IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 97-5801

LISA GOODLIN,

Appellant,

v.

MEDTRONIC, INC.,

Appellee.

Appeal from the United States District Court
for the Southern District of Florida

BRIEF FOR APPELLANT LISA GOODLIN

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April 28, 1998

Lisa Goodlin v. Medtronic, Inc., No. 97-5801

CERTIFICATE OF INTERESTED PERSONS AND
CORPORATE DISCLOSURE STATEMENT
OF PLAINTIFF-APPELLANT LISA GOODLIN

Pursuant to Federal Rule of Appellate Procedure 26.1 and Eleventh Circuit Rule 26.1, plaintiff-appellant Lisa Goodlin hereby states that the following individuals and entities have an interest in the outcome of this case:

Robert L. Cowles

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Alvin B. Davis

Michelle Fongyee

L. Dianne Mason

Medtronic, Inc.

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John Nichols

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STATEMENT REGARDING ORAL ARGUMENT

Appellant requests oral argument. The issue in this case--whether the Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360c, et seq., preempt state-law claims based on injuries caused by medical devices that received pre-market approval from the Food and Drug Administration and leave plaintiffs without any remedy--is of considerable importance. Proper resolution of the issue depends on an understanding of relevant case law, federal statutes, and agency regulations governing medical devices. Oral argument will aid the Court in evaluating these complex legal authorities.

CERTIFICATE OF TYPE SIZE AND STYLE

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STATEMENT OF JURISDICTION

This appeal is from a decision of the district court granting summary judgment to Defendant-Appellee. The district court had jurisdiction under 28 U.S.C. § 1332 based on diversity of citizenship. R1-2. The district court's judgment was entered on October 31, 1997, and disposed of all claims of all parties. R3-60-1. Appellant filed this appeal on November 13, 1997. R3-61. This Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUE ON APPEAL

In a product liability action to recover damages for injuries caused by a medical device that received premarket approval from the Food and Drug Administration, whether the Medical Device Amendments to the Food, Drug, and Cosmetic Act, 28 U.S.C. § 360c, et seq. ("MDA"), preempts the plaintiff's state-law tort claims.

STATEMENT OF THE CASE

This appeal involves a suit to recover for injuries suffered by plaintiff Lisa Goodlin from a pacemaker manufactured by defendant Medtronic, Inc. On Medtronic's motion for summary judgment, the district court held that the MDA preempted all of Lisa Goodlin's claims. R3-59.

Because an understanding of the structure of the MDA is important to understanding this case, Part A, below, offers a general description of the MDA. Part B describes the Supreme Court's decision in Medtronic, Inc. v. Lohr, __ U.S. __, 116 S. Ct. 2240 (1996), in which the Court considered the scope of the MDA's preemption provision. Part C sets forth the facts of this case and a summary of the district court's opinion.

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 gave 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 divides 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 that do go through 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 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. See Addendum 1a. Congress further authorized the FDA to grant to states and localities exemptions from preemption in certain circumstances. 21 U.S.C. § 360k(b) (see Addendum 1a).

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 Lohr, 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. 4. 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 this Court, the Supreme Court held that none of the Lohrs' claims was 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. 116 S.Ct. at 2251 (majority); id. at 2263-64 (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 2254-55 (majority); id. at 2263-64 (O'Connor, J., concurring in part and dissenting in part). (3) A tort claim premised on state-law duties "equal to, or substantially identical to" requirements imposed under the MDA or FDA regulations is not preempted. Id. at 2255-56 (majority); id. at 2264 (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. 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 2257. 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 2258.

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.[1]

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[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. Id. at 2252 (distinguishing Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992)). The plurality found it

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 the plurality opinion (see supra note 1) because he was not convinced that MDA preemption of common-law claims would be "rare." Id. at 2262. 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 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. 116 S. Ct. at 2260-61. 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.

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

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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 2258-59.

