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THE IMPACT OF *LOHR v. MEDTRONIC* ON THE FIRST CIRCUIT'S APPLICATION OF THE MEDICAL DEVICE AMENDMENTS

I. INTRODUCTION

In *Lohr v. Medtronic, Inc.*,¹ the Supreme Court of the United States attempted to resolve whether Congress intended that the federal Medical Device Amendments of 1976 ("MDA") preempt state law for remedying medical device related injuries.² Prior to the *Lohr* decision, there was a three-way split among the circuits regarding the proper application of MDA preemption.³ In its ruling, the Court decisively held that the MDA did not necessarily preempt a plaintiff's ability to bring suit against a medical device manufacturer.⁴

Prior to *Lohr*, the First Circuit Court of Appeals of the United States ruled differently with respect to the MDA preemption of state tort claims.⁵ In *Talbott v. C.R. Bard, Inc.*,⁶ the First Circuit Court of Appeals ruled that the MDA preempted all state tort claims, and dismissed the plaintiffs' case.⁷ This decision came a year after C.R. Bard plead guilty in federal district court to 391 criminal violations relating to the use of the same type of catheter that was used in the *Talbot* case.⁸ In *United States v. C.R. Baed, Inc.*,⁹ the district court judge imposed criminal and civil fines on C.R.

¹ 116 S.Ct. 2240 (1996).

² *Id.* at 2250.

³ See *infra* notes 59 - 93.

⁴ 116 S. Ct. 2239-40. The *Lohr* decision paved the way for plaintiffs to sue medical manufacturers for all common-law causes of action despite running afoul with the federal preemption statute. *Id.* at 2252.

⁵ See *infra* part IV(A).

⁶ 865 F. Supp. 37 (D. Mass. 1994), *aff'd*, 63 F.3d 25 (1st Cir. 1995).

⁷ *Talbott*, 63 F.3d at 31. A heart catheter, intended to prolong the victim's life, malfunctioned by failing to deflate after being inserted in one of her coronary arteries, resulting in the victim's death. *Id.* at 39, 41. The victim's heirs sued C.R. Bard, the manufacturer of the catheter, for wrongful death, and also state tort claims of negligence, fraudulent misrepresentation and concealment, breach of express and implied warranties, negligence in hiring and training, battery, conspiracy, unfair trade practices, and negligent infliction of emotional distress. *Id.* at 42. The plaintiffs sought punitive and compensatory damages. *Id.*

⁸ *United States v. C.R. Bard, Inc.*, 848 F. Supp. 287 (D.Mass. 1994).

⁹ 848 F. Supp. 287 (D.Mass. 1994).

Bard, totaling sixty-one million dollars.¹⁰ The court recognized the harm caused by C.R. Bard's criminal behavior and acknowledged that the criminal penalties it imposed could not adequately compensate these victims.¹¹ The court noted that civil suits would provide a more complete remedy for these victims.¹² In *Talbott*, however, the First Circuit held that the MDA preempted any state tort claims against the defendant.¹³

This note will review the history of the MDA and analyze the differing interpretations of various circuits. It will also examine the the First Circuit's recent interpretation and application of the MDA. Finally, this comment will discuss the implications of the *Lohr* decision for attorneys in the First Circuit.

II. HISTORY OF THE MDA

Congress enacted the MDA in 1938 in response to the rapid growth of medical device technology. By enacting these amendments, Congress gave the Food and Drug Administration ("FDA") the authority to regulate medical devices under the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA").¹⁴ Under these amendments, the FDA had limited power to seize adulterated devices and to criminally prosecute the manufacturers and distributors of such devices.¹⁵ Specifically, the MDA allowed the FDA to exercise this authority only after manufacturers sold their medical devices through interstate commerce.¹⁶ The advancement of medical technology forced the FDA to approve medical devices prior to distribution.¹⁷ The introduction of intrauterine devices ("IUDs") and cardiac pacemakers

¹⁰ *Id.* at 292-93.

¹¹ *Id.*

¹² *Id.*

¹³ *Talbott*, 865 F. Supp. 37, 45-50 (D. Mass. 1994), *aff'd*, 63 F.3d 25, 31 (1st Cir. 1995).

¹⁴ See Federal Food, Drug, and Cosmetic Act of 1938, ch. 675, 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301-395 (1994)) (prohibiting commerce of adulterated or misbranded medical devices).

¹⁵ See Robert B. Leflar, *Public Accountability and Medical Device Regulation*, 2 HARV. J.L. & TECH. 1, 6 (1989).

¹⁶ *Id.* at 6-7.

¹⁷ See Angela W. Kronenberg, *King v. Collagen Corporation: FDA Approval Insulates Medical Device Manufacturers from State Common Law Liability*, 11 J. CONTEMP. HEALTH L. & POL'Y 563 (1995).

into the marketplace during the 1960s prompted more extensive regulation.¹⁸

In 1969, the Secretary of Health, Education, and Welfare formed a committee ("Cooper Committee") to research and recommend procedures for regulating medical devices.¹⁹ The Cooper Committee's research laid the foundation for the 1976 Medical Device Amendments.²⁰ The committee set forth additional controls to ensure the safety and effectiveness of new consumer products.²¹ Concurrently, the FDA sought to implement a more comprehensive, but flexible, legislative scheme to regulate medical devices.²²

Congress enacted the Medical Device Amendments of 1976 to provide the FDA with a "comprehensive, yet flexible mechanism" to protect public health by ensuring safe and effective regulation of medical devices.²³ Congress also intended to encourage the development of safe medical devices by providing a highly regulated research process.²⁴ While

¹⁸ 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, 156 (1994).

