

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

REPLY BRIEF FOR APPELLANT
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CERTIFICATE OF TYPE SIZE AND STYLE

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INTRODUCTION

Appellee Medtronic, Inc.'s brief errs on several basic points. First, it disregards the majority opinion of the Supreme Court in Medtronic v. Lohr, 518 U.S. 470 (1996), instead relying on an amalgam of views expressed in minority opinions and ultimately elevating the opinion of a single concurring Justice above the opinion of the five-Justice majority. Second, it exaggerates the significance of the premarket approval ("PMA") process. Finally, it repeatedly asks this Court to follow pre-Lohr cases, the reasoning of which is inconsistent with the Supreme Court's decision.

In contrast, Ms. Goodlin's argument is based on the holding and reasoning of the Lohr majority and is supported by the long-held views of the Food and Drug Administration ("FDA"). Relying on these authorities, Ms. Goodlin demonstrated in her opening brief that the preemption provision of the Medical Device Amendments ("MDA"), 21 U.S.C. § 360k(a), does not preempt her claims for defective design of Medtronic's 4004M pacemaker lead. As discussed in that brief, and as further explained below, the decision of the district court finding that the MDA preempts Ms. Goodlin's damages claims should be reversed.

ARGUMENT

A. Express Preemption

1. Appellant Goodlin's argument is based on part V of Justice Stevens' opinion in Medtronic v. Lohr, 518 U.S. at 492-502, which garnered five votes and constitutes the heart of the opinion of the Court. That opinion requires specificity for both the federal requirement and the counterpart state requirement for preemption to occur. Id. at 500-01; see Opening Br. 17-18.

Trying to avoid the specificity requirement, Medtronic argues that the five-Justice Opinion of the Court does not constitute precedent. Rather, Medtronic urges this Court to piece together a majority opinion from Justice Breyer's concurrence and Justice O'Connor's partial concurrence and partial dissent. Medtronic's theory is that Justice Breyer's views as expressed in his concurrence are inconsistent with the views expressed in part V of the majority opinion, which he joined. Therefore, Medtronic in effect says, this Court should disregard Justice Breyer's joinder in the majority opinion, and thereby consider the five-Justice opinion to be a four-Justice opinion. That plea is flatly wrong and should be rejected.

First, Lohr contains only one judgment of the Court, a majority opinion joined by five Members of the Court. That majority opinion, and only that

opinion, establishes the precedent. That precedent, as discussed in Appellant's opening brief, requires a finding of no preemption in this case. See Opening Brief at 16-23.

Second, Medtronic's theory is based on the faulty premise that Justice Breyer's concurrence is inconsistent with his joinder in the majority opinion. Justice Breyer's separate opinion reflects his view that preemption occurs in cases of direct conflicts between specific state and federal requirements. See 518 U.S. at 503-04. His example--where federal law requires a two-inch hearing aid wire but state law requires a one-inch hearing aid wire--is device specific and presents a situation where the state requirement is a clear counterpart to the federal requirement. That is, the two requirements address precisely the same matter, the length of a hearing aid wire. Id. at 504. Thus, contrary to Medtronic's contention, Justice Breyer's concurrence, like the majority opinion in which he joined, requires specificity on both the federal and the state sides of the preemption equation. Accordingly, even if Lohr's precedent were established by Justice Breyer's concurrence rather than by the majority opinion, that precedent would still require specificity for both the federal and the counterpart state requirements.

2. Medtronic correctly states that PMA has a preemptive effect. It errs, however, by overstating the scope of the preemption. The counterpart state

requirement to a federal PMA requirement is a state PMA. That is, a state requirement that a pacemaker lead receive state premarket approval prior to marketing would address the same topic and at the same level of specificity as a federal requirement that a pacemaker lead receive PMA from the FDA. On the other hand, a product liability claim for design defect is not a counterpart requirement to a PMA; that claim does not address the same topic (marketing approval).

This understanding of the preemptive scope of PMA is consistent with Lohr and with the long-held views of the FDA. Thus, in 1978, the FDA explained that California could continue to require a device to undergo its own state PMA until the date on which the FDA determined that federal PMA was not required for that device. 45 Fed. Reg. 67321, 67323 (1980).

Medtronic cites to this same FDA statement to establish that a PMA can have preemptive effect. Again, the parties do not disagree there. The question is: What is the counterpart requirement to a federal PMA applicable to a particular device? Again, the answer is: a state PMA requirement for that same device. The mere existence of the federal PMA scheme does not generally preempt the existence of state PMA schemes. Preemption under section 360k(a) looks for

device-specific counterparts. Lohr, 518 U.S. at 500-01 (majority); id. at 505 (Breyer, J., concurring).

