Medtronic v. Lohr: State Lawsuits May Proceed against Medical Device Manufacturers

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Premarket approval is supposed to benefit consumers, not create a rose garden, free from liability, for manufacturers.¹

I. INTRODUCTION

After laying her daughter down to sleep, Lora Lohr began to feel as if she was losing consciousness. When Lohr, a cardiac technician, reached for her pulse she found none. At the hospital, her physician discovered that she was suffering from complete heart block.² The wire in her pacemaker had failed to deliver the necessary impulses to her heart.³ As Lohr stated "the device that was supposed to keep me alive almost killed me."⁴ After three years of painful surgeries and complications, Lohr sued the pacemaker's manufacturer,


³Sharon Schmickle, Medtronic, Consumers Square Off, STAR TRIB., Apr. 24, 1996, at 5A. The pacemaker's lead wire consisted of a thin, insulated wire that connected the pacemaker to the patient's heart. Id.

Medtronic, for the cost of her medical treatment. Medtronic refused to pay these claims and Lohr filed a tort liability suit in the State of Florida.

After the United States Supreme Court’s landmark decision in Cipollone v. Ligget Group Inc., medical device manufacturers have successfully asserted federal preemption as a defense against state product liability suits. Many federal courts have upheld this defense in common law actions brought against medical device manufacturers. Although these courts agree about the existence of the preemption defense, they have disagreed about its scope. In Medtronic v. Lohr, the Supreme Court attempted to resolve this dispute by defining the scope of the preemption defense applicable under the Medical Device Amendments. In fashioning its decision, the Court balanced the need to protect public health against the desire to encourage medical innovation.

This comment discusses the Medical Device Amendments of the Federal Food, Drug, and Cosmetic Act and its effect on the marketing of medical products. Part II examines the statutory language of the MDA and its regulatory impact on medical devices. Part III explores the history of the preemption doctrine established by the Supreme Court in Cipollone. Part IV delineates the facts and procedural history of Medtronic v. Lohr and analyzes the effect of this case on the federal preemption of state common law suits. Finally, Part V assesses the impact of this decision on the medical device industry and the expansiveness of the preemption doctrine.

5Supreme Court to Hear Pacemaker Litigation (National Public Radio broadcast, Apr. 23, 1996). As Lohr stated: "I've had to have five operations due to one lead wire. . . . I'm looking at them having to crack my entire chest open to pull more wires out because I have too much hardware in my body from that one lead wire going bad. I've accrued $200,000 worth of medical bills, [and] more to come." Id.

6Michael Unger, Supreme Court Hands Defeat to Medical Device Companies, NEWSDAY, June 27, 1996, at A53. Lohr sued after Medtronic rejected her request for about $10,000 in medical bills and lost wages. Id.


9See Anne-Marie Dega, The Battle Over Medical Device Regulation: Do the Federal Medical Device Amendments Preempt State Tort Law Claims, 27 LOY. U. CHI. L.J. 615 (1996) (discussing the division among courts as to whether the Medical Device Amendments should preempt state common law actions).

II. MEDICAL DEVICE AMENDMENTS

The Medical Device Amendments (MDA) of the Federal Food, Drug and Cosmetic Act of 1976 govern the regulation of medical devices.\textsuperscript{11} Congress enacted the MDA "to provide for the safety and effectiveness of medical devices intended for human use...."\textsuperscript{12} Prior to these amendments, the FDA lacked the ability to review the safety of medical devices before their entry into the market.\textsuperscript{13} In the early 1970s, an intrauterine device (IUD) called the Dalkon shield caused thousands of women to suffer toxic shock, infertility, and pelvic infections due to a design defect.\textsuperscript{14} However, by the time the Federal Drug Administration (FDA) became aware of these injuries, these devices had already inflicted permanent physical damage.\textsuperscript{15} To correct this system, Congress enacted the MDA to protect consumers before these dangerous products reached the market.\textsuperscript{16}

The MDA classifies medical devices into three different categories based upon the level of regulation or control necessary to provide a reasonable assurance of safety to society. Every medical device is subject to general controls that require reporting and record keeping procedures and establish adequate labeling standards.\textsuperscript{17} Class I devices pose little or no threat to public health or safety and are subject to only general controls.\textsuperscript{18} Class II devices are subject to general and special controls.\textsuperscript{19} Special controls include performance standards,

\begin{itemize}
\item \textsuperscript{11}21 U.S.C. § 301 (1972).
\item \textsuperscript{12}21 U.S.C. § 301 (1976).
\item \textsuperscript{13}See Gail H. Javitt, I've Got You Under My Skin-And I Can't Get Redress: An Analysis of Recent Case Law Addressing Preemption of Manufacturer Liability for Class III Medical Devices, 49 FOOD & DRUG L.J. 553, 558 (1994) (discussing the number of injuries caused by medical devices before the passage of the MDA).
\item \textsuperscript{14}See In re A.H. Robins Co., 880 F.2d 709, 710-12 (4th Cir.), cert. denied, 493 U.S. 959 (1989).
\item \textsuperscript{15}See Mary G. Boguslaski, Classification and Performance Standards Under the 1976 Medical Device Amendments, 40 FOOD DRUG COSM. L.J. 421, 423 (1985) (detailing the legislative history of the MDA along with a discussion of the injuries caused by intrauterine devices).
\item \textsuperscript{17}See Bianca I. Truitt, Comment, Injured Consumers and the FDA: Should Federal Preemption Protect Medical Device Manufacturers Under A Quasi-Governmental Immunity?, 15 J. LEGAL MED. 155, 157 (1994) (discussing the general, minimum controls on all three classes of medical devices).
\item \textsuperscript{18}21 U.S.C. § 360c(a)(1)(A) (West 1997); see also Robert S. Adler & Richard A. Mann, Preemption and Medical Devices: The Courts Run Amok, 59 MO. L. REV. 895, 912 (1994) (examples of Class I devices include tongue depressors, ice bags, elastic bandages, and crutches).
\item \textsuperscript{19}21 U.S.C. § 360c(a)(1)(13); see Adler & Mann, supra note 18, at 913 (Class II devices include hearing aids, resuscitators, and hypodermic needles).
\end{itemize}
postmarket surveillance, patient registries and other guidelines. The MDA subjects Class III devices to special scrutiny because, although they aim to support or sustain human life, Class III devices exist within the human body and present an "unreasonable risk of illness or injury" if not properly regulated.