¹⁹ *Id.* at 155-156. The "Cooper Committee" received its name from its chairman, Dr. Theodore Cooper, the director of the National Heart and Lung Institute at that time. James S. Benson et al., *The FDA's Regulation of Medical Devices: A Decade of Change*, 43 FOOD DRUG COSM. L.J. 495 (1988). The Committee's report uncovered 10,000 device-related injuries and 751 deaths in the preceding ten years. Leflar, *supra* note 14, at 6.

²⁰ Benson, *supra* note 18, at 495.

²¹ *Id.* The late 1960s marked the start of a decade in which twenty-six consumer protection laws were passed. See Robert Adler, *The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 FOOD DRUG COSM. L.J. 511, 512 (1988) (noting time commonly referred to as the "consumer decade").

²² Adler, *supra* note 20, at 511.

²³ *Id.* The MDA was enacted largely as a result of the injuries suffered by women using the Dalkon Shield contraceptive device. *Ministry of Health v. Shiley, Inc.*, 858 F. Supp. 1426, 1434 (C.D. Cal. 1994). Thousands of women suffered from toxic shock, infertility, and pelvic infections caused by an ill-conceived and poorly designed IUD. *In re A.H. Robins Co.*, 880 F.2d 709, 710-12 (4th Cir. 1989). Several witnesses testifying during a Health Subcommittee Hearing in 1975, concluded that many of the deaths and illnesses attributable to the Dalkon Shield could have been prevented if legislation controlling medical devices was in place. *Bravman v. Baxter Healthcare Corp.*, 842 F. Supp. 747, 753-54 (S.D.N.Y. 1994) (citing S. Rep. No. 33, 94th Cong., 2d Sess. 3 (1975), reprinted in 1976 U.S.C.C.A.N. 1070, 1071).

²⁴ Truitt, *supra* note 17, at 157. The three goals of the MDA are to: (1) assure public

striving to protect consumers against unsafe products, the MDA also sought to protect innovation and advancement of medical devices from governmental restrictions.²⁵

In creating the regulatory scheme of the MDA, Congress recognized that medical devices differ both in composition and risk.²⁶ As a result, Congress created three different classes of devices and instructed the FDA to intensely regulate those devices which pose a high risk to the public.²⁷ Of the classes created, "Class III" devices pose the greatest health risk.²⁸

The MDA requires manufacturers of "Class III" medical devices to obtain FDA approval through either of two methods before manufacturers place the products into the market: pre-market approval application or pre-market application notification.²⁹ Pre-market approval application ("PMA") requires manufacturers to conduct extensive testing to prove the clinical safety and effectiveness of the device.³⁰ FDA staff members and

protection against unsafe and ineffective devices; (2) ensure that health practitioners can be confident about the medical equipment they use or prescribe for their patients; and (3) provide market protection for pioneers of new medical technologies. H.R. Rep. No. 808, 14 n.1 (1990), *reprinted in* 1990 U.S.C.C.A.N. 6305, 6308 n.1.

²⁵ H.R. Rep. No. 808, at 14 n.1 (1990), *reprinted in* 1990 U.S.C.C.A.N. 6305, 6308 n.1.

²⁶ Truitt, *supra* note 17, at 159.

²⁷ David A. Kessler et al., *The Federal Regulation of Medical Devices*, 317 NEW ENG. J. MED. 357, 364 (1987). "Class I" covers devices that are neither intended for significant medical use nor likely to threaten human health. 21 U.S.C. § 360c (a)(1)(A) (1994). Examples of this class include elastic bandages and ice bags. Alder, *supra* note 20, at 512. "Class II" devices require higher performance standards because the general controls under "Class I" fail to provide reasonable assurance of their safety and effectiveness. 21 U.S.C. § 360c (a)(1)(B) (1994). Examples of this class include syringes, hearing aids and bone plates. Alder, *supra* note 20, at 513.

"Class III" devices present either a potentially unreasonable risk of illness or injury, or include those devices intended for significant medical use. 21 U.S.C. § 360c (a)(1)(C) (1994). This class requires pre-market approval and cannot be placed into the market until extensive testing in lab and clinical data proves their safety and effectiveness. *Id.* Examples of "Class III" devices are pacemakers, IUDS, and artificial hearts. Alder, *supra* note 20, at 513.

²⁸ See 21 U.S.C. § 360c (a)(1)(C) (1994). Recognizing that Class III devices pose the greatest risk to the public, Congress tailored the regulatory scheme of the MDA to apply to Class III devices. Alder, *supra* note 20, at 513.

²⁹ Benson, *supra* note 18, at 499.

³⁰ *Id.* at 500.

outside experts must approve the PMA before the FDA will approve the device for commercial use.³¹

Pre-market notification allows a company to market a new medical device without obtaining FDA approval if the manufacturer establishes that the device is "substantially equivalent" to a device approved before 1976.³² Pre-market notification attempts to decrease the amount of time between filing the application and the actual approval.³³ The FDA requires significantly less information for pre-market notification method than for pre-market approval.³⁴

Initially, most "Class III" medical devices reached the market through pre-market notification, thus receiving less stringent scrutiny by the FDA.³⁵ Congress recognized this trend and amended the pre-market notification requirements.³⁶ Now a manufacturer using pre-market notification must disclose more information and provide clinical data demonstrating that the device is safe and effective.³⁷

III. PREEMPTION OF STATE TORT LAW UNDER THE MDA

The MDA expressly preempts competing state requirements.³⁸ Section § 360k(a) of the MDA provides in pertinent part:

³¹ *Id.* The safety and effectiveness of a device is determined with reference to the persons for whose use the device is intended and to the conditions of use prescribed, recommended, or suggested in the labeling of the device. Regulators must weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use. 21 U.S.C. § 360c (a)(2).