2262-63. 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 2264. 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

In January 1991, Ms. Goodlin was implanted with a Medtronic pacemaker and its related components, including the model 4004M lead. R1-2-(2-3). (A pacemaker lead is a wire that delivers the pacemaker's electrical impulse to the heart.) Ms. Goodlin is dependent on a pacemaker to sustain her life. R1-2-3.

Medtronic's 4004M lead received PMA from the FDA. Sometime after Ms. Goodlin had the Medtronic pacemaker implanted, however, the FDA discovered during an inspection that the survival probability of the pacemaker lead was low--that is, that the probability of lead failure was high. R3-59-4. The FDA subsequently instructed Medtronic to issue a Health Safety Alert letter informing physicians about the pacemaker's flaw. Id. In that letter, Medtronic told physicians to "consider whether prophylactic replacement would be appropriate, especially . . . [for]

pacemaker-dependent patients." Medtronic's letter said that physicians should replace the pacemaker lead if "the risk of continued use outweigh[ed] the risk associated with implanting a new lead." Id. Because Ms. Goodlin was pacemaker-dependent, and in accordance with the Health Safety Alert, her physician extracted the 4004M lead and replaced it with another Medtronic lead. R1-2-3.

Having been forced to undergo open-heart surgery to replace Medtronic's 4004M lead, Ms. Goodlin sued Medtronic, alleging negligent design and strict liability under Florida state law. See generally R1-2 (Amended Complaint). Although the specific lead removed from Ms. Goodlin showed no sign of failure, R3-59- 4, the low survival probability of the 4004M presented an unacceptable risk to her.

Medtronic moved for summary judgment, arguing that section 360k(a) of the MDA expressly preempts product liability claims related to devices that have received premarket approval from the FDA. R1-24. In granting Medtronic's motion, the district court first reviewed the Supreme Court's decision in Medtronic v. Lohr, 116 S. Ct. 2240, where, as explained above, the Supreme Court held that the MDA did not preempt design, manufacturing, and labeling claims related to a Class III device marketed pursuant to an FDA finding that the device was "substantially equivalent" to a device on the market prior to the MDA's enactment. The district

court justified a different outcome here because, unlike the pacemaker lead at issue in Lohr, the 4004M received premarket approval. The court held that "when the FDA grants a device PMA, and specifically reviews that portion of the device which is later found defective, the safeness and effectiveness if the device is presumed, and a plaintiff may only allege state law design claims for strict liability and negligence that are based on a manufacturer's lack of compliance with the PMA requirements." R3-59-12. The court then held that, because the FDA had approved use of the 4004M lead, claims based on allegations that the lead was defective were preempted. R3-59-13. However, the court did not address whether the MDA did not preempt Ms. Goodlin's claims because they were premised on Florida common-law duties of "general applicability" not specifically developed "with respect to" medical devices. See Lohr, 116 S. Ct. at 2258.

Further, the district court held that, to the extent Ms. Goodlin's tort claims were based on Medtronic's alleged failure to comply with federal regulations, she could validly state such claims but had not done so in her complaint. R3-59-16.

STANDARD OF REVIEW

The district court's holding that Plaintiff's state-law claims are barred as a matter of law is subject to de novo review by this Court. Medtronic, Inc. v. Lohr, 56 F.3d 1335, 1341 (11th Cir. 1995).

SUMMARY OF ARGUMENT

Two years ago in Medtronic v. Lohr, the Supreme Court rejected appellee Medtronic's attempt to immunize itself from tort liability in a context almost identical to that presented here. As in this case, Lohr involved injury allegedly caused by a defective Medtronic pacemaker lead. As in this case, Medtronic argued there that the MDA preempted all of the plaintiffs' state-law damages claims. The Supreme Court's majority opinion requires that, for the MDA to preempt a common-law claim, that claim must be developed "with respect to" devices and must correspond to some device-specific federal requirement. Here, no federal pacemaker-lead-specific requirement is in effect. Indeed, Medtronic--not the FDA--designed the 4004M lead. And no state-law claim developed "with respect to" devices is at issue here. Rather, both of Ms. Goodlin's claims are based on state-law duties of "general applicability."