A medical device manufacturer may introduce its product to the market under three different procedures stipulated by the FDA: 1) premarket approval (PMA); 2) premarket notification; or 3) the investigational device exemption. Generally, before a new Class III device can be placed on the market, it must meet premarket approval standards. The manufacturer must prove the safety and efficacy of the device to the FDA before receiving approval to market the product. Under the premarket notification exemption, devices which were on market before May 28, 1976 need not meet general PMA requirements. If a device is labeled "substantially equivalent," a limited form of review exists whereby a manufacturer must submit an application for premarket notification as specified in section 510(k) of the MDA. Premarket notification procedures require a manufacturer to submit an application at least ninety days prior to introducing a device to the market. The FDA then makes a determination of whether the device qualifies as "substantially equivalent." Eighty to ninety percent of medical devices receive approval under the premarket notification standard. In 1990, Congress enacted the Safe Medical Device Act to stiffen the requirements for companies seeking to market their products under the loophole created by section 510(k). The new rules require manufacturers to

20 Adler & Mann, supra note 18, at 913.

21 U.S.C. § 360c(a)(1)(c); see Adler & Mann, supra note 18, at 914 (Examples of Class III devices include pacemakers, cardiac catheters, hip replacements, and heart valves).

22 U.S.C. § 360e(c)(1). The PMA standard requires an applicant to submit any known evidence showing whether the device is safe and effective.

23 21 U.S.C. § 360e(d)(B)(i)(2)(A)-(E). The FDA must approve an application for PMA unless: (1) there is a failure to establish a reasonable assurance that the device is safe or effective under the recommended conditions of use; (2) the manufacturing methods do not conform to the requirements for good manufacturing practices; (3) the proposed labeling is false or misleading; or (4) the device does not conform to an applicable performance standard. Id.


include a 510(k) statement or 510(k) summary along with garnering Class III certification in order to market a device as "substantially equivalent."\textsuperscript{30}

Many differences exist between the premarket notification process and the PMA procedure. The premarket notification process typically entails twenty hours to complete, while the PMA process requires 1,200 hours.\textsuperscript{31} In addition, the PMA process requires the device to be tested by a panel of experts for safety and effectiveness.\textsuperscript{32} In contrast, the premarket notification demands only raw data to support the assertion that the device is "substantially equivalent" to a device which existed prior to 1976.\textsuperscript{33} This shortcut permits a device to be marketed without ever being reviewed or approved by the FDA. This loophole allows a medical device manufacturer to secure the preemptive powers of the MDA without ever being subjected to the regulatory controls established by this law.

Under the investigational device exemption, a manufacturer allows physicians to test medical devices in clinical trials before introducing these products to the market. The FDA classifies these products under the investigational device exemption (IDE).\textsuperscript{34} The IDE process is designed to encourage innovation in order to develop new medical devices. Recently, the Sixth Circuit, in \textit{Martin v. Telectronics Pacing Systems}, held that a plaintiff's product liability claims were preempted by the MDA under section 360k(a).\textsuperscript{35} Due to the specific rules for products approved under the IDE, the Sixth Circuit held that state claims relating to these devices should be preempted by conflicting federal requirements.\textsuperscript{36} To foster the creation of new medical devices, the IDE procedure allows products to be marketed without being subjected to the rigorous PMA process. This encourages innovation, but fails to provide the safeguards pledged in enacting the MDA.

III. PREEMPTION

The Supremacy Clause of the Constitution provides that the laws of the United States "shall be the Supreme Law of the Land; and the judges in every State shall be bound thereby, anything in the Constitution or Laws of any state


\textsuperscript{32} 21 U.S.C. § 360e(c) (1994).


\textsuperscript{34} 21 U.S.C. § 812.3(g).

\textsuperscript{35} 70 F.3d 39 (6th Cir. 1995) (remanded by the Supreme Court to be considered in light of the holding in Lohr). \textit{See infra} notes 58-62 and accompanying text for a discussion of the MDA's preemption section 360k(a).

\textsuperscript{36} 70 F.3d at 41. The court stated that the "representations that can, cannot, and must be made about an investigational device are all determined by the FDA." \textit{Id.} at 42.
to the contrary notwithstanding."

The intent behind the preemption doctrine was to provide uniform laws and regulations for individuals and businesses across the country. To avoid conflicting sets of rules, a state law which imposes different standards than a federal law will be preempted. However, the police powers granted to the states under the Constitution will not be preempted absent "the clear and manifest purpose of Congress to do so."

Prior to the 1980s, few courts allowed the preemption defense to invalidate state product liability suits. Then, in the landmark case of Cipollone v. Liggett Group, the Supreme Court ruled that a federal law governing advertising on cigarette packages preempted state actions based on claims that manufacturers failed to warn smokers about the danger of this activity. In Cipollone, the son of a deceased smoker challenged the Third Circuit's preemption of his state tort claim. The Federal Cigarette Labeling and Advertising Act of 1965 stated that it would be a violation of this law "to fail to disclose, clearly and prominently, in all advertising and on every pack, box, carton or container [of cigarettes] that cigarette smoking is dangerous to health and may cause death from cancer and other diseases." This act also included an explicit preemption provision. However, this provision "merely prohibited state and federal rulemaking bodies from mandating particular cautionary statements" and did not preempt state law damage actions.