³² S. Rep. No. 94-33, at 56-57 (1976), *reprinted in* 1976 U.S.C.C.A.N. 1070, 1108-09. The FDA requires manufacturers wishing to sell or distribute a substantially equivalent device to notify the FDA 90 days before doing so. 21 U.S.C. § 360(k) (1994). The manufacturer must also indicate in which of the three classes the device falls and ensure the FDA that the device complies with all applicable regulatory requirements. *Id.*

³³ See Benson, *supra* note 19, at 499-500.

³⁴ Truitt, *supra* note 17, at 159. The average time for approval under the premarket notification method is 20 hours, whereas under the pre-market application method the average time is 1200 hours. *Id.*

³⁵ Paul H. Sunshine, *The Preemptive Scope of the Medical Device Amendments of 1976*, 50 FOOD & DRUG L.J. 191, 198-99 (1995).

³⁶ See The Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 4(a), 104 Stat. 4511, 4515 (1990) (codified as amended at 21 U.S.C. § 360c (I) (1994)).

³⁷ See 21 U.S.C. § 360c (I)(1)(A)(ii) (1994).

³⁸ See 21 U.S.C. § 360k (a) (1994). The primary factor in determining whether federal preemption exists is that a court must find Congressional intent to preempt. *Rice v.*

[N]o 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 [Act] to the device, and (2) which related to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this [Act].³⁹

The statute, however, allows a state to petition in certain circumstances for exemption from federal preemption.⁴⁰ The exemption requirements provide state exemption from the MDA under two sets of circumstances.⁴¹ First, a state cause of action may be exempt if state requirements are more stringent than those under the MDA.⁴² Second, Congress allows exemption where compelling local conditions exist, and compliance with state requirements would not violate any of the requirements imposed by the MDA.⁴³

The statute also expressly empowers the FDA to implement the MDA.⁴⁴ § 360(h) gives the FDA the power to require the manufacturer of medical devices to repair, replace or refund the cost of a device presenting an "unreasonable risk" of harm to public health.⁴⁵ This section further

Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947). There are two ways a court may determine Congressional intent to preempt: express intention or implied intention. *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977). Express intention occurs when the wording in the regulation expressly provides an intent to preempt state law. *Id.* Implied intention occurs when the court finds an implied intention to preempt based on any number of factors, such as the comprehensive nature of the regulations or a direct conflict between state and federal law. *Hillsborough County v. Automated Medical Lab.*, 471 U.S. 707, 713 (1985).

³⁹ See 21 U.S.C. § 360k (a) (1994).

⁴⁰ See 21 U.S.C. § 360k (b) (1994).

⁴¹ *Id.*

⁴² *Id.*

⁴³ 21 U.S.C. § 360k (b) (1994).

⁴⁴ 21 U.S.C. § 360h (d) (1994).

⁴⁵ 21 U.S.C. § 360k (b) (1994). The FDA must determine: 1) that a device intended for human use that is brought into the market presents an unreasonable risk of substantial harm to the public health; 2) that the FDA might reasonably believe that "the device was not properly designed or manufactured with reference to the state of the art as it existed at the time of its design and manufacture"; 3) that the FDA might reasonable believe that no person other than the "manufacturer, importer, distributor, or retailer" failed to exercise due care in the "installation, maintenance, repair, and or use of the device;" and 4) that notification to the public would not be sufficient to remove the unreasonable risk of harm. 21 U.S.C. § 360h (b)(1)(A)(i)-(iv) (1996).

states that compliance with an order issued pursuant to § 360(h) shall not relieve any person from liability under federal or state law.⁴⁶

Preemption applicability is also grounded in FDA regulations.⁴⁷ Preemption applies when: 1) the state "establishes or continues in effect with respect to a device intended for human use any requirement"; 2) the requirement is "different from, or in addition to, any requirement applicable" to a device under the MDA; and 3) the state requirement pertains "to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device" under the MDA.⁴⁸

IV. PREEMPTION IN TORT CASES

In *Cipollone v. Liggett Group, Inc.*,⁴⁹ the Supreme Court of the United States considered the issue of whether a federal statute can preempt state tort law.⁵⁰ The *Cipollone* court inquired whether the Federal Cigarette Labeling and Advertising Act of 1969 ("1969 Act") preempted the plaintiffs' state law claims.⁵¹ A majority of the Court held that the Federal Cigarette Labeling and Advertising Act of 1965 ("1965 Act") did not preempt the plaintiffs' state law tort claims.⁵² A plurality, however, held that the 1969 Act preempted only some of the plaintiffs' tort claims.⁵³ The Su-

⁴⁶ 21 U.S.C. § 360h (d) (1994).

⁴⁷ 21 C.F.R. 808.1(b) (1994). § 808.1 (b) states in pertinent part:

[The MDA] prescribes a general rule that . . . no State or political subdivision . . . may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law, which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.

Id.

⁴⁸ 21 U.S.C. § 360k (1994).

⁴⁹ 505 U.S. 504 (1992).

⁵⁰ *Id.*

⁵¹ *See id.* at 516-24 (addressing the issue of federal preemption of state tort claims). The plaintiff brought the following five claims: failing to provide adequate warnings about the health risks of smoking; expressly warranting products that were dangerous to consumers' health; attempting to neutralize statutory warning effects; ignoring medical advice on the dangers of smoking; and conspiring to prevent medical evidence from reaching the general public. *Id.* at 524-30.

