the issue of whether the MDA preempted state claims. *See Haudrich*, 169 Ill. 2d at 525 (preemption issue waived by failure to raise in court below). And the United States Supreme Court denied the petition for certiorari in *Kernats*.

Notwithstanding the *Medtronic* decision, described in Part B. above, on December 11, 1998, the Appellate Court of Illinois for the First District, delivered a split opinion affirming the judgment and ruling of the circuit court. *See Appendix A* at 21. In reaching its decision, the two justices that joined in the decision of the court simply surveyed the federal case law to determine that the weight of federal case law was in favor of preemption, and “hold that Mr. Weiland’s state law claims are preempted by the MDA.” *Appendix A* at 21. Justice Zwick, dissenting, stated that he would reverse the finding of preemption based on *Medtronic*. *See Appendix A* at 26.

STANDARD OF REVIEW

As in all cases involving summary judgment, this Court conducts a *de novo* review. *Outboard Marine Corp. v. Liberty Mut. Ins. Co.*, 154 Ill. 2d 90, 102, 607 N.E.2d 1204, 1209 (Ill. 1992); *Espinoza v. Elgin, Joliet and Eastern Railway Company*, 165 Ill. 2d 107, 113, 649 N.E.2d 1323, 1326 (Ill. 1995).

ARGUMENT

The issue in this appeal is whether 21 U.S.C. § 360k(a), the preemption provision of the MDA, preempts common-law claims of product liability and breach of implied warranties brought against the seller of a defective pacemaker. The breadth of the position urged by defendant Teletronics cannot be understated. The company maintains that, because its product was given marketing approval by the FDA, it is entitled to sweeping immunity from all state-law damages suits, regardless of the magnitude of its misconduct or the severity of the plaintiff's injuries. As explained below, Teletronics' position is not tenable in light of the governing authorities.

The United States Supreme Court's decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), in which the Court rejected a medical device manufacturer's broad claim of preemption and held that state-law causes of action for design defect, manufacturing defect, and failure to warn were not preempted, supplies the appropriate analytical framework for considering whether section 360k(a) preempts Mr. Weiland's common-law claims. *Medtronic* dictates that for preemption of a state-law damages action to occur, the federal medical device "requirement" must be "specific" *and* the state-law duty under which the plaintiff has sued must be "specific," rather than based on a general duty to act non-negligently or to produce non-defective products. *See id.* at 501-02. Moreover, as the *Medtronic* court unanimously held, state-law claims are never preempted to the extent that the duties on which they are based parallel applicable federal requirements.

With this basic rubric in mind, Part I below introduces the preemption topic and explains the constitutionally-based presumption against preemption and, in particular, how that presumption applies to state-law damages claims in the context of medical devices. Part II explains why Mr. Weiland'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. APPLICABLE PREEMPTION PRINCIPLES.

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, and 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*, 4 Wheat. 316, 427, 4 L. Ed. 579 (1819); *Cipollone v. Liggett Group, Inc.*, 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.* at 516.

The Supremacy Clause is restricted by other 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, a party seeking preemption of state law bears a heavy burden. There is a strong presumption *against* preemption that may be overcome only by "clear and manifest" congressional intent to the contrary. *Hillsborough County, Florida v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 715 (1985); *see also Hawaiian Airlines, Inc. v. Norris*, 512 U.S. 246, 252 (1994); *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 605, 611 (1991).

Thus, "[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). Put differently, "[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 and North Western Transportation 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)).

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 its citizens. *See, e.g., Medtronic*, 518 U.S. at 484-86.

Furthermore, in this case, where the MDA's allegedly preemptive federal regulatory scheme does not itself provide a damages remedy, preemption would leave injured individuals without any state *or* federal remedy. In that situation, 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).

B. Preemption And The Federal-State Balance

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 v. Rath Packing Co.*, 430 U.S. 519, 525 (1977); *see also Philip H. Corboy & Todd A. Smith, Federal Preemption of Product Liability Law: Federalism and the Theory of Implied Preemption*, 15 American Journal of Trial Advocacy 435, 444-57 (1992) (detailed analysis placing the presumption against preemption in the context of the Tenth Amendment and federalist principles). 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).