In 1969, Congress modified the preemption section of the 1965 law. The new section read: "No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provi-

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37 U.S. CONST. art. VI, cl. 2.


39 Lars Noah, Reconceptualizing Federal Preemption of Tort Claims as the Government Standards Defense, 37 WM. & MARY L. REV. 903, 907-08 (1996) (discussing the appropriate degree of preemption which should be inferred from the Cipollone decision. The author believes that Cipollone has been misinterpreted and preemption should be limited to cases where a defendant can show compliance with an applicable safety requirement).


41 Id. at 513 (quoting 29 Fed. Reg. 8325 (1964)).

42 The preemption section of the 1965 act stated:
(a) No statement relating to smoking and health, other than the statement required by section 4 of this Act, shall be required on any cigarette package.
(b) No statement relating to smoking and health shall be required in the advertising of any cigarettes the packages of which are labeled in conformity with the Provisions of this Act.

Id. at 514.

43 Id. at 518. The Court reasoned that the preemption section "superseded only positive enactments by legislatures or administrative agencies that mandate particular warning labels." 505 U.S. at 518-19.
sions of this Act." By enacting a statutory provision explicitly preempts state law, the *Cipollone* Court needed to look no further than the express language of the statute to infer preemption. The 1969 Act banned not only "statements relating to smoking, but requirement[s] or prohibition[s] ... imposed under state law." The broader language of the revised preemption section was found to encompass state law actions. The Court held that the terms "requirements" and "prohibition" included not only "state statutes or positive enactments of law, but also common law damage actions premised on a breach of a legal duty." The Court noted that "common law damage actions ... are premised on the existence of a legal duty, and it is difficult to say that such actions do not impose 'requirements or prohibitions.'" However, the Court limited the preemption defense to plaintiff's failure to warn claim. The preemption section was not read to apply to express warranty, intentional fraud, misrepresentation or conspiracy actions. In the 1969 revisions, Congress defined the scope of preemption in the express language of the statute. The statute's considerable detail and specific requirements for cigarette advertising justified a determination that Congress intended federal law to control this practice. Following *Cipollone*, courts have interpreted the term "requirement" to include state tort lawsuits. In determining whether the preemption defense applies, courts should examine Congressional intent in creating the particular legislation. Federal legislation preempts state laws when "the scheme of federal regulation is sufficiently comprehensive to make reasonable the inference that Congress 'left no room' for supplementary state regulation." The party

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46Id. at 519.
47Id.
48Id. at 519-21 (quoting 15 U.S.C. § 1334 (b)).
49Cipollone, 505 U.S. at 522; see also Noah, supra note 39.
50Cipollone, 505 U.S. at 530-31.
51The Court noted that its analysis should be governed entirely by the express language of the Act. Id. at 517.
52See 15 U.S.C. § 1333 (West 1997); see also Mark Hermann & Geoffrey J. Ritts, *Preemption and Medical Devices: A Response to Adler & Mann*, 51 FOOD & DRUG L.J. 1, 7 (1996) (arguing that the use of the term 'requirement' in the medical device amendments preemption clause is consistent with *Cipollone*’s preemption of state lawsuits).
53CSX Trans. v. Easterwood, 113 S. Ct. 1732 (1993) (holding that federal regulations preempted the state from allowing the plaintiff a common law negligence recovery); see cases cited supra note 8 and accompanying text; see also Hermann & Ritts, supra note 52, at 1 n.4.
asserting preemption bears the burden of proof and must demonstrate an unmistakable intent by Congress to preempt the area of law. To assess Congress' intent, one commentator has suggested that courts employ a two-part test to determine the breadth of federal preemption. First, a court must examine the federal law to determine whether it applies to the particular device. Next, the court should "analyze each of the plaintiff's claims to determine whether it imposes requirements that are 'different from' or 'in addition to' the federal requirements." If a state common law action creates additional requirements on a device, the federal statute will preempt the application of state law.

The MDA contains an express preemption provision clause in section 360k(a) that states:

[N]o state or political subdivision of a 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.

In enacting the MDA, Congress empowered the FDA to promulgate regulations to enforce this law. The FDA propagated a regulation recognizing the preemptive power of section 360k(a). This regulation, 21 C.F.R. Section 808.1(b), prohibits states from continuing requirements "having the force and effect of law, whether established by statute, ordinance, regulation or court decisions, as state requirements subject to preemption by federal law."

55 See Stephen D. Harris, Preemption of State Tort Claims Under the Medical Device Amendments, 24 COLO. L. REV. 2217, 2218 (1995) (discussing the two-part test employed to resolve preemption claims under the MDA).

56 Id.

57 Id. at 2218 n. 36 (quoting Slater v. Optical Corp., 961 F.2d 1330-1333 (7th Cir. 1992).

58 See, e.g., Cynthia B. Stewart, Casenote, Medical Device Litigation: Federal Preemption of State Tort Claims: King v. Collagen Corp., 2 J. PHARMACY & L. 357 (1993) (declaring the King decision consistent with the majority viewpoint as well as FDA intent in preempting state law claims).


60 21 U.S.C. § 371(a); see Marilyn P. Westerfield, Federal Preemption and the FDA: What Does Congress Want?, 58 U. CIN. L. REV. 263 (1994) (stating that since Congress has not expressly stated otherwise, the FDA should continue to regulate the medical device industry).