⁵² *See id.* at 530 (construing statute's preemption provision narrowly resulting in a presumption against preemption).

⁵³ *See id.* at 530-31 (noting 1969 Act created a preemptive effect with respect to state common law claims).

preme Court emphasized, through its decision, that lower courts must closely examine the plain language of a statute in order to ascertain Congressional intent.⁵⁴

Justice Blackmun concurred with the plurality, but dissented in part, reasoning that the 1969 Act obligated the Court to infer preemption only where Congress "clear[ly] and manifest[ly]" intended to preempt state law claims.⁵⁵ Justice Blackmun argued that there were distinct differences between the state tort law and the 1969 Act that significantly weakened the plurality's holding.⁵⁶

After *Cipollone*, defendant manufacturers began to raise MDA's preemptive scope as a defense against state tort actions.⁵⁷ Three different interpretations of the MDA emerged after the *Cipollone* decision.⁵⁸ The First Circuit held that the MDA preempts all state tort claims, the Eleventh Circuit held that the MDA preempts some state tort claims, and the Ninth Circuit interpreted the MDA to not preempt any state tort claims.⁵⁹

A. Total Preemption of State Tort Law Claims

The majority of federal circuits have held that the MDA preempts all state tort claims.⁶⁰ These courts have held that the MDA preemption

⁵⁴ *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 520-21 (1992).

⁵⁵ See *id.* at 542 n.6 (Blackmun, J., concurring in part and dissenting in part) (noting every court of appeals considering the issue unable to find express preemption).

⁵⁶ See *Cipollone*, 505 U.S. at 534-39 (1992) (Blackmun, J., concurring in part and dissenting in part) (finding modified language of section 5(b), 15 U.S.C. § 1331(2) no more "clearly" exhibits intent to preempt than language of the 1965 Act).

⁵⁷ See Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. REV. 895, 916 (1994) (listing 22 rulings where courts held MDA preemption of state tort claims under *Cipollone* rationale).

⁵⁸ See *e.g.*, *Talbott v. C.R. Bard, Inc.*, 63 F.3d 25, 31 (1st Cir. 1995) (holding MDA preempts all state tort claims); *Lohr v. Medtronic, Inc.*, 56 F.3d 1135, 1338-38 (11th Cir. 1995) (ruling MDA preempts some state tort claims and not others); *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995) (interpreting FDA regulations as providing no state common law preemption).

⁵⁹ See *infra* notes 60-94.

⁶⁰ See *e.g.*, *Mendes v. Medtronic, Inc.*, 18 F.3d 13, 18-19 (1st Cir. 1994) (finding allegations of negligent manufacturing and distribution, failure to warn, and breach of implied warranty claims with respect to a defective pacemaker preempted); *King v. Collagen Corp.*, 983 F.2d 1130, 1133 (1st Cir. 1993) (holding state tort claims relating to Zyderm device preempted); *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1422 (5th Cir. 1993) (ruling state tort claims regarding Zyderm anti-wrinkle device preempted).

clause sweeps broadly to include state common law tort actions if "different from or in addition to" the federal law.⁶¹ The courts reasoned that ruling for a plaintiff would judicially create state imposed requirements on the manufacturer which differ from the FDA's regulations.⁶²

Talbott illustrates the First Circuit's reasoning.⁶³ In April 1994, C.R. Bard, Inc. plead guilty to 391 felonies arising out of its willful and knowing violations of FDA regulations and federal laws.⁶⁴ After learning of C.R. Bard's criminal proceedings, the heirs of Eunice Beaver, filed a civil suit alleging wrongful death, negligence and breach of warranty against C.R. Bard.⁶⁵ Ms. Beaver died after a heart catheter, manufactured by C.R. Bard and used in a procedure intended to enhance her health and extend her life, malfunctioned.⁶⁶ The First Circuit upheld the district court's decision to dismiss the plaintiffs' claims, relying on previous First Circuit decisions. It also affirmed the district court's holding that § 360k(a) of the MDA preempted all of the plaintiffs' claims.⁶⁷

The *Talbott* court determined state tort law fell within section 360k(a) because it imposed "requirements" to only include state statutes and regulations, and not common law cause of actions.⁶⁸ The district court analyzed each of the plaintiffs' claims individually, allowing the First Circuit to adopt the district court's finding and conclude that each claim imposed an additional regulation.⁶⁹ Applying similar reasoning to previous First Circuit cases regarding MDA preemption, the *Talbott* court decided the MDA preempted the plaintiffs' state tort claims.⁷⁰

⁶¹ *Stamps*, 984 F.2d at 1421.

⁶² *King*, 983 F.2d at 1135-36.

⁶³ See *Talbott v. C.R. Bard, Inc.*, 63 F.3d 25, 30-31 (1st Cir. 1995) (holding § 360k(a) of the MDA preempts all the plaintiffs' state tort claims).

⁶⁴ See *United States v. C.R. Bard, Inc.*, 848 F. Supp. 287, 292-93 (D. Mass 1994) (finding C.R. Bard, Inc. culpable and imposing a fine of sixty-one million dollars for violations).

⁶⁵ *Talbott*, 63 F.3d at 31.

⁶⁶ *Talbott*, 865 F. Supp. at 37.

⁶⁷ See *Talbott*, 63 F.3d at 31 (relying on *King* as authority for its decision).

⁶⁸ *Id.* at 27. The court reasoned that the plaintiff's reading of "requirements" to only include state statutes and regulations, not common law causes of actions, had already been dismissed by the First Circuit in *King v. Collagen Corp.*, 983 F.2d 1130, 113-36 (1st Cir. 1993) and in *Mendes v. Medtronic, Inc.*, 18 F.3d 13, 16 (1st Cir. 1994).