The presumption against preemption works in tandem with another aspect of the Supreme Court's federalism jurisprudence: the Eleventh Amendment. That Amendment provides that states, and state officers in certain circumstances, are immune from suit in federal court. *See Edelman v. Jordan*, 415 U.S. 651 (1974). Congress may override that judgment pursuant to its legislative

powers under the Fourteenth Amendment. *See Fitzpatrick v. Bitzer*, 427 U.S. 445 (1976). However, the Supreme Court has insisted that Congress do so in unmistakably clear terms (referred to as the “plain-statement rule”) and has enforced that edict very strictly. *See, e.g., Atascadero State Hosp. v. Scanlon*, 473 U.S. 234, 238-46 (1985). Because the same principles of federalism that support Eleventh Amendment jurisprudence also undergird Supremacy Clause jurisprudence, the plain-statement rule should be just as stringently enforced in the preemption context as in the Eleventh Amendment context. *See Gregory*, 501 U.S. at 460-67; *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 607-09 (1991); *accord Cipollone*, 505 U.S. at 533 n.1 (Blackmun, J., joined by Kennedy and Souter, JJ., concurring in part, concurring in the judgment in part, and dissenting in part) (suggesting identity of Eleventh Amendment plain-statement rule and “clear and manifest” preemption standard).

A genuine plain-statement rule not only honors principles of federalism, but facilitates the proper role between the legislative branch and the judicial branch, by requiring Congress to say precisely what it means:

Congress gains little from writing ambiguous statutes. Particularly when it legislates in an area affected by state tort law, Congress has much to gain by making explicit its intent to preempt state law. Namely, clarity achieves certainty in statutory application and helps to avoid litigation over legislative meaning. Even more fundamentally, requiring that Congress speak clearly will help ensure that its decision to preempt is the product of a deliberate policy choice. 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.

Moreover, unlike judicial interpretations of constitutional principles that can be overturned only by the Supreme Court or constitutional amendment, Congress can overrule judicial preemption decisions. Thus, if Congress disagrees with a judicial refusal to find preemption, it can rewrite the statute to make preemption explicit. This may increase pressure on Congress to respond to the current “tort reform”

campaign, as special interest groups may seek to ensure that express preemption clauses are incorporated into regulatory legislation. Nonetheless, the legislature is precisely where decisions regarding state versus federal policy should lie in the first instance.

Betsy J. Grey, *Make Congress Speak Clearly: Federal Preemption of State Tort Remedies*, 77 B.U.L. Rev. 559, 627 (1997); *see also Jones*, 430 U.S. at 525 (presumption against preemption "provides assurance that the 'federal-state balance' will not be disturbed unintentionally by Congress or unnecessarily by the courts") (quoting *United States v. Bass*, 404 U.S. 336, 349 (1971)).

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 Mr. Weiland's favor.

C. 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 charged by Congress with administering a statutory scheme are entitled to substantial deference. *Hillsborough County*, 471 U.S. at 714-715 (citing *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 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). In *Medtronic*, the United States Supreme Court gave those regulations deference. 518 U.S. at 496-97, 498-99 (majority opinion); *see id.* at 505-06 (Breyer, J., concurring).

II. UNDER *MEDTRONIC*, MR. WEILAND'S DAMAGES CLAIMS ARE NOT PREEMPTED.

In holding that section 360k(a) did not preempt the plaintiffs' damages claims in *Medtronic v. Lohr*, the United States Supreme Court looked to both the statutory language and the existing FDA

regulations and noted the "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 is applicable to a PMA device and requires reversal of the circuit court and appellate court decisions in this case.²

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

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):

[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.

² 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.

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 addressed manufacturing and duty-to-warn claims, its rationale—that the state-law duties are general duties to use due care or to inform—applies fully to other claims concerning both PMA and non-PMA products. *See, e.g., Niehoff v. Surgidev*, 950 S.W.2d 816, 822 (Ky. 1997) (no preemption 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), *review denied*, 1997 Cal. Lexis 833 (Feb. 19, 1997); *see also Oja v. Howmedica*, 111 F.3d 782, 789 (10th Cir. 1997) (no preemption because "the general state common law requirements imposed by [plaintiff's] failure to warn claim were not specifically developed 'with respect to' medical devices. Instead, . . . claim is predicated upon a general duty applicable to every manufacturer . . .").

Plaintiff's claims here are indisputably based on common-law duties of general applicability. Nothing about the common-law duties at issue here is limited to medical devices, just as nothing about the common-law duties on which the Lohrs relied in *Medtronic* was limited to medical devices.

The court below reached a contrary conclusion by purporting to tally the decisions of post-*Medtronic* federal trial and appellate courts addressing this issue. Thus, in disagreeing with a prior

decision of the same court finding insufficient specificity on the state-law side, *see Kernats v. Smith Industries Medical Systems, Inc.*, 283 Ill. App. 3d 455, 465-66, 669 N.E.2d 1300, 1309 (1996), *appeal denied*, 675 N.E.2d 634 (Ill. 1996), *cert. denied*, 118 S. Ct. 684 (1998), the court stated that its finding of state-law specificity was based on the "prevailing view of the federal courts at [the] time." Appendix A at 20.