Similarly, the existence of one federal device-specific requirement does not preempt all state requirements applicable to that device. The federal requirement preempts only the counterpart state requirement. To use Justice Breyer's example, a federal rule that hearing aids must have two-inch wires would preempt a state rule that hearing aids have a one-inch wire but would not preempt state rules regarding the packaging of hearing aids. Lohr, 518 U.S. at 505. Thus, the federal requirement that a device cannot be marketed without federal PMA would preempt a state requirement that the device undergo state PMA but would not preempt state rules regarding other aspects of that device.

3. The design of the 4004M lead originated with Medtronic and was not mandated by any federal requirement. Medtronic argues the PMA somehow converts the manufacturer's choice of design into a federally required design. Appellee Br. 28, 30. Medtronic made a similar argument in Lohr. Although that case involved a device marketed under a finding of substantial equivalence, not PMA, the FDA's response to Medtronic is fully applicable here.

There is an additional reason why the defective-design claims would not be preempted by a substantial equivalence determination, even if it were

deemed tantamount to the determination of safety and effectiveness required for premarket approval. Neither the FDCA nor the FDA's regulations prescribe criteria for the design of devices. The design of devices originates with its manufacturer. Even if design specifications could be characterized as "requirement[s]" in some sense, once the FDA clears the device under Section 510(k), they are not "requirement[s] *applicable* to the device *under th[e Act]*." 21 U.S.C. 360k(a) (2) (emphasis added); see also 21 U.S.C. 360k(a)(1). Instead, the specifications are applicable to the 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." Cf. *American Airlines, Inc. v. Wolens*, 115 S. Ct. [817,] 824 [1995].

Brief for the United States as Amicus Curiae in Medtronic v. Lohr, S. Ct. No. 95-754, 1996 WL 118035, at *20-21 (underlined emphasis added; italics in original).

The FDA allowed Medtronic to market the 4004M lead; it did not require it to do so. The FDA allowed the 4004M to use polyurethane insulation; it did not require that the 4004M to do so. Indeed, after the device was on the market, the FDA expressed concerns about its safety. R3-59-4. No federal requirement

mandates the use of polyurethane in pacemaker leads; many leads do not use that material. Medtronic's assertion that the PMA converted its design into a federal requirement is simply wrong.

4. Medtronic's brief barely mentions the FDA's view of preemption and relegates to a footnote its response to Ms. Goodlin's discussion. Appellee Br. 29 n.10. Despite Medtronic's short response, a few comments are in order.

First, the FDA's view is entitled to "substantial weight," as the Supreme Court recognized. Lohr, 518 U.S. at 496 (majority); see id. at 505-06 (Breyer, J., concurring). Deference is appropriate in part because the statutory scheme requires the FDA to consider applications for exemption of state requirements from preemption, 21 U.S.C. § 360k(b), which necessarily requires the FDA to determine whether the state requirements are preempted in the first place. See Lohr, 518 U.S. at 496 (making same point regarding § 360k(b)).

Second, Ms. Goodlin is not asking this Court to rely on a proposed regulation. Rather, as stated in the opening brief, the proposed regulation is useful in that its stated purpose is to clarify the FDA's longstanding view of the scope of preemption under section 360k(a). Aside from the proposed rule, the FDA's views are available to the Court from a number of sources. Most obviously, the FDA has an existing regulation on this topic, 21 C.F.R. § 808.1(d)(1), which states that

state-law requirements of general applicability are not subject to preemption under 21 U.S.C. § 360k(a). See Lohr, 518 U.S. at 496-97 (making same point regarding 21 C.F.R. § 808.1(d)(1)). In addition, the FDA expressed its views regarding preemption of state-law damages claims through two briefs in the Supreme Court: an amicus brief in Lohr, 1996 WL 118035 (filed Mar. 15, 1996), and a recent amicus brief in Smith v. Kernats, S. Ct. No. 96-1405 (filed Nov. 1997) (attached in relevant part as Addendum 4a-7a to Appellant Br.). Going back a bit further, the FDA submitted an amicus brief in 1994 in another PMA preemption case, Talbott v. Bard, No. 94-1951 (1st Cir.) (filed Nov. 1994), in which it stated its disagreement with the view that "premarket approval procedures that apply to Class III devices constitute 'specific requirements' within the meaning of 21 C.F.R. § 808.1(d)." See Addendum 3a.