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

In addition, the Court in Lohr gave "substantial weight" to the FDA's interpretation of the MDA's preemption provision. The FDA recently 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 Lohr, also reflects the agency's recognition of its own limitations. As the FDA recognizes, its general regulatory review and approval processes cannot guarantee the safety of medical devices. "Accordingly, compliance with general FDA requirements should not broadly preempt State common law remedies, which provide an important (and frequently the only) mechanism for persons to seek redress for injuries resulting from defective medical devices." 62 Fed. Reg. 65384, 65387 (1997).

At a minimum, Ms. Goodlin's claims are not preempted to the extent that they are based on failure to comply with federal regulations. Although the district court found that Ms. Goodlin's complaint did not state such claims, the district court erred because those claims are not separate causes of action. Showing non-compliance with federal regulations is one way in which Ms. Goodlin may prove her claims of negligence and strict liability. Moreover, the complaint here is similar to the

complaint in Lohr, as to which the Supreme Court found that non-compliance claims were adequately pled.

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. Goodlin'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. Medtronic's argument runs contrary to that expectation and should be rejected here.

ARGUMENT

Section 360k(a) of the MDA expressly preempts certain state law. Section 360k(a) provides:

> [N]o 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 a device under this chapter.

Four fundamental principles should guide the Court's consideration of the scope of this provision. First, because of the importance of preserving our delicate state-federal balance, Hillsborough County v. Automated Medical Laboratories, Inc.,

471 U.S. 707, 713 (1985), there is a strong presumption against preemption that may only be overcome by "clear and manifest" Congressional intent to oust state and local law. Id. at 715; see Hawaiian Airlines, Inc. v. Norris, 512 U.S. 246, ___, 114 S. Ct. 2239, 2243 (1994); Wisconsin Public Intervenor v. Mortier, 501 U.S. 597, 605, 611 (1991). Second, this powerful presumption is even stronger where, as here, preemption would displace the historic power of the state to protect the health and safety of its citizens. Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947). Third, where a finding of preemption of common-law claims would leave injured individuals without any state or federal remedy, as is the case here, the Supreme Court ascribes preemptive intent to Congress only in the most compelling circumstances. Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 251 (1984); see also English v. General Electric Co., 496 U.S. 72, 87-90 (1990). Finally, in the preemption context, as in others, the views of the agency charged with administering the statutory scheme are entitled to deference. Lohr, 116 S. Ct. at 2256; Hillsborough County, 471 U.S. at 714.

A. The Supreme Court's Decision In *Lohr* Requires A Finding Of No Preemption In This Case.

In holding that section 360k(a) did not preempt the plaintiffs' damages claims in Medtronic v. Lohr, the 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." 116 S. Ct. at 2257. 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. at 2257-58. Although Lohr 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 in this case.

1. Under Lohr, preemption under section 360k(a) requires a high degree of specificity and substantive overlap with regard to both the potentially preemptive federal requirement and the potentially preempted state law. On the federal side, just as with respect to a 510(k) device, the FDA does "not 'require' [a PMA device] to take any particular form for any particular reason." Id. at 2254. The PMA process, while more scientifically rigorous than 510(k), applies to devices generally: It demands that all PMA devices have a "reasonable assurance" of safety and effectiveness, 21 U.S.C. § 360e(d)(2), but it does not "require"--to use the language of section 360k(a)--any specific design. Thus, as Lohr states in referring to FDA labeling and manufacturing

rules, PMA regulations place no "specific mandate on manufacturers or producers" concerning device design. 116 S. Ct. at 2258.

Here, the FDA required Medtronic to follow the PMA process before marketing the 4004M lead, but neither the FDA nor the MDA imposed any specific requirement on the lead's design. Like the design of the 510(k) pacemaker lead at issue in Lohr, the design of the PMA pacemaker lead at issue here originated with Medtronic. The FDA "did not 'require' Medtronic['s] pacemaker to take any particular form for any particular reason." Id. at 2254. "[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).