First, to the extent that tallying decisions is an appropriate substitute for independent analysis, the most recent federal appeals court decision, *Goodlin v. Medtronic*, 167 F.3d 1367 (11th Cir. 1999), which was issued after the decision below, holds that the MDA does not preempt common-law claims and, specifically, design claims much like those at issue here. Moreover, the court's tally of cases downplayed the decisions of other state appellate courts, many of which have held that the Supreme Court meant what it said in *Medtronic*—that state laws of general applicability are not among those laws targeted for preemption by section 360k(a). *See Niehoff*. 950 S.W.2d at 822 (no preemption because "Kentucky's strict liability case law and statutes [on which plaintiff relies] are laws of general applicability to all products and fall beyond the scope of the federal preemption under § 360k"); *Walker 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); *Kernats*, 283 Ill. App. 3d at 465-66, 669 N.E.2d at 1309 ("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.

Second, a few courts, including the federal court on which the court below relied most heavily, have simply refused to follow the *Medtronic* majority on the ground that it is incompatible with Justice Breyer's concurrence. *See, e.g., Mitchell v. Collagen Corp.*, 126 F.3d 902, 912 (7th Cir.

1997) (discussing "tension" between majority opinion and Justice Breyer's concurrence), *cert. denied*, 118 S. Ct. 1300 (1998); *Papike v. Tambrands*, 107 F.3d 737, 742 (9th Cir. 1997). Those courts have 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—in effect, overruling—a majority opinion of the Supreme Court of the United States. *See supra* note 2.

In any event, the *Medtronic* majority and Justice Breyer's separate concurrence are consistent with one another. Although 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, 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 *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. *Medtronic*, 518 U.S. at 504 (Breyer, J., concurring). Thus, this Court need go no further than *Medtronic* to hold that Mr.

Weiland's claims are not preempted because those claims are premised on state duties of general applicability.

In addition, 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, Plaintiff'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 section 360k(b) authorizes the FDA to exempt state laws from preemption. *See* Appendix E. The decision whether to exempt a law from preemption necessarily requires the agency first to determine whether that law would be preempted in the first place. *Medtronic*, 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 Mr. Weiland.

In addition, here, the FDA is ceding authority to the states, not trying to claim power for itself. Thus, the FDA's position cannot be explained away based on self-interest. Moreover, 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 (accord[ing] dispositive weight to FDA's views of its regulatory scheme). 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 forcefully reiterating 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 Industries Medical Systems v. Kernats*, S. Ct. No. 96-1405, at 17 (filed Dec. 1997) (Appendix G). 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 a position taken in litigation if it represents the agency's "fair and considered judgment on the matter." *Auer v. Robbins*, 519 U.S. 452, 462 (1997). Here, where the government's position is based on two decades of "considered judgment" on the preemptive scope of section 360k(a), the Solicitor General's brief in *Kernats* provides additional support for reversal.

For all these reasons, the MDA does not preempt Plaintiff's claims because they are based on state-law duties of general applicability.

B. The FDA's Premarket Approval Of Teletronics' Pacemaker Does Not Preempt Plaintiff's Claims.

The court below found that the FDA's premarket approval ("PMA") of the device created a specific federal requirement sufficient to satisfy the federal-side of section 360k(a)'s preemption equation; and Teletronics' arguments in the courts below have focussed on that point. The lack of specificity on the state-law side of the preemption equation is dispositive under the *Medtronic* analysis. Therefore, the Court need not reach the federal side of the equation. Nonetheless, as recently stated by the Eleventh Circuit Court of Appeals, *see Goodlin*, 167 F.3d 1367, and previously stated by the United States, *see infra* p. ___ & Appendix G, the fact that a device receives PMA has no preemptive effect on a plaintiff's common-law claims. That is, the grant of PMA does not equate to a specific federal requirement.

The granting of PMA is not a specific preemption-triggering requirement under section 360k(a). Thus, although the FDA required Teletronics to follow the PMA process before marketing the pacemaker, neither the FDA nor the MDA imposed any specific requirement on the pacemaker's design. Like the design of the 510(k) pacemaker lead at issue in *Medtronic*, the design of the PMA pacemaker at issue here originated with the company. The FDA "did not 'require' [the company's] pacemaker to take any particular form for any particular reason." *Medtronic*, 518 U.S. at 493. "[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 March 15, 1996).

Although the criteria for granting PMA are more demanding than the criteria for the marketing process 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. The PMA process contains no rules similar to the FDA's device-specific labeling rules, see, e.g., 21 C.F.R. 801.420 (labeling for hearing aids), or 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 United States Solicitor General 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.(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 *Smith Industries Medical Systems v. Kernats*, S. Ct. No. 96-1405, at 17 (Appendix G).

The United States Court of Appeals for the Eleventh Circuit recently adopted this reasoning, holding that PMA does not preempt a state-law design-defect claim. *Goodlin*, 167 F.3d at 1376. That court, focusing 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," explained that preemption under § 360k(a) required "imposition of some identifiable precondition that applies to the device in question." *Id.* at 1374. As the 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 pacemaker lead at issue. *Id.* at 1374-75.

