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Weiland v. Telectronics Pacing Systems, Inc.:
Illinois Reexamines Medical
Device Preemption

ADRIAN S. ALLEN*

INTRODUCTION

In *Medtronic, Inc. v. Lohr*,¹ the Supreme Court took up the subject of federal preemption of state common-law tort claims against the manufacturers of medical devices.² The Supreme Court's decision to take the case was motivated in part by the division among the circuit courts as to what benefits the Medical Device Amendments of 1976 ("MDA")³ conferred upon medical device manufacturers who followed the requirements of the Food and Drug Administration's ("FDA") premarket approval ("PMA") process.⁴ The importance of the issue was indicated by the number of parties that joined in the dispute over whether compliance with the PMA process should allow the preemption of state common-law tort claims.⁵ However, the Supreme Court's resolution of the case failed to definitively resolve the issue and left several other issues open.⁶ The issue of the preemptive result of compliance with the PMA process upon state common-law tort claims continues to splinter the circuits and divide federal and state courts.⁷

* J.D. Candidate, 2001, Indiana University School of Law—Bloomington; B.A., 1996, Indiana University—Northwest. I wish to thank my wife, Lisa Allen, for her love and support. I would also like to thank the Black and Downes families for their support.

1. 518 U.S. 470 (1996).

2. *Id.* at 474.

3. 21 U.S.C. §§ 360c-360k, 379-379a (1994 & Supp. IV 1998).

4. *Lohr*, 518 U.S. at 484.

5. Westlaw has links to seventeen briefs by amici curiae. Amici curiae on behalf of the petitioner included, for example, Brief of Amicus Curiae General Motors Corp., *Lohr* (Nos. 95-754, 95-886), 1996 WL 109601, and Brief of the American Insurance Ass'n et al., *Lohr* (Nos. 95-754, 95-886), 1996 WL 109605. Amici curiae on behalf of the respondent included, for example, Brief of the State of Florida et al., *Lohr* (Nos. 95-754, 95-886), 1996 WL 109592, Brief Amicus Curiae of the State of California, *Lohr* (Nos. 95-754, 95-886), 1996 WL 109599, and Brief Amicus Curiae of American Ass'n of Retired Persons et al., *Lohr* (Nos. 95-754, 95-886), 1996 WL 109611.

6. See *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1371 & n.7 (11th Cir. 1999) (noting that while *Lohr* can be regarded as holding that compliance with the section 510(k) process did not preempt state common-law claims, it left open the issue of whether compliance with the PMA process would preempt state common-law claims).

7. Compare *id.* at 1382 (holding that the MDA did not preempt common-law claims under Florida law for negligent design and strict products liability), *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 159 F.3d 817, 823 (3d Cir. 1998) (stating that the MDA would not disallow any viable state law claim of fraudulent misrepresentation), and *Haidak v. Collagen Corp.*, 67 F. Supp. 2d 21, 23 (D. Mass. 1999) (holding that PMA of collagen products under the MDA did not preempt plaintiff's claims), with *Mitchell v. Collagen Corp.*, 126 F.3d 902, 911-13 (7th Cir. 1997) (holding that the PMA process preempted most state common-law claims with limited exceptions), and *Heymach v. Cardiac Pacemakers, Inc.*, 698 N.Y.S.2d 837, 840-42 (N.Y. Sup. Ct. 1999) (refusing to follow precedent of the appellate court in finding that a

Weiland v. Telectronics Pacing Systems, Inc.,⁸ a recent decision of the Supreme Court of Illinois, is indicative of this state of affairs. In overruling a decision that PMA did not preempt any state common-law tort claims, the court in *Weiland* stated that in reference to the contrary decision of the Seventh Circuit Court of Appeals in *Mitchell v. Collagen Corp.*, "we believe, the case from the Seventh Circuit was wrongly decided."⁹ The divergence of the Seventh Circuit and the Supreme Court of Illinois, as an example of the conflicting court decisions on this issue, indicates the need for the U.S. Supreme Court to reexamine the issue of PMA of medical devices and subsequent preemption of state common-law tort claims in order to bