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Rosemary V. Bourne

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Medtronic v. Lohr

In response to a conflict among the circuits, the United States Supreme Court, in *Medtronic v. Lohr*, 116 S. Ct. 2240 (1996), addressed federal pre-emption of state tort suits for Class III medical devices under the Medical Device Amendments of 1976. The Court, in an opinion by Justice Stevens, held that the Medical Device Amendments did not pre-empt state negligent design claims in product liability suits for defective Class III medical devices, negligent manufacture or labeling claims, and common-law requirements that are substantial equivalents of requirements under federal law. With this decision, the Court effectively eliminated federal pre-emption of Class III medical device products liability cases, opening the door for numerous state lawsuits. Moreover, although the application of pre-emption principles to the Medical Device Amendments is clear after *Medtronic*, the division of the Court in the case suggests that the scope of federal pre-emption of common-law claims in other contexts is far from resolved.

In an attempt to alleviate public apprehension regarding medical devices in the early 1970s, Congress passed the Medical Device Amendments Act of 1976 ("MDA"). The MDA grouped these devices into three classes. Since Class III devices were deemed to pose the most potential danger to the public, they had to

State Common-Law Claims Involving Class III Medical Devices Are Not Pre-Empted By The Medical Device Amendments Of 1976

By Rosemary V. Bourne

meet the most stringent requirements in order to receive approval from the Food and Drug Administration ("FDA"). The FDA required Class III devices to pass a strict "premarket approval" ("PMA") to insure the device's safety and effectiveness. Congress, however, created two exceptions to the PMA requirement because of the sheer number of already existing devices and the time involved in the FDA approval process. Those exceptions allowed any pre-1976 Class III device or substantial equivalent to be sold with far less burdensome requirements until the FDA could rule on the PMA.

In October of 1982, Medtronic, a manufacturer of medical devices, notified the FDA that it planned to sell the Model 4011 pacemaker lead, a part of the pacemaker that transmits electric impulses to the heart. Pursuant to the "substantial equivalent" exception created by the MDA, the FDA granted temporary approval of the device, allowing Medtronic to put the pace-

makers with the Model 4011 leads on the market. In 1987, Lora Lohr ("Lohr") received a pacemaker with the Medtronic lead to regulate her heartbeat. When the pacemaker lead failed several years later, Mrs. Lohr suffered injury to her heart that resulted in emergency surgery.

The Lohrs then sued Medtronic for negligence and strict liability in Florida state court in 1993. The case was removed to federal district court on Medtronic's motion where the district court found their state law claims pre-empted and dismissed the Lohrs' complaint. On appeal, the United States Court of Appeals for the Eleventh Circuit reversed in part and affirmed in part, holding that the negligent design claims were not pre-empted, but the negligent manufacturing and failure to warn claims were pre-empted by FDA regulations. The Supreme Court granted certiorari to resolve the pre-emption issue.

The Court began by discussing two general principles about federal pre-emption. First, in deference to the boundaries of federalism, the Court emphasized that a state law based on its police power would not be pre-empted unless it was the "clear and manifest purpose of Congress." *Medtronic*, 116 S. Ct. at 2250. Second, the Court underscored the importance of discerning congressional purpose in the particular context of a pre-emption case, to determine the

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existence and scope of federal pre-emption. *Id.* To ascertain congressional intent, the Court stated that it must analyze not only the statutory language of the pre-emption statute itself, but must also consider the pre-emption language within the framework of the entire statute. *Id.* at 2250-51.

Speaking for only a plurality of four justices, Justice Stevens discussed the issue of whether 21 U.S.C. § 360k(a) pre-empted all common-law claims. The plurality based its reasoning on statutory language, legislative history, and in particular, the purpose of the statute. *Id.* at 2251-53. Section 360k(a) states in pertinent part:

[N]o State . . . may establish or continue in effect with respect to a [medical] 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.

Id. at 2248-49. The plurality rejected Medtronic's blanket assertion that any state common-law claim would qualify as a "requirement . . . different from, or in addition to" existing FDA regulations for purposes of pre-emption under the statute. *Id.* at 2251. The plurality found Medtronic's position particularly unconvincing because it effectively would have

deprived a plaintiff injured by a medical device of any remedy. *Id.* Federal pre-emption would not permit relief for the injured party under state tort law, and federal law would not grant relief because the MDA has no provision for a private cause of action. *Id.* Congress, the plurality reasoned, could not have intended such an unjust result when, ostensibly, the purpose of the statute was to protect consumers from defective medical devices. *Id.*