Thus here, although the FDA reviewed Teletronics' application to market its pacemaker, including information about product design, the product used by Mr. Weiland was approved through

the general premarket approval process and was not subject to any FDA-mandated design requirements. To the extent that Telectronics suggests that PMA establishes a design requirement by "requiring" a company to market a device with the design specified in the PMA application, that suggestion is sophistry. PMA *allows* a company to market a device with a design of the company's own choosing. PMA does not "require," to use the language of section 360k(a), that the device have that design or that the company market the device at all. *See* Brief for the United States as *Amicus Curiae* in *Smith Industries Medical Systems v. Kernats*, S. Ct. No. 96-1405, at 15 (Appendix G). The FDA could issue a performance standard requiring pacemaker leads to meet certain specifications, *see* 21 C.F.R. § 861.1(b)(3), in which case a defective design claim that challenged the safety of a lead 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 side of the preemption equation were satisfied and whether the common-law design defect claim constituted a state requirement related to the safety or effectiveness of a medical device. But at least there, one could comprehend the notion of comparing the federal design requirement to the theory behind the damages claim. The impossibility of comparing a federal requirement and a counterpart state requirement shows that section 360k(a) does not preempt the claims alleged here.

The FDA agrees that a PMA does not impose device-specific requirements sufficient to preempt claims such as Mr. Weiland'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 these regulations, the FDA explained 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) (highlighting italicized statutory language). 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).

Accordingly, because the FDA has issued no device-specific regulations regarding pacemaker design, section 360k(a) cannot preempt either of Plaintiff's claims regarding Teletronics' pacemaker.

III. IN ENACTING THE MDA, CONGRESS RECOGNIZED THE CONTINUING VALIDITY OF COMMON-LAW CLAIMS.

In *Medtronic*, four members of the United States Supreme Court emphasized that section 360k(a) simply does not preempt common-law claims. 518 U.S. at 502. Five members of the Court (but no opinion of the Court) stated that section 360k(a) preempts such claims in some circumstances. *Id.* at 504-05 (Breyer, J., concurring); *id.* at 509 (O'Connor, J., joined by Rehnquist, C.J., Scalia and Thomas, J.J., concurring in part and dissenting in part). In this case, this Court need not reach the question 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 appellate court's decision finding complete preemption of Mr. Weiland's 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 v. Norris*, 114 S. Ct. at 2243. 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 v. Kerr-McGee Corp.*, 464 U.S. at 251 ("Congress would [not], without comment, remove all means of judicial recourse for those injured by illegal conduct."); *cf. Medtronic*, 518 U.S. at 498 n.18 (majority) ("FDA's narrow understanding of the scope of § 360k(a) is obvious from the full text of the regulation [21 C.F.R. § 808.1(d)]").

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 focussed 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.*

Furthermore, the Court should be "loath to infer a tacit trade-off between regulation and liability when it appears that even the regulated industry was unaware of the purported bargain until relatively late in the day. [R]esearch reveals that 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 . . . it seems unlikely 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." *Id.* at 1381.

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 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); *see Michael v. Shiley, Inc.*, 46 F.3d 1316, 1326 (3d Cir.) (Congress "gave indication in 21 U.S.C. § 360h that at least some common law remedies would remain in conjunction with FDA regulation"), *cert. denied*, 516 U.S. 815 (1995).

As the Supreme Court observed in a related context in *Silkwood v. Kerr-McGee Corp.*, "the only congressional discussion concerning the relationship between the . . . [statute] and state tort remedies indicates that Congress assumed that such remedies would be available." 464 U.S. at 251. In these 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.

CONCLUSION

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

Dated: May 4, 1999

Respectfully submitted,

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APPENDIX

TABLE OF CONTENTS TO APPENDIX

APPENDIX A

Affidavit of Intent to File a Petition for Leave to Appeal and Notice of Filing for same dated December 30, 1998.

APPENDIX B

Opinion of the Appellate Court, First District, Fifth Division in *Weiland v. Telectronics Pacing Systems, Inc.*, No. 1-95-2736, dated December 11, 1998.

APPENDIX C

Order of this Court allowing the Plaintiff-Appellant's petition for leave to appeal dated March 31, 1999.

APPENDIX D

Notice of Election to File Supplemental Brief and Notice of Filing for same dated April 13, 1999.

APPENDIX E

Principal statutory provisions involved:
21 U.S.C. § 360k
21 U.S.C. § 360h(d)

APPENDIX F

Principal regulatory provision involved:
21 C.F.R. § 808.1(d)

APPENDIX G

Brief for the United States as *amicus curiae* in opposition to petition for a writ of certiorari in *Smith Industries Medical Systems v. Kernats*.

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.