61 21 C.F.R. § 808.1(d) (West 1997). "State or local requirements are preempted only when the FDA has established specific counterpart regulations or there are other specific requirements applicable to the particular device under the act...." Id.
FDA's regulation narrowed the meaning of the term requirement to a "specific counterpart regulation or specific requirement[s] applicable to a particular device." In enacting amendments to the MDA in 1990 and 1992, Congress left Section 808.1(b) intact and inferred that this regulation is consistent with MDA's preemption of common law actions. Since the meaning of the term "requirement" is ambiguous in the statute, courts continue to struggle with the degree of specificity which will trigger preemption under the MDA.

Before the Supreme Court granted certiorari to hear Medtronic v. Lohr, every federal appellate court except one followed the precedent established in Cipollone to preempt most common law actions brought against devices approved under the MDA. The First, Third, Fifth, Eighth, and Eleventh Circuits rejected reading any device-specific requirements into section 360k(a). The First Circuit exemplified the majority position in Mendes v. Medtronic. In Mendes, the court held that the MDA preempts a plaintiff's state claims for implied warranty, negligent manufacturing and failure to warn. The Seventh Circuit also interpreted the statement "no requirement or prohibition" to include state common law rules. In contrast, the Fifth Circuit, in Moore v. Kimberly-Clark Corp., allowed a plaintiff's defective design claims to escape preemption under the requirement standard of section 360k(a). The Moore court held that since no federal regulations existed to govern tampon design, composition, or construction, the preemption clause did not apply.

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64 See generally Dega, supra note 9; Hermann & Ritts, supra note 52, at 1 n.4-5.

65 Lohr v. Medtronic, 56 F.3d 1335 (11th Cir. 1995), rev'd, 116 S. Ct. 2240 (1996); Michael v. Shiley, Inc., 46 F.3d 1316 (3d Cir. 1995); Reeves v. Acromed Corp., 44 F.3d 300 (5th Cir. 1995) Martello v. CIBA Vision Corp., 42 F.3d 1167 (8th Cir. 1994); Mendes v. Medtronic, Inc., 18 F.3d 13 (1st Cir. 1994). But see Anguianov v. E.I. Du Pont de Nemours Co., Inc. 44 F.3d 806 (9th Cir. 1995). The Ninth Circuit is the only circuit to demand that the MDA’s requirements be device-specific for the preemption clause to apply. Id.

66 18 F.3d at 13.

67 Id.


70 867 F.2d at 243.
The majority position advocates that the statutory language of the MDA preempts state requirements including jury judgments in state lawsuits which conflict with federal rules.

In comparison, the minority viewpoint espoused in *Kennedy v. Collagen Corp.* held that the MDA's PMA process did not constitute a specific federal requirement.71 The PMA process standardizes its approval process for all Class III devices, rather than making device-specific requirements.72 In *Kennedy*, the Ninth Circuit required device specificity based on its statutory interpretation of section 808.1 and held that "courts should not ignore the specific regulation of a particular Class III device."73 The court found further evidence of the lack of congressional intent to preempt state action from the MDA's Savings Clause.74 This clause states that "compliance with an order issued under this section shall not relieve any person from liability under Federal or State law."75 *Kennedy* diverged from the majority viewpoint based on the lack of specific requirements applicable to a particular device. Without additional requirements which conflict with federal law, the MDA's preemption clause did not apply.

The different standards utilized by the FDA to test medical devices have received differing levels of preemption by the courts.76 Every device approved under the investigational device exemption has received complete preemption against state lawsuits. Similarly, most courts have ruled that federal preemption will apply to claims against devices marketed under the PMA. However, courts have split as to whether state suits will be preempted when devices are marketed under the premarket notification standard in section 510(k).77 The Eleventh Circuit preempted Lohr's negligent manufacturing and warning claims. However, her negligent design and strict liability suits were allowed to proceed against Medtronic. The Supreme Court sought to resolve

71 67 F.3d 1453, 1458 (9th Cir. 1995); see also Larsen v. Pacesetter Sys., Inc., 837 P.2d 1273 (Haw. 1992), Haudrich v. Howmedica, 642 N.E.2d 206 (Ill. Ct. App. 1994) (advocating the position that the MDA does not preempt common law actions).

72 See 21 C.F.R. § 814.1-818.45.

73 *Kennedy*, 67 F.3d at 1459.

74 *Id.* at 1460; see 21 U.S.C. § 360h(d).

75 21 U.S.C. § 360h(d). The clause also states, "[i]n 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." *Id.*

76 See Hermann & Ritts, *supra* note 52, at 2 n.9 (detailing the levels of preemption given to Class II and III devices). See also *Kennedy*, 67 F.3d at 1458-59.

77 Hermann & Ritts, *supra* note 52, at 2, n.4-8 (presenting a listing of the cases which have invoked preemption under the MDA).
the conflict between different circuits by granting certiorari to Medtronic v. Lohr.\textsuperscript{78}

IV. FACTS OF LOHR

A. District Court

The plaintiff, Lora Lohr, received a pacemaker manufactured by Medtronic in 1987. Three years later, the pacemaker failed and Lohr required emergency surgery to treat her condition. Lohr, only twenty-seven when her pacemaker failed, received four more operations to fix the damage caused by the defective pacemaker.\textsuperscript{79} Lohr sued Medtronic under Florida tort law for claims of negligent design, manufacturing, and warning in marketing the pacemaker.\textsuperscript{80} In its defense, Medtronic argued that the MDA’s preemption clause barred states from imposing requirements different from federal law. Based on the precedent established in Cipollone, these requirements included state common law actions. Medtronic successfully removed this case to federal court and motioned for summary judgment.\textsuperscript{81} The district court denied Medtronic’s motion in December 1993, but reconsidered its decision in light of the Eleventh Circuit’s holding in Duncan v. Iolab Corp.\textsuperscript{82} Upon remand, the court interpreted Duncan to preempt all state law suits based on negligence and strict liability and granted Medtronic’s motion for summary judgment.\textsuperscript{83}

B. Eleventh Circuit Court of Appeals

The Eleventh Circuit narrowed the district court’s approach by affirming in part and reversing in part.\textsuperscript{84} The court based its holding on the applicable preemption language in the MDA and on the fact that the device was not subjected to the full PMA approval process.\textsuperscript{85} The FDA regulations state that the MDA "allows preemption when the FDA has established counterpart regulations or there exists requirements applicable to a particular device under the Act."\textsuperscript{86} In addressing the negligent design claim, the court held that the

\textsuperscript{78} Lohr, 116 S. Ct. 806 (1996).