Further, Lohr held that, for preemption to occur, the MDA requires a great deal of specificity on the state-law side of the preemption equation--a specificity generally absent from state damages suits and clearly absent in this case. Addressing the argument that the Lohrs' manufacturing and labeling claims were preempted, the Supreme Court majority 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 [plaintiffs'] 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 [] claims based on allegedly defective manufacturing or labeling are pre-empted by the MDA.

Id. at 2258; see id. at 2257. 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); 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 . . . ."). Thus, under Lohr, the fact that the 4004M received PMA does not bar Ms. Goodlin's claims.

2. The district court reached a contrary conclusion because it relied not on the majority opinion in Lohr, but on its reading of Justice Breyer's concurrence and Justice O'Connor's partial dissent, which was joined by three other Justices. The district court stated that, "under the view announced by the five [concurring and partially dissenting] Justices in Lohr, when a manufacturer's device receives a PMA, and that portion of the device which is later found defective actually received an extensive review in the PMA, the only state tort law design claims that survive the MDA's pre-emption provision are those that specifically enforce the federal requirements." R3-59-10. In fact, however, the opinions of the five concurring and partially dissenting Justices do not require any such conclusion.

Indeed, Justice Breyer's view is contrary to that stated by the district court for several reasons. First, and dispositive here, Justice Breyer formed part of the majority opinion and joined section V, on which Ms. Goodlin's arguments, above, are based. As the district court recognized, R3-59-10, the majority opinion--not the concurrence--constitutes the precedent. Second, Justice Breyer's separate concurrence emphasizes

his view that the FDA has the power to determine, within its broad statutory mandate, which kinds of federal law have preemptive effect. 116 S. Ct. at 2260; id. at 2261 ("At least in present circumstances, no law forces the FDA to make its requirements pre-emptive if it does not think it appropriate"). And the FDA has expressly stated that it does not believe that PMA preempts damages claims. See infra p. 24.

Third, although Justice Breyer stated that he thought the MDA could preempt damages claims in some instances, his example was based, not on generally-applicable MDA requirements, but on a device-specific conflict: where a federal regulation required hearing aids to have two-inch wires and a common-law claim was premised on the notion that hearing aids must have one-inch wires. 116 S. Ct. at 2259. Here, of course, the FDA has established no regulations regarding the design of pacemaker leads and Ms. Goodlin's negligent design and strict liability claims in no way conflict with Medtronic's duties under the MDA. Moreover, as noted above, Ms. Goodlin's common-law claims are based on duties of general applicability--"the general duty of every manufacturer to use due care to avoid foreseeable dangers in its products," id. at 2258 (majority)--not on a device-specific duty like the one-inch wire requirement in Justice Breyer's example. Because Ms. Goodlin's common-law claims would "impose[] no substantive requirement specifically with respect to the device at issue here," her claims do not implicate Justice Breyer's concern. Brief for

the United States as Amicus Curiae in Smith Industries Medical Systems v. Kernats, S. Ct. No. 96-1405, at 17 (Addendum 6a); see Connelly v. Iolab Corp., 927 S.W.2d 848, 854 (Mo. 1996). Accordingly, the district court erred both in its reading of Justice Breyer's concurrence and, more importantly, in failing to follow the rationale of the majority opinion.

In addition, the partial dissent does not require a finding that section 360k(a) preempts design defect claims regarding PMA devices where the claims go beyond enforcing federal requirements. The dissent's view was that the MDA preempts claims that would impose requirements above and beyond those imposed by the FDA. 116 S. Ct. at 2264. Thus, the dissent agreed with the majority that the Lohrs' design claims were not preempted because no federal requirements applied to the design of the Medtronic pacemaker lead at issue in that case. Id. Yet here too, no federal requirements dictate how the 4004M pacemaker lead was designed. And where there is no specific federal requirement, there is no preemption under section 360k(a).