⁶⁹ See *Talbott*, 65 F.3d at 31 (noting district judge's opinion reaching the correct result should not be re-analyzed by reviewing court).

⁷⁰ See *id.* at 27 (using *King* and *Mendes* as authority for its ruling).

B. Preemption of Only Some State Tort Law Claims

The Eleventh Circuit has refrained from interpreting § 360k(a) as a total preemption of common law state tort claims.⁷¹ In *Lohr v. Medtronic, Inc.*,⁷² the Eleventh Circuit found the MDA to preempt only two of the plaintiffs' state tort claims.⁷³ Unlike *Talbott*, the litigant in *Lohr* presented court with a device that reached the market under the pre-notification process.⁷⁴ The FDA found the Medtronic pacemaker "substantially equivalent" to an earlier marketed device, allowing Medtronic to market the pacemaker without satisfying the PMA process requirements.⁷⁵

The *Lohr* court resolved the issue of whether Congress intended to protect the public and encourage development of medical devices by preempting state laws.⁷⁶ The court examined the phrase "state requirement" and concluded that the MDA preemption provision encompassed some state tort claims.⁷⁷ The court also held that the MDA's clause providing state exemption did not allow a finding that the MDA preempted all state law liability.⁷⁸ The court held that the MDA preempted the plaintiffs'

⁷¹ See *Lohr v. Medtronic*, 56 F.3d 1335, 1338-39 (11th Cir. 1995) (holding MDA preemption of only two, and not all the plaintiff's claims). See also *Ministry of Health v. Shiley, Inc.*, 858 F. Supp. 1426, 1431 (C.D. Cal. 1994) (establishing partial preemption under the MDA); *Mitchell v. Collagen Corp.*, 67 F.3d 1268, 1278-86 (7th Cir. 1995) (holding express warranty claim not preempted while rest of claims are preempted).

⁷² 56 F.3d 1135 (11th Cir. 1995).

⁷³ See *id.* at 1340-52 (alleging claims of negligent design, manufacturing, failure to warn and strict liability in tort). The plaintiff received a pacemaker manufactured by Medtronic, Inc. which failed several years after it was implanted. *Id.* at 1339. The plaintiff was forced to undergo emergency surgery because of a defective component in the pacemaker. *Id.*

⁷⁴ See *Lohr*, 56 F.3d at 1340 (noting device underwent less stringent regulation despite being a Class III device).

⁷⁵ *Id.* The FDA found the lead component to be a substantially-equivalent device because the device had the same intended use as a previously approved device, possessed similar technological characteristics of the device and was as safe and effective as the earlier device. *Id.*

⁷⁶ See *Lohr v. Medtronic*, 56 F.3d 1335, 1339 n.1 (11th Cir. 1995) ((citing *Mertens v. Hewitt Ass'n.*, 508 U.S. 248 (1993)). The court held that "courts must be mindful of the fact that legislative acts reflect many competing interests and should not allow vague notions about a statutes overall purpose to overcome its text." *Id.*

⁷⁷ *Id.* at 1341-42.

⁷⁸ See *id.* at 1342-43 (noting MDA's exemption clause did not explicitly state tort liability must be maintained).

claims of negligent manufacturing and failure to warn consumers, but did not preempt the plaintiffs' claims of negligent design and strict liability.⁷⁹

C. No Preemption of State Tort Claims

The Ninth Circuit refused to find total preemption and held that the MDA preempts none of the plaintiffs' state tort claims.⁸⁰ The court interpreted "requirement" to include state common law claims.⁸¹ The court, favored the plaintiffs' claims and relied heavily on the legislative history's emphasis on ensuring consumer safety.⁸² Additionally, the court relied on the FDA's interpretation of the MDA to support the conclusion that Congress did not intend to preempt state tort claims.⁸³

In *Kennedy v. Collagen Corp.*,⁸⁴ the Ninth Circuit interpreted the FDA regulations to preempt none of the plaintiffs' state claims.⁸⁵ The plaintiff alleged she developed an auto-immune disease after receiving a Zyderm Collagen Implant, and brought six separate tort claims.⁸⁶ The dis-

⁷⁹ *Id.* at 1350-52.

⁸⁰ *See, eg., Oja v. Howmedica, Inc.*, 848 F. Supp. 905, 907 (D. Colo. 1994) (holding no preemption of state product liability claim for defective hip replacement device); *Mulligan v. Pfizer, Inc.*, 850 F. Supp. 633, 636 (S.D. Ohio 1994) (ruling MDA did not preempt strict liability, negligence and breach of implied warranty, claims regarding knee device); *Fogel v. Steinfeld*, 620 N.Y.S.2d 875, 883 (N.Y. Sup. Ct. 1994) (ruling defective design, breach of warranty and failure-to-warn claims against pacemaker manufacturer were not preempted).

⁸¹ *Callan v. G.D. Searle & Co.*, 709 F. Supp. 662, 667 (D. Md. 1989).

⁸² *See id.* at 667 (stating MDA legislative history lacks Congressional intent to preempt state tort law). The courts recognize a strong presumption against preemption absent a clear statement of Congressional intent in matters relating to public health and safety. *See Desmarais v. Dow Corning Corp.*, 712 F. Supp. 13, 16 (D. Conn. 1989). Also the courts point to the legislative history's emphasis on ensuring consumer safety, therefore the plaintiffs must be ensured an opportunity for judicial recourse. *Haudrich v. Howmedica, Inc.*, 267 Ill. App. 3d 630, 644, 642 N.E.2d 206, 217 (Ill. App. Ct. 1994).