\textsuperscript{79} See Device Makers Can Face State Suits Over Defects, MOD. HEALTHCARE, July 1, 1996, at 14.

\textsuperscript{80} Lohr, 56 F.3d at 1340. The FDA approved Medtronic’s pacemaker in 1982, after determining that it was substantially equivalent to other devices on the market prior to 1976.

\textsuperscript{81} Id.

\textsuperscript{82} 12 F.3d 194 (11th Cir. 1994).

\textsuperscript{83} Lohr, 56 F.3d at 1340.

\textsuperscript{84} Id. at 1335.

\textsuperscript{85} Id. at 1348-49.

\textsuperscript{86} Id. at 1339.
MDA did not establish specific design requirements on 510(k) devices. Under the 510(k) process, the FDA made no examination of the safety of a device. Since no specific design requirements existed, the MDA did not preempt a state law cause of action for the negligent design of a medical device.

Turning to the negligent manufacturing claims, the court held that the "good manufacturing practice regulations in the MDA" were specific requirements which justified the preemption of these claims. Since the plaintiffs' negligent manufacturing claim constituted a specific manufacturing requirement different from or in addition to the GMP regulations, the MDA preempted this claim. Additionally, the court reasoned that the plaintiff's failure to warn claim was a specific requirement triggering preemption. Despite their lack of device specificity, the labeling regulations were specific about "what standards a manufacture must follow when designing the packaging and labeling of its product." Finally, the court held that the MDA did not prevent a manufacturer from creating an unreasonably dangerous product through specific design requirements; therefore, the strict liability claim would not be preempted.

This holding exemplifies the position advocated by the majority of jurisdictions that the MDA does not have to create device-specific regulations for state lawsuits to be preempted. The Eleventh Circuit ruled that a determination of whether the MDA preempts a state lawsuit must occur on a claim by claim basis in order to "best carry out Congressional design." In seeking certiorari, Medtronic argued that design defects are preempted by the MDA's preemption clause. Meanwhile, Lohr also sought Supreme Court

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87 Lohr, 56 F.3d at 1349-52. The court looked to the legislative history of the MDA and found that Congress recognized the differences between the two process: We can view the MDA as a compromise between device manufacturers and Congress. In exchange for the financial and time burdens placed upon manufacturers by the MDA, the manufacturers were assured a nationally uniform and predictable regulatory and liability climate. A rule preempting liability based on grandfathering would give the benefits of a uniform, predictable liability climate to devices that never paid the MDA's regulatory "price" for market entry. Id. at 1349.

88 Id. at 1350; see Good Manufacturing Practice Regulations (GMP), 21 U.S.C. § 360j(f); 21 C.F.R. §§ 820.1-820.198.

89 Lohr, 56 F.3d at 1350.

90 Id. at 1351.

91 Id. at 1351; see 21 C.F.R. §§ 801.109, 807.87(e) (labeling regulations).

92 Lohr, 56 F.3d at 1352.

93 Id. at 1344. The Ninth Circuit is the only circuit which accepts the position that a requirement must be device-specific; see also Anguiano, 44 F.3d at 809.

94 Lohr, 56 F.3d at 1352.

review of this case based on the denial of her negligent manufacturing and failure to warn claims.

C. Supreme Court

In a five to four decision, the Supreme Court ruled that common law claims against medical device manufacturers of Class III devices for negligent design, manufacturing, and labeling are not preempted under the MDA. The decision sought to resolve the twenty-year old debate over whether the statutory language in the MDA, or the regulations established by the FDA, guaranteed manufacturers immunity from state suits. The Court found Medtronic's argument that common law cause of action constitutes a requirement under 360k(a) to be implausible. If the Court adopted Medtronic's view of the preemption clause, Justice Stevens concluded that "Congress [would have] effectively precluded state courts from affording consumers any protections from injuries resulting from a defective medical device." Since the MDA delineates no private causes of action, this would effectively bar "most, if not all, relief for persons injured by defective medical devices."

1. Negligent Design Claims Under Section 510(k)

In holding that Lohr's negligent design claims were not preempted, the Court looked to the expressed statutory language in the MDA. Since Congress fashioned the language in the preemption section ambiguously, the Court looked to the FDA for guidance in interpreting the statute and unanimously determined that the MDA does not create specific, federal design requirements for 510(k) devices which conflict with state tort laws. The premarket notification process under section 510(k) centers on the equivalence of a device, not ensuring the safety of the product or requiring the device to take any particular form. The standard offers little of the consumer protection promised in the statute and the exemption process did nothing to improve the

96 Lohr, 116 S. Ct. at 2240. Justice Stevens' majority opinion was joined by Justices Ginsberg, Kennedy, Souter, and a separate concurrence in the result by Justice Breyer.

97 Id. at 2244. The Court stated that Medtronic's preemption argument was "not only unpersuasive, it is implausible." Id. at 2251.