In 1984, the FDA stated in an advisory opinion that it did not believe that section 360k(a) preempted state requirements regarding "general enforcement," including "legal remedies available under the State judicial system." The FDA further stated that section 360k(a) preempts state requirements "applicable to a device only when the FDA has established specific counterpart regulations or there are other specific requirements applicable to a particular device or class of

devices under the act; it is necessary that an FDA requirement exist before a State requirement is preempted." Addendum 5a.

And in 1977, when it proposed a regulation interpreting section 360k(a), the FDA stated that "general State or local law provisions governing the enforcement of requirements applicable to devices" are not preempted because "[s]uch general enforcement provisions are not themselves requirements." 42 Fed. Reg. 30383, 30384 (1977).

Other examples, particularly from Federal Register commentary, exist, but an exhaustive list is not necessary. The point is that the proposed rule reflects and restates the FDA's longstanding view that section 360k(a) does not preempt damages claims such as Ms. Goodlin's. Whether or not one looks to the proposed rule, FDA's position regarding the preemptive scope of section 360k(a) in general and of the preemptive effect of PMA specifically is clear. And, as recognized by the Supreme Court in Lohr, that view is entitled to "substantial weight." 518 U.S. at 496.

5. Medtronic further asserts that if Ms. Goodlin were to prevail in this case, it would be required to change the design of the 4004M lead. Appellee Br. 40. Again, Medtronic is wrong.

First, this argument makes no sense in the context of this case because Medtronic no longer markets the 4004M lead.

Second, a jury verdict in favor of Ms. Goodlin would not necessarily imply that the 4004M should have been designed in a different manner. If Ms. Goodlin were to prevail on strict liability grounds, R1-2-3, the jury's verdict would not imply that the device should have been redesigned at all. Cf. Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 276 n.3 (1984) (Powell, J., dissenting) ("There is no element of regulation when compensatory damages are awarded, especially when liability is imposed without fault as authorized by state law.").

Third, even if Medtronic still marketed the 4004M lead, Medtronic would no more have to redesign the lead than would any manufacturer who lost a product liability suit. Some manufacturers may choose to change their products after losing lawsuits, but many do not. For instance, despite dozens of lawsuits over the Shiley heart valve, it took years before FDA regulatory pressure drove the device from the market. See The Bjork-Shiley Heart Valve: Earn As You Learn, Staff Report of the Subcommittee on Oversight and Investigations of the Energy and Commerce Committee of the U.S. House of Representatives, 101st Cong., 2d Sess., Comm. Print 101-R, at 7-20 (Feb. 1990).

Finally, even if the 4004M were still on the market, and even if the jury's verdict implied that the 4004M lead should be redesigned, that verdict would not be "different from, or in addition to," 21 U.S.C. § 360k(a), a federal requirement. Nothing in the statute or FDA regulations prevents a company from redesigning its products. Indeed, the 4004M was a revised version of an earlier approved Medtronic pacemaker lead. R1-24-Exh. E (at 14).

6. In direct conflict with this Court's and the Supreme Court's decisions in Lohr, 56 F.3d 1335, 1343 & n.8 (11th Cir. 1995); 518 U.S. at 495, 497 (majority); id. at 513 (partial dissent), Medtronic contends that Ms. Goodlin's claims are preempted, even to the extent that they are based on failure to comply with federal regulations. Appellee Br. 43-46. According to Medtronic, Ms. Goodlin's claims assert state-law duties that flow to patients, whereas the federal regulations flow to the FDA. Medtronic concludes that the duties are therefore not "parallel," and thus that the state-law duties are preempted.

Medtronic's argument is without merit. All of the duties imposed on manufacturers by FDA regulations create responsibilities for which the manufacturers are answerable in the first instance to the FDA. At the same time, each of the duties is established for the ultimate purpose of protecting patients. Thus, Medtronic's distinction between the manufacturing and labeling duties at

issue in Lohr, see Appellee Br. 45 n.17, and the design duties at issue here must fail. The FDA has promulgated manufacturing and labeling regulations for the purpose of ensuring the quality of medical devices, but the duty to comply with those regulations is a duty owed the FDA. Similarly, FDA regulations incorporate a duty to design in a reasonably safe and effective and a non-negligent manner. That duty is owed to the FDA in the first instance, but it exists for the good of patients.