⁸³ *See Oja*, 848 F. Supp. at 906 n.1 (noting FDA regulations impose limits on preemption). *See also Elbert v. Howmedica, Inc.*, 841 F. Supp. 327, 331-32 (D. Haw. 1993) (finding underlying regulations not preempting state tort claims).

⁸⁴ 67 F.3d 1453 (9th Cir. 1995).

⁸⁵ *Id.* at 1459-60.

⁸⁶ *See id.* 67 F.3d at 1454 (noting plaintiff claims included negligence, strict liability, breach of warranty, battery, conspiracy, and loss of consortium).

trict court granted Collagen's motion for summary judgment, finding the MDA preempted each of the plaintiffs' claims.⁸⁷

The United States Court of Appeals for the Ninth Circuit reversed the district court's holding of total preemption.⁸⁸ The court examined the FDA's interpretation of the MDA preemption clause to determine which state claims the clause preempted.⁸⁹ The court emphasized the traditional presumption against preemption and found that Congress failed to specify a "state requirement" under the MDA.⁹⁰

The *Kennedy* court found that PMA approval did not constitute a "specific requirement."⁹¹ The court reasoned that if state claims were always preempted in cases where the device had been approved through the PMA process, plaintiffs would never obtain an adequate remedy.⁹² The court further stated that if the court prevents plaintiffs from judicial recourse, it would subvert Congress' original intent of protecting consumers.⁹³ Consequently, the *Kennedy* court held that the MDA preempted none of the plaintiff's state tort claims.⁹⁴

V. LOHR V. MEDTRONIC⁹⁵

With a distinct split among the circuits regarding the MDA preemption provision, the Supreme Court of the United States acknowledged the need to define the preemptive scope of the MDA.⁹⁶ After Ms. Lohr's

⁸⁷ *Id.* at 1455.

⁸⁸ *Id.* at 1460.

⁸⁹ See *Kennedy v. Collagen*, 67 F.3d 1453, at 1457-59 (9th Cir. 1995) (reiterating that FDA interpretations control because Congress charged the FDA with implementation of the MDA).

⁹⁰ *Kennedy*, 67 F.3d at 1457.

⁹¹ See *id.* at 1459 (noting although PMA involves specific requirements does not mean it acts as a specific requirement).

⁹² See *id.* (noting interpretation leaves Class III device consumers without judicial recourse).

⁹³ See *id.* at 1457-60 (noting PMA must benefit consumers, not "create a rose garden, free from liability, for manufacturers").

⁹⁴ *Kennedy v. Collagen*, 67 F.3d 1453, at 1459-60 (9th Cir. 1995).

⁹⁵ 116 S. Ct. 2240 (1996).

⁹⁶ See *id.* On January 19, 1996, the Court granted the petition for certiorari filed in *Lohr v. Medtronic, Inc.*, 56 F.3d 1335 (11th Cir. 1995), *cert. granted*, 116 S. Ct. 806 (1996) (Nos. 95-754, 95-886). The First Circuit applied total preemption, the Eleventh Circuit applied partial preemption, and the Ninth Circuit applied no preemption. See also *supra* notes 49-94.

Medtronic pacemaker failed resulting in a "complete heart block" and emergency surgery, the Lohrs filed suit against Medtronic in Florida state court.⁹⁷ They attempted to demonstrate Medtronic's liability on the theories of strict liability and negligent manufacturing.⁹⁸ The negligence count alleged a breach of Medtronic's duty to use reasonable care in the design, manufacture, assembly and sale of the subject pacemaker.⁹⁹ The breach of duty included using defective materials in the lead of the catheter and the company's failure to warn physicians about the tendency of the pacemaker to fail.¹⁰⁰ The plaintiffs further alleged that the device's inherent defective condition made Medtronic strictly liable.¹⁰¹

Medtronic removed the case to federal district court and filed a motion for summary judgment, arguing that 21 U.S.C. § 360k(a) preempted both the negligence and strict liability clause.¹⁰² The district court found no authority to support Medtronic's argument.¹⁰³ The court found that the MDA did not entirely exempt a manufacturer from liability where it allegedly violated the FDA's regulations.¹⁰⁴ Shortly after the district court decided *Lohr*, the United States Court of Appeals for the Eleventh Circuit concluded that § 360k required preemption of some state common law claims brought against a manufacturer of a medical device.¹⁰⁵ The district court reconsidered its previous ruling in light of the Eleventh Circuit's in-

⁹⁷ See *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1340 (11th Cir. 1995). The crosspetitioner, Lora Lohr, is dependent on pacemaker technology for the proper functioning of her heart. *Id.* In 1987, she received a Medtronic pacemaker implant equipped with one of the Company's Model 4011 pacemaker leads. *Id.* On December 30, 1990, the pacemaker failed resulting in a "complete heart block" that required emergency surgery. *Id.* The lead is the portion of a pacemaker that transmits the heartbeat, steadying the electrical signal from the "pulse generator" to the heart itself. *Id.* According to Lohr's physician, the malfunction of the pacemaker was caused by a defect in the lead of the pacemaker. *Id.*

⁹⁸ *Lohr*, 116 S. Ct. at 2247.

⁹⁹ See *id.* at 1347-49 (noting complaint of defective lead materials and failure to warn about pacemaker's tendency to fail).