98 Id. at 2251.


100 Lohr, 116 S. Ct. at 2255.

101 Id. at 2252-53. Justice Stevens held that Congress "was primarily concerned with the problem of specific, conflicting State statutes and regulations rather than the general duties enforced by common-law actions." Id. at 2252.
safety of medical devices, rather it maintained the status quo. The FDA allowed Lohr's pacemaker, as a device substantially equivalent to one which existed before 1976, to be marketed without being subjected to the rigorous standards in the full PMA process. Therefore, the MDA does not preempt negligent design state lawsuits since the FDA did not examine the merits or safety of the pacemaker.

2. "Requirement" Under Section 360k(a)

Medtronic argued that a common law action qualifies as a requirement under section 360k(a) of the MDA. If upheld, medical device manufacturers would receive complete immunity from design defect liability suits despite congressional intent to enact more stringent safeguards. In Justice Stevens' majority opinion, he stated that "preemption will occur only where a particular state requirement threatens to interfere with a specific federal interest." State requirements must differ from or add additional requirements to a federal law to invoke the preemption doctrine. In Lohr, the state tort laws were not specifically designed to regulate medical devices. Rather, these statutes were generally designed to govern a variety of circumstances and to provide plaintiffs with remedies not available under the MDA. Under this system, no direct conflict exists between federal and state law. Therefore, these state laws do not qualify as the type of requirements which Congress and the FDA feared would impede the implementation and enforcement of uniform national requirements.

In contrast to Cipollone, the Court believed that Florida's tort laws did not qualify as an additional requirement which necessitated federal preemption. Justice Stevens asserted that "[n]othing in 360k(a) denied Florida the right to provide a traditional damages remedy for violations of common law duties, even if those duties parallel federal requirements." Section 360k(a) is limited to "device-specific enactments of positive law by legislative or administrative bodies, not the application of general rules of common law by judges and juries." The damage remedy available under state tort law merely provides an additional reason for manufacturers to comply with identical federal remedies. This rationale comports with the regulations promulgated by the FDA.

In reversing the appellate court's preemption of Lohr's manufacturing and labeling claims, the Supreme Court held that these federal standards were

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102 Id. at 2254.
103 Lohr, 116 S. Ct. at 2254.
104 Id. at 2255.
105 Id. at 2256.
106 Id. at 2252.
107 Lohr, 116 S. Ct. at 2255-56.
applicable to the device in question. However, the good manufacturing requirements reflect generally applicable regulations governing the pacemaker. These requirements differ from the specific regulations which the MDA's preemption clause introduced to protect manufacturers from facing contradictory state requirements. Justice Stevens stated that "given the critical importance of device-specificity in the FDA's construction of 360k(a), it is apparent that few, if any, common law duties have been preempted by this statute." Cipollone's expansive view of the term "requirement" has been severely curtailed in Lohr by requiring a higher degree of device-specificity.

The Court stopped short of declaring that common law actions will never be requirements within the meaning of section 360k(a). However, the Court did suggest that few common law requirements are device-specific so that "it will be rare indeed for a court hearing a common-law cause of action to issue a decree that has the effect of establishing a substantive requirement for a specific device." This viewpoint is consistent with the Court's prior refusal to "remove all means of judicial recourse for those injured by illegal conduct." Justice Stevens explicitly stated that "we cannot accept Medtronic's argument that by using the term 'requirement,' Congress clearly signaled its intent to deprive States of any role in protecting consumers from the dangers inherent in many medical devices." As a result, Lohr's common law action was remanded to the district court to determine Medtronic's liability under Florida tort law.

3. Breyer's Concurrence

Justice Stephen Breyer issued the fifth and deciding vote which created questions over the authority of the majority's holding. In his pivotal concurrence, Justice Breyer held that there may be instances where federal law does not preclude state lawsuits. However, he may have limited the Court's holding to cases brought against medical devices approved by the FDA under the premarket notification process. Therefore, the Court's holding may not apply to devices approved under the more rigid premarket process. Justice Breyer described his view of the preemption doctrine by stating, "Believe that ordinarily, insofar as the MDA preempts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also preempt a similar requirement that takes the form of a standard of care or

108 Id. at 2257.
109 Id. at 2259.
110 Id. at 2259 (citing 21 C.F.R. § 808.1(d)(6)(ii) (1995)).
112 Lohr, 116 S. Ct. at 2252.
113 Id. at 2259.
114 Id.
behavior imposed by a state tort law action."115 Justice Breyer rejected Justice Stevens’ view that the term ‘any requirement’ in the MDA’s preemption clause does not encompass the requirements imposed through state common law actions.116 Justice Breyer found this approach to be inconsistent with the express language of the MDA and the Court’s prior decision in Cipollone.117 Justice Breyer held that section 360(k) preempts state actions when compliance with both federal regulations and state common law standards is impossible.118 Unlike Justice Stevens, Justice Breyer believed that future incidents of MDA preemption of common law "will not be few or rare."119

Justice Breyer believed that a requirement need not be device-specific to fall within the MDA’s preemptive scope.120 Preemption will apply when the application of state law conflicts with the requirements of the MDA and when FDA regulations conflict with the liability creating premises of a common law action.121 When the federal regulatory scheme is "so pervasive as to infer Congress left no room for supplementation by the states," preemption of state actions should occur.122 In looking at the applicable regulations, Justice Breyer concluded that "[no] indication exists that either Congress or the FDA intended that the relevant FDA regulations [would] occupy entirely any relevant field."123

Due to Justice Breyer’s concurrence, no clear guidance exists for federal preemption questions except for devices approved under the limited 510(k) process.124 Therefore, Justice Breyer’s concurrence leaves unanswered what will occur with devices approved under the PMA. As one commentator stated,
the *Lohr* opinion "created more of a mess than before."\(^1\) With Justice Breyer's swing vote casting doubt over the expansiveness of the preemption doctrine, the question of how *Lohr* relates to *Cipollone* remains unanswered and frustrates the Court's objective in granting certiorari to this case.