Medtronic relies on Papas v. Upjohn Co., 985 F.2d 516 (11th Cir.), cert. denied, 510 U.S. 913 (1993), for the proposition that a statute such as the MDA "leaves states with no authority to police manufacturers' compliance with the federal procedures." Id. at 518-19. To the extent that Medtronic seeks to apply Papas, a pesticide case, in the MDA context to bar common-law claims based on violations of requirements "equal to, or substantially identical, to requirements imposed' under federal law," that result is foreclosed by Lohr. See 518 U.S. at 495-97.¹

¹ Attempting to minimize the significance of a preemption ruling in this case, Medtronic states that the Court can find preemption here without ruling as to all PMA devices. Appellee Br. 27, 35. The problem with that argument is that the facts regarding the PMA of the 4004M lead are not unique to the device in any

B. Implied Preemption

Medtronic argues that, even if section 360k(a) does not expressly preempt Ms. Goodlin's damages claims, the Food, Drug, and Cosmetic Act impliedly preempts her claims. Its theory is that state law conflicts with federal law insofar as state law would hold Medtronic liable for injury caused by a product that the FDA authorized it to market. Appellee Br. 47-49. This bold grab for judicially-created immunity from tort liability should be rejected.

The FDA "authorized" Medtronic to market the pacemaker lead at issue in Lohr; the FDA authorized the marketing of every other medical device lawfully sold in the United States since 1976, and the FDA authorizes the marketing of every drug lawfully sold in the United States. See 21 U.S.C. § 355. But under Medtronic's implied preemption theory, no product liability action could be maintained against a manufacturer for injuries caused by any drug or medical device lawfully sold in the United States. In the drug context, the courts have rejected that argument; and the same result is warranted here. See, e.g., Hurley v. Lederle Laboratories, 863 F.2d 1173, 1176-78 & n.2 (5th Cir. 1988) (rejecting

significant way. The PMA review process was not special in this case. Indeed, the approval letter and attached conditions of approval for the 4004M lead are in the standard FDA approval form. R1-24-Exh. E (at Exh. 3).

argument that FDCA and PHSA preempt claims regarding vaccines and reviewing case law); see also Hearings Before a Subcomm. of the Comm. on Commerce of the U.S. Senate on S. 1944, 73d Cong., 2d Sess. 400, 403 (1933) (rejecting proposal to include private right of action for damages caused by faulty or unsafe products regulated under the FDCA on ground that such right of action already existed under state common law).

Indeed, under Medtronic's view, implied preemption would bar damages actions involving any product subject to federal regulation. However, the Supreme Court has already rejected that theory. In Cipollone v. Liggett Group, 505 U.S. 504 (1992), for example, seven members of the Court held that the 1965 Act expressly preempted state regulatory law but did not preempt common law. "[T]here is no general inherent conflict between federal pre-emption of state [regulatory] requirements and the continued vitality of state common law damages actions." Id. at 518 (plurality); id. at 533-34 (Blackmun, J., concurring).

Again, in Silkwood v. Kerr-McGee Corp., the Court acknowledged that the Atomic Energy Act preempted state positive law directly "regulating the safety aspects of nuclear development." 464 U.S. at 250. Yet the Court held that the plaintiff's state damages action concerning an unsafe nuclear plant was not preempted. The Court found that it would be improper to interpret federal statutes

to "remove all means of judicial recourse" for those seeking compensation for injuries without a clear statement to that effect. Id. at 251.

Here, in the context of a statute containing an express preemption provision, the argument against implied preemption is even stronger. Congress is presumed to carry out its policies through the text of enacted legislation. Thus, where it has expressly addressed preemption of state law in a particular statutory provision, as in 21 U.S.C. § 360k, that provision is assumed to be a "reliable indicium" of congressional intent. Cipollone, 505 U.S. at 517. Although this presumption "does not . . . entirely foreclose[] any possibility of implied preemption," an "express definition of the pre-emptive reach of a statute 'implies'--i.e., supports a reasonable inference--that Congress did not intend to pre-empt other matters." Freightliner Corp. v. Myrick, 514 U.S. 280, 288 (1995).

In any event, this case does not present a conflict between state and federal law. As discussed above, see supra p.10, a jury verdict in favor of Ms. Goodlin would only require Medtronic to pay damages to Ms. Goodlin. It would not require Medtronic to take any action inconsistent with federal requirements. Thus, implied preemption does not apply here.

CONCLUSION

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

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Respectfully submitted,

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