¹⁰⁰ *Id.*

¹⁰¹ *Id.* at 2248. A third count alleging breach of warranty was dismissed for failure to state a claim under Florida law. *Id.*

¹⁰² *Id.*

¹⁰³ *Lohr v. Medtronic, Inc.*, 116 S. Ct. 2240, 2247 (1996).

¹⁰⁴ See *id.* at 2248 (citing from application for petition for certiorari review).

¹⁰⁵ See generally *Duncan v. Iolab Corp.*, 12 F.3d 194 (11th Cir. 1994) (finding § 360k(a) to be somewhat preemptive of state common law actions involving medical devices).

terpretation of §360k, reversed its earlier decision, and dismissed the Lohr's complaint.¹⁰⁶

On appeal, the Eleventh Circuit reversed and affirmed parts of the district court's holding.¹⁰⁷ The Court of Appeals decided that "common law actions are state requirements within the meaning of § 360k(a)" and preemption could not be avoided by alleging that the negligence flowed from a violation of federal standards.¹⁰⁸ The court found the term "requirement" unclear and turned to the FDA's regulations regarding preemption for guidance.¹⁰⁹ Under these regulations, the court concluded that the federal requirements "should, in some way, be 'restricted by nature' to a particular process, procedure, or device and should not be completely open-ended."¹¹⁰

From this analysis, the court concluded that the MDA did not preempt the Lohr's negligent design claims.¹¹¹ However, it concluded that the FDA's general "good manufacturing practices" regulations and the FDA labeling requirements did result in preemption of the negligent manufacturing and failure-to-warn claims.¹¹² The court held there was no preemption of the strict liability claims insofar as the plaintiffs alleged an unreasonable dangerous design.¹¹³ The court precluded the plaintiffs from reviving the negligent manufacturing or failure-to-warn claims under a strict liability theory.¹¹⁴

Medtronic filed a petition seeking review of the Court of Appeal's decision in that it affirmed the district court's ruling that allowed the Lohrs

¹⁰⁶ See *Lohr*, 116 S. Ct at 2248 (finding preemption based on 11th Circuit's *Duncan* analysis).

¹⁰⁷ See *Meditronic, Inc. v. Lohr & Lohr v. Meditronic, Inc.*, 56 F.3d 1335, 1342-44 (11th Cir. 1995).

¹⁰⁸ *Id.* at 1342.

¹⁰⁹ See *id.* at 1344 (noting regulations provided no preempted state requirements unless FDA has established specific requirements applicable to particular device).

¹¹⁰ See *Lohr*, 56 F.3d at 1346 (noting federal regulation did not specifically address pacemakers, yet not be so broad either).

¹¹¹ See *id.* at 1347-49 (rejecting Medtronics contention that FDA's finding of "substantial equivalence" had any significance with respect to pacemaker's safety).

¹¹² See *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1350 (11th Cir. 1995); 21 C.F.R. §§ 820.20-820.198 (explaining FDA regulations establish general requirements for most steps in every device's manufacture); see also 21 C.F.R. § 801.109 (1995) (noting FDA labeling requirements require devices to bear warnings).

¹¹³ *Lohr*, 56 F.3d at 1351-52.

¹¹⁴ *Id.*

to go forward with their claims of strict liability and negligent manufacturing.¹¹⁵ Subsequently, the Lohrs filed a cross-petition seeking review of the judgment in that it upheld the preemption defense.¹¹⁶ The Supreme Court granted both petitions acknowledging the need for it to define MDA's preemptive scope.¹¹⁷ The Court concluded that none of the Lohrs' state law claims are preempted.¹¹⁸

The Court upheld the Eleventh Circuit holding that the Lohrs' design claims could go forward.¹¹⁹ Additionally, the Lohrs were allowed to proceed with the manufacture and failure-to-warn claims.¹²⁰ The plurality found Medtronic's claim of preemption to be "not only unpersuasive, [but] implausible."¹²¹ The plurality further stated that given the ambiguities in the statute and the scope of preclusion that would occur otherwise, the Court could not accept Medtronic's theory that by using the term "requirement," Congress clearly intended to deprive states of a role in protecting consumers.¹²²

Justice Breyer, concurring in part, agreed with the plurality, but was not convinced that future incidents of MDA preemption of common law claims will be "few and rare."¹²³ The Justices concurring in part and dissenting in part, disagreed with the plurality's view that the MDA preempts

¹¹⁵ *Lohr v. Medtronic*, 116 S. Ct. 2240, 2247 (1996).

¹¹⁶ *Id.*

¹¹⁷ *See id.* (recognizing division between circuits over which state common law claims are preempted by MDA).

¹¹⁸ *See id.*, 116 S. Ct. at 2258 (noting critical importance of device specificity and Court's construction of § 360k resulted in very little preemption).

¹¹⁹ *Id.*

¹²⁰ *Lohr v. Medtronic*, 116 S. Ct. 2240, 2258 (1996).

¹²¹ *See id.* at 2251 (1996) (stating Medtronic's interpretation requires greater interference with state legal remedies).