4. Dissent

Justices O'Connor, Scalia, Thomas, and Rehnquist concurred with part of the ruling, but dissented from the main part of the opinion. Justice O'Connor referred to the majority's opinion as "bewildering and seemingly without guiding principle."\(^2\) In contrast to the majority holding, Justice O'Connor professed that a state law claim would be preempted if it imposes any requirement "different from" or "in addition to" the requirements under federal law.\(^3\) Justice O'Connor rejected the concept of device-specificity as a prerequisite to bringing suit by stating that "[t]he statute makes no mention of a requirement of specificity."\(^4\) When the language of the statute is clear, a court need not seek an agency's interpretation of the statute.\(^5\) Thus, a court need look no further than the express language of the statute to conclude whether the preemption doctrine will apply.

Justice O'Connor believed that the majority's opinion contradicted the Court's prior ruling in *Cipollone*.\(^6\) She referred to Justice Stevens' attempt to differentiate the statute in *Cipollone* as "neither clear nor persuasive."\(^7\) In Justice O'Connor's opinion, *Cipollone* declared that common law actions may not impose requirements in addition to those dictated in federal laws. In analyzing section 360(k)'s ordinary meaning, Justice O'Connor held that this provision clearly preempts any state common law action which imposes a requirement "different from" or "in addition to" those applicable under the MDA.\(^8\) The dissent held that the majority's analysis was at odds with the plain meaning of the MDA and the general understanding of common law damage actions.\(^9\)

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\(^2\) *Lohr*, 116 S. Ct. at 2262.

\(^3\) *Id.* at 2263.

\(^4\) *Id.*


\(^6\) In light of Justice Breyer's agreement with this position, a majority of the court held that the MDA does in certain instances preempt state law actions. *Lohr*, 116 S. Ct. at 2263.

\(^7\) *Id.*

\(^8\) *Id.*

\(^9\) *Id.*
Justice O'Connor concluded by stating that the MDA contained specific manufacturing and labeling requirements which were applicable to Medtronic's pacemaker. The dissent believed that these requirements were specific enough under section 360(k) to preempt Lohr's state actions and comprehensive enough to preempt any common law claim based on negligent manufacturing and labeling. Therefore, Lohr's negligent design claims could proceed, but her negligent manufacturing and warning claims were preempted by federal law. Unlike the majority opinion, Justice O'Connor disagreed with the contention that "few, if any common law duties will be preempted by the MDA." Due to the MDA's broad use of the term 'requirement,' manufacturers may argue against state jury decisions which establish conflicting standards with those dictated by federal regulations.

V. LOHR'S IMPACT ON THE MEDICAL DEVICE INDUSTRY

Based on the plurality holding in Lohr, the preemption defense may still be available to companies who market medical devices under the PMA procedure. In Lohr, the Court found significant differences between the PMA and the premarket notification procedure in section 510(k). Due to the lack of scrutiny in the premarket notification process, the MDA does not impose any requirements on devices grandfathered through the regulatory process. However, the more stringent standards embodied in the PMA may justify a finding of a requirement under section 360(k). Since state common law actions may impose requirements 'different from' or 'in addition to' the PMA standards, preemption will continue to occur when state tort claims directly conflict with federal requirements imposed on medical devices. However, post-Lohr decisions have adopted the majority's holding that the PMA does not impose specific requirements triggering preemption. Even in one post-Lohr case involving device-specific regulatory requirements, the preemption defense has not been extended.

134 *Lohr*, 116 S. Ct. at 2264.
135 *Id.*
136 *Id.* (quoting Stevens assertion).
137 However, the enactment of the Safe Medical Device Act of 1990 creates greater FDA scrutiny of 510(k) devices. This may allow manufacturers to argue that the current 510(k) process more closely assimilates the requirements of the PMA.
Justice Breyer's concurrence along with the four dissenting Justices indicates that a majority of the Court believes the term 'requirement' to encompass state law claims under certain circumstances. Justice Breyer's concurrence has been interpreted to hold that if a federal requirement conflicts with the "liability creating premise of a plaintiff state law tort suit," then the MDA will preempt this action. This mixed signal to both plaintiffs and defendants may "create further litigation as lower courts struggle to give meaning to the Supreme Court's opinion." Since the Court's decision in Lohr, a number of courts have adopted the previous "minority" viewpoint and have allowed plaintiffs to bring state law causes of action under the MDA. The resolution of this conflict remains unresolved by the Court's plurality holding.

In the post-Lohr case of Comeau v. Heller, the court revisited the applicability of the preemption doctrine to state law claims. The manufacturer in this case argued that Justice Stevens' distinction between the PMA and the premarket notification process limits Lohr to its particular facts. However, this court held that the Supreme Court failed to limit its decision to devices approved under section 510(k). Based on this interpretation, the court allowed the plaintiff's state lawsuit to proceed despite approval of the device under the full PMA process. Prior to the Lohr decision, lower courts construed the preemption provision in section 360(k) to expressly prohibit any requirement

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116 S. Ct. at 2260, 2264.

142 Papike v. Tambrands, 107 F.3d 737, 742 (9th Cir. 1997).


146 Id.

147 Id.

"different from" or "in addition to" the FDA's medical device requirements. Now, companies seeking to market medical devices approved under the section 510(k) process may no longer defend against state law actions by claiming federal preemption under section 360(k).