3. Medtronic suggested below that premarket approval establishes a design requirement by "requiring" a company to market a device with the design specified in the PMA application. That suggestion is sophistry. The PMA allows a company to market a device with a design of the company's own choosing. To use the language of section 360k(a), a PMA does not "require" that the device have that

design or that the company market the device at all. See 62 Fed. Reg. at 65387; Brief for the United States as Amicus Curiae in Smith Industries Medical Systems v. Kernats, S. Ct. No. 96-1405, at 15 (Addendum 5a). 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 Lohr, 116 S. Ct. at 2259 (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.

Similarly, the FDA could have conditioned approval of the 4004M lead on Medtronic's satisfying certain design requirements. Here, however, the "Conditions of Approval" attached to the letter granting PMA to the 4004M lead is an FDA form document. R1-24-Exh.E (at Exh. 3). The document says nothing specific to the 4004M. Indicative of the document's generic character, it is dated November 1986--more than two years prior to the PMA letter. Id. Exh. E (at Exh. 3 at 3).

In order for a state-law requirement to be "different from or in addition to" a federal requirement, there must be a relevant federal requirement. Here, federal law imposes no requirement on the 4004M lead for Ms. Goodlin's common-law claims to be "different from or in addition to." The impossibility of comparing a federal requirement and a counterpart state requirement shows that section 360k(a) does not preempt the claims alleged here. This analysis is consistent with all three of the opinions in Lohr, and the district court erred in holding otherwise.

B. The FDA Agrees That Premarket Approval Does Not Preempt Damages Claims.

In light of the foregoing, the district court's ruling must be reversed because it cannot be squared with Lohr. Although no further inquiry is therefore necessary, the FDA's views on the scope of section 360k(a) provide additional support for reversal.

In Lohr, the Court gave "substantial weight" to the FDA's interpretation of section 360k(a). 116 S. Ct. at 2256 (majority); see also id. at 2260-61 (Breyer, J., concurring in part and concurring in the judgment). As the Court recognized, deference to the FDA's views is particularly appropriate here because section 360k(b) authorizes the FDA to exempt state laws from preemption. See Addendum 1a. 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. 116 S. Ct.

at 2255-56 ("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. Goodlin.

Since Lohr, the lower courts have continued to reach inconsistent conclusions about the scope of section 360k(a) and, in particular, the provision's effect on common-law claims related to injuries from PMA devices and investigational devices. "In light of the confusion among the lower courts . . . and in accordance with the Supreme Court's recognition that FDA's interpretation of the preemptive effect of section [360k(a)] is entitled to substantial weight," the FDA recently issued a proposed rule to clarify the scope of preemption. 62 Fed. Reg. 65384 (1997) (amending 21 C.F.R. § 808.1(d)).

As a general matter, the FDA's proposed rule is based on the agency's view that section 360k(a) does not "prevent a party who is injured by a defective medical device from seeking redress under a State's common law." Id. at 65386. Rather, "[b]y its plain terms, section [360k(a)] does not prevent a State from imposing

common law duties on manufacturers of medical devices unless those duties are 'requirements' of the kind described in the statute." Id. The FDA explained that the MDA preempts common-law claims only when (1) the FDA has expressly imposed, by regulation or order, "a specific substantive requirement applicable to the particular medical device," and (2) the state common law "imposes a substantive requirement applicable to the same particular medical device that is different from, or in addition to, FDA's counterpart requirement." Id. at 65387. "FDA requirements that are applicable to devices in general, or that are established by means other than through regulation or order, should generally not result in preemption of State tort claims." Id.

In this case, the district court held that "the PMA process does produce device-specific requirements for safety and effectiveness." R3-59-14. Similarly, arguing for complete preemption of Ms. Goodlin's claims, Medtronic relied on the nature of the PMA application process. See R1-24-(3-5). The FDA, on the other hand, has stated that the PMA process "does not signify . . . that Congress or FDA has established a specific Federal requirement (e.g. with respect to the design of the device) that supplants a State common law duty." 62 Fed. Reg. at 65387. Rather, a PMA "signifies that the manufacturer's proposal for marketing or use of the device in

question satisfies the relevant statutory criteria" for approval. Id.[2] Therefore, under the FDA's view, PMA does not preempt design-defect claims. Accordingly, the district court's understanding of premarket approval (and Medtronic's presentation of it) directly contradict the agency's expert view. For this additional reason, the decision below should be reversed.