¹²² *See id.* at 2252 (expressing Court's concern of intruding into state sovereignty). The Court explains that Congress was mainly concerned with the problem of conflicting state statutes and regulations, rather than general duties enforced by common law actions. *Id.* at 2253. The Court also cites to legislative history to support the position that §360k (a) was not intended to preempt most general common law actions. *Id.*

¹²³ *See id.* (stating MDA will sometimes preempt a state law tort suit). Justice Breyer concludes a federal requirement preempts a state requirement if: (1) the state requirement conflicts with the federal requirement, with because compliance is impossible or the state requirement stands as an obstacle to the execution of Congress' objectives, or (2) the scheme of the federal requirement is so persuasive as to make a reasonable inference that Congress left no room for the states to supplement it. *Id.*

“few, if any common law.”¹²⁴ These Justices interpreted section 360k(a) not to preclude states from imposing different or additional remedies, but only different or additional requirements.¹²⁵ Despite different reasoning, a unanimous Supreme Court rejected the complete preemption argument proffered by Medtronic.¹²⁶

VI. LOHR'S IMPACT ON THE FIRST CIRCUIT

In *Comeau v. Heller*,¹²⁷ the First Circuit addressed the MDA issue and its preemptive scope for the first time since *Lohr*.¹²⁸ Ms. Comeau allegedly received a defective SciMed angioplasty catheter and brought a products liability action in Massachusetts state court against SciMed.¹²⁹ SciMed attempted to remove the case to federal court by arguing that the catheter involved was a “Class III” medical device subject to the MDA regulatory scheme.¹³⁰

SciMed attempted to assert federal jurisdiction by arguing that the “complete preemption” doctrine, created by the First Circuit’s application of the MDA, was an “independent corollary” of the well plead complaint rule.¹³¹ Considering the recent *Lohr* decision, the *Comeau* court found the

¹²⁴ *Id.* at 2259.

¹²⁵ *See id.* at 2259-60 (stating manufacturing and failure-to-warn claims, if successful, would impose different or additional requirements to federal requirements).

¹²⁶ *See Lohr v. Medtronic*, 116 S. Ct. 2240, 2257 (1996) (finding MDA preemption only when particular state requirements threaten to interfere with specific federal interests).

¹²⁷ 945 F. Supp. 7 (D. Mass. 1996).

¹²⁸ *See id.* at 9 (holding MDA did not completely preempt state common law claims). Plaintiff alleged that her injuries were caused by a defective catheter. *Id.* The first angioplasty disclosed a filling defect initially suspected to be a clot. *Id.* Following the second angioplasty, Ms. Comeau went into cardiac arrest and underwent bypass surgery. *Id.* The surgeon found that the obstruction in the filling defect was not a clot, but rather a plastic protective sheath from the angioplasty catheter used in previous surgery. *Id.*

¹²⁹ *See id.* at 7 (noting plaintiff also brought negligent actions against physician and state).

¹³⁰ *See id.* at 9 (discussing SciMed’s contention that MDA authorizes jurisdiction in federal court).

¹³¹ *See id.* (stating Supreme Court held an “independent corollary” of the well-pleaded complaint rule exists). The “independent corollary” exists if: “a federal cause of action completely preempts a state cause of action, [in which case] any complaint that comes within the scope of the federal cause of action necessarily ‘arises under’ federal law.” *See id.*, 945 F. Supp. at 9 (citing *Franchise Tax Bd. of California v. Construction Laborers Vacation Trust*, 463 U.S. 1, 22-24 (1983)). Therefore, under the “complete preemption” doctrine, a defendant may remove a case to federal court, even if no federal claims are

"complete preemption" doctrine not to be applicable in the context of the MDA.¹³² The court concluded that it lacked subject matter jurisdiction over the claims, and remanded the case back to state court.¹³³

SciMed distinguished *Lohr* by asserting that *Lohr* did not address cases involving "Class III" medical devices subjected to the PMA process, and therefore, *Lohr* was not applicable to Ms. Comeau's claim.¹³⁴ The court noted that the Supreme Court was aware of the distinction between a PMA and a premarket notification device, and still did not limit its holding to only one process.¹³⁵ The *Comeau* court refused to read the *Lohr* decision and decide what the Supreme Court failed to hold explicitly.¹³⁶

The court hesitantly concluded that the MDA does not completely preempt state tort claims.¹³⁷ It did state that some of the plaintiffs' claims maybe subject to the MDA preemption.¹³⁸ However, the court recognized the issue at bar pertained to subject matter jurisdiction and not preemption.¹³⁹ In *Comeau*, the First Circuit leaves the impression that it agrees with the dissent in *Lohr*, insofar as that some common law actions are subject to MDA preemption.¹⁴⁰

VII. CONCLUSION

The language used in *Comeau* opinion exemplifies the First Circuit's reluctance to find a presumption against preemption. Since the *Lohr* decision, the First Circuit has applied *Lohr's* holding found mostly in product liability cases involving devices other than medical devices. The First Circuit has found preemption in these cases, reasoning that *Lohr* pertained to medical devices only. *Comeau* is the only case in the First Circuit which involves a medical device, and the court not to apply *Lohr*, but rather removed it back to state court. With the history of the First Circuit's appli-

presented on the face of the complaint. *Id.*

¹³² See *Comeau*, 945 F. Supp. at 9 (concluding *Lohr* curtailed MDA's total preemption).

¹³³ *Id.* at 12.

¹³⁴ See *id.* at 11-12 (noting the device in *Lohr* was subjected to premarket notification).

¹³⁵ See *Comeau v. Heller*, 945 F. Supp. 7, 12 (D. Mass. 1996) (recognizing Supreme Court did not limit its holding to either process).

¹³⁶ *Id.*

¹³⁷ *Id.*

¹³⁸ *Id.*

¹³⁹ See *id.* (stating after *Lohr*, the short answer to complete preemption is no).

¹⁴⁰ *Comeau v. Heller*, 945 F. Supp. 7, 10 (D. Mass. 1996).

cation of the MDA preemption provision, and its recent decisions after *Lohr*, the First Circuit still seeks to apply preemption. Although the First Circuit has not directly addressed preemption of the MDA, the First Circuit has shown its reluctance to follow *Lohr* in full.

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