The impact of the Court's holding in Lohr may affect thousands of lawsuits involving other allegedly defective medical devices. These devices range from silicone breast implants, hearing aids, heart valves, and hip or knee replacements. In addition, the decision on the expansiveness of the preemption doctrine prompted dozens of other industries to submit friend-of-the-court briefs. The holding in Lohr has prompted courts to limit the preemption doctrine in areas other than medical device litigation. An estimated eleven million people currently have implanted medical devices. According to most commentators, if Medtronic had won this case, all manufacturers of medical devices would have been immunized from liability despite the harm inflicted by their devices. The Supreme Court found this argument to be contrary to Congressional intent. In enacting the MDA, Congress attempted to institute a federal law which would prevent consumers from suffering injuries from dangerous medical devices such as the Dalkon shield. However, during the past twenty years, the MDA has served to limit consumers' ability to seek damages for injuries suffered from these products. As courts begin to reinterpret the MDA based on the holding in Lohr, it will be

149 See also Brian J. Donato et al., Medtronic v. Lohr: Has Device Preemption Been Totally Preempted?, BIOMEDICAL MARKET NEWS., Aug. 1, 1996.

150 See Paul Barrett, Lora Lohr's Pacemaker May Alter Liability Law, WALL ST. J., Apr. 9, 1996, at B1 (U.S. District Court Judge Sam Pointer Jr. stated in a March 25th opinion that the Lohr holding could "significantly affect" the thousands of silicone breast implants lawsuits around the country).

151 See Kathryn Ericson, Friends of the Court Step Up As U.S. Supreme Court Prepares to Hear Medical Device Preemption Case, WEST LEGAL NEWS, Apr. 10, 1996, at 1996 WL 259713 (this article provides a complete list of the friend of the court briefs submitted in Lohr).


153 See Medical Device Makers Face State Courts Suits, Federal Law No Shield, Supreme Court Rules, CHICAGO TRIB., June 27, 1996.


155 See Javitt, supra note 13.
interesting to assess whether the Congressional goal of providing safer medical devices will be achieved.

With the curtailment of the preemption doctrine, the *Lohr* decision may have a chilling effect on the innovation of new medical devices. As Rep. Thomas Bliley stated in his response to the *Lohr* decision, "[w]ho will be willing to supply American patients with pacemakers and heart pumps, knowing that they can be hauled into any one of fifty different state courts even if they scrupulously comply with the rigorous standards set forth by the FDA?" The possibility of being held liable for innovative medical products may serve to reduce the impetus to market experimental medical devices. Higher liability premiums, elevated number of lawsuits, and increased costs of medical devices may result from the lack of preemption of state actions. Funding will be deterred from research and development of new medical products. The desire to balance the conflicting ideals of public health versus medical innovation makes the medical device industry unique. By being implanted into individuals to help sustain or support life, these devices lack the guarantee of success which can be expected of devices in other industries.

Under the *Lohr* ruling, a jury rather than the FDA will determine what constitutes a safe medical device. This will subject manufacturers to divergent state product liability laws nationwide. In attempting to resolve the dispute over the scope of the MDA's preemption clause, the Supreme Court failed to provide clear guidelines to manufacturers in all industries who engage in state commerce. The *Lohr* ruling may have potentially far-reaching ramifications for the health care industry. The right to sue medical device manufacturers may lead to fewer lawsuits against physicians, hospitals, and other health care delivery organizations as plaintiffs look to the deep-pockets of corporations. In this era of tort reform at both the state and federal level, the *Lohr* decision may strengthen the push for product liability reform in Congress and state legislatures. However, the state tort law system should continue to function "as an incentive for manufacturers to continue to improve their products as well as to disclose developments in product safety and their

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158 *Id.*

159 Brief of the American Insurance Association, the American Tort Reform Association and the National Association of Manufacturers as Amici Curiae in Support of Petitioner, *Medtronic v. Lohr*, 116 S. Ct. 2240 (1996). Victor Schwartz, one of the attorneys who filed this friend-of-the-court brief, stated: "What this boils down to is whether we want to have the experts at the FDA tell us what is a safe pacemaker or do we want a jury deciding it one way in Brooklyn and another way in Missouri?" See *Barrett*, *supra* note 9.

160 *Borzo*, *supra* note 157.
Under *Lohr*, manufacturers will no longer be shielded from liability despite the harm their products cause. As a result, injured plaintiffs will now be guaranteed their due process rights to remuneration against a corporation no longer protected by the federal preemption defense.

VI. CONCLUSION

Prior to *Lohr*, the majority of jurisdictions preempted state product liability suits for devices cleared for marketing and distribution under the MDA. With the Court’s plurality opinion, there exists the potential for regulatory chaos with corporations being subjected to different laws imposed by various states. The Court in *Lohr* alludes to, but fails to explicitly define the scope of federal preemption. For a common law tort action to be preempted by the MDA, the state law must impose requirements on a device in addition to those required by federal law. In its regulatory process, the FDA did not impose specific design requirements on Medtronic’s pacemaker triggering preemption under section 360(k). In addition, the Court believed that the Lohr’s labeling claims should not be preempted, since the FDA’s labeling requirements were not device-specific, but generally applicable to all devices. However, devices which the FDA subjects to device-specific regulations may still be protected from state action through federal preemption. The *Lohr* ruling eliminates the federal preemption defense in product liability cases involving devices cleared by the FDA under section 510(k). However, the preemption defense may still exist for companies whose devices have been cleared under either the investigational device exemption or the PMA standard. With the continuing vitality of the preemption defense in question, manufacturers must be prepared to face tort liability suits for placing defective products on the market. By allowing plaintiffs state law remedies, the goal of the MDA may finally be achieved as manufacturers take responsibility for the products which they market.

ROBERT A. GERBERRY

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