C. Ms. Goodlin's Claims Are Not Preempted To The Extent That They Are Based On Failure To Comply With Federal Regulations.

The district court correctly held that the MDA does not preempt Ms. Goodlin's claims to the extent that her claims are based on Medtronic's failure to comply with FDA regulations. R3-59-16. This result directly follows from Lohr, where all nine Justices agreed that section 360k(a) does not preempt such claims. However, the district court erred in finding that the complaint did not raise such a claim. Id.

"The failure to comply with FDA regulations is not a separate claim." National Bank of Commerce v. Kimberly-Clark Corp., 38 F.3d 988, 992 n.2 (8th Cir. 1994). Rather, FDA regulations serve as one standard by which to measure the defendant's

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[2] Thus, the PMA granted to the 4004M lead would preempt a state premarket approval requirement. That is, Florida could not decide to require its own PMA application as a condition to marketing the device in the state. See 45 Fed. Reg. at 67323.

conduct. Id. As in National Bank of Commerce, Ms. Goodlin is not asserting an implied cause of action under the regulations; she is contending that her "ability to recover under state tort law is only limited to the extent that it seeks to impose duties on [the defendant] in addition to or different from those imposed by the FDA regulations." Id.

As the Supreme Court explained, "Nothing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." Lohr, 116 S. Ct. at 2255. In Lohr, the plaintiffs' negligence claim alleged that Medtronic had "breached its duty in the design, assembly, and sale of the pacemaker by negligently designing, manufacturing, assembling and selling a device which was unreasonably dangerous to the user. . . ." Lohr Complaint, Addendum 9a at ¶ 6. Their strict liability claim alleged that "the device was in a defective condition and was unreasonably dangerous to foreseeable users by reason of the defects alleged above." Id. 10a at ¶ 12. Thus, like Ms. Goodlin's complaint, R1-2-(3-4), the Lohrs' complaint nowhere specifically alleged failure to comply with federal regulations. Nonetheless, the Court recognized that, "[a]lthough the precise contours of their theory of recovery have not yet been defined, . . . it is clear that the Lohrs' allegations may include claims that Medtronic has, to the extent they exist, violated FDA regulations." 116 S. Ct. at 2255 (majority); id. at

2264 (partial dissent) (same); see also Medtronic v. Lohr, 56 F.3d 1335, 1343 & n.8 (11th Cir. 1995) (recognizing claims but finding preemption); Easterling v. Cardiac Pacemakers, Inc., 986 F. Supp. 366, 375 (E.D. La. 1997) (although "complaint does not specifically refer to violations of FDA or PMA standards," recognizing claims adequately alleged and not preempted to extent they mirror FDA regulations). The complaint in this case is similar to the Lohr complaint and the result should be similar as well: Ms. Goodlin's allegations "may include claims that Medtronic has . . .violated FDA regulations."

D. In Enacting The MDA, Congress Recognized the Continung Validity Of Common-Law Claims.

In Lohr, four members of the Supreme Court strongly suggested that section 360k(a) simply does not preempt common-law claims. 116 S. Ct. 2259. Five members of the Court (but no opinion of the Court) stated that section 360k(a) preempts such claims in some circumstances. Id. at 2259 (Breyer, J., concurring); id. at 2262 (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.

Nonetheless, the district court's decision finding complete preemption of Ms. Goodlin'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. Lohr, 116 S. Ct. at 2257 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)]"). In fact, 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. Id. 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.

CONCLUSION

For the foregoing reasons, this Court should reverse the decision of the district court and remand the case for further proceedings.

Dated: April 28, 1998

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 28, 1998, I caused two copies of the foregoing Brief of Appellant and one copy of the accompanying Record Excerpts to be served by first class mail on each of the following counsel, who have entered their appearance in this appeal:

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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
- the complaint in Lohr v. Medtronic

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.