The plurality referred to interpretations of the term "requirements" in other contexts as support for its conclusion that the "requirements" in § 360k(a) did not encompass all common-law claims. The plurality distinguished the Court's previous holding in *Cippollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992) that a "statute pre-empting certain state 'requirements' could also pre-empt common-law damages claims," stressing that the interpretation of requirements in the statute in that case did not preclude all common-law claims. *Medtronic* at 2251. In contrast, in this case, the effects of adopting Medtronic's interpretation of the statute would result in exclusion of all common-law claims. *Id.*

Justice Breyer added a fifth vote and joined the opinion of the Court in discussing the specific question of whether the Lohrs' common-law claims were pre-empted. *Id.* at 2254. The Court addressed Medtronic's argument that an FDA substantial equivalent determination for the pacemaker

lead constituted a "requirement" that pre-empted the Lohrs' negligent design claim. *Id.* In holding that a substantial equivalent determination was not a "requirement" that pre-empted the negligent design claim, the Court reasoned that the determination did not amount to FDA approval because the lead was still required to pass the eventual premarket approval for Class III medical devices. *Id.* Nor did a substantial equivalent classification provide any protection to the public. Instead, by requiring Medtronic to follow "good manufacturing practices," and to list and label such devices, the classification merely allowed Medtronic to compete with exempt pre-1976 medical devices. *Id.*

Next, the Court reached the Lohrs' identity of requirements claims. *Id.* at 2255. Although § 360k pre-empted state causes of action that create additional "requirements" from FDA regulations, the Court was unwilling to find that a damages action seeking to enforce an FDA regulation was an additional requirement. *Id.* In order to be pre-empted, the Court noted that there must be state law claims that are "different from or in addition to" the FDA requirements. *Id.* Unlike federal law, Florida law requires negligence to be proven to recover damages in labeling or manufacturing claims. *Id.* The Court, however, stated that this requirement, while technically different from the FDA, was insufficient to trigger pre-emption. *Id.* In the Court's view, state requirements that made it more diffi-

cult for a plaintiff to recover damages were not pre-empted by § 360k. *Id.* As a further justification for its conclusion, the Court emphasized that in determining the scope of pre-emption, courts must look to FDA regulations. *Id.* Here, the Court stated that FDA regulations supported the Lohrs' position. *Id.* at 2256.

Next, the Court noted that the FDA did promulgate federal requirements for the labeling and manufacture of medical devices, and the Court acknowledged that these regulations constituted requirements. *Id.* Nevertheless, the Court considered the general nature of the regulations insufficient to pre-empt state common-law claims in this case. *Id.* Section 360k(a)(1) requires that the federal requirement must be "applicable to the device," and under FDA regulations, "preempt state law only if they are specific counterpart regulations or specific to a particular device." *Id.* at 2257. In this case, the Court, after comparing the state and federal requirements, held that the manufacturing and labeling claims were not pre-empted because common-law tort actions were not developed specifically "with respect to" medical devices. *Id.* at 2258.

Finally, the Court refused to respond to the Lohrs' assertion that § 360k never pre-empts common-law claims. *Id.* at 2258. The Court concluded that it was unnecessary to reach this issue because none of the claims in the case had been pre-empted. *Id.* at 2259. The Court stated in dicta, however, that

it would be "rare indeed" to find pre-emption of common-law claims under the statute. *Id.*

Justice Breyer's concurring opinion stressed that the MDA could sometimes pre-empt a state law tort suit. *Id.* As support, Justice Breyer cited the Court's decision in *Cipollone*. *Id.* He rejected the plurality's distinctions between the meaning of "requirements" in the context of § 360k and the meaning of requirements in the *Cipollone* statute. *Id.* at 2262.

Justice O'Connor concurred in part and dissented in part. She concluded that state common-law causes of action were "requirements" under the statute and would therefore be pre-empted where such requirements differed from the MDA. *Id.* Although Justice O'Connor agreed that the negligent design claims and violation of federal requirements claims were not pre-empted, she argued that the labeling and manufacturing claims should have been pre-empted because they created requirements "different from and in addition to" the federal requirements. *Id.* at 2264.

In *Medtronic v. Lohr*, the Supreme Court gave control of common-law product liability lawsuits for defective medical devices back to the States, and effectively eliminated one of the only defenses left for medical device manufacturers. If the cost of defending these actions becomes prohibitively high, the practical result may be a halt in the advances in technology for medical devices. Additionally, the differing opin-

ions of the Supreme Court in this case raise the question of when, if ever, common-law claims will be pre-empted in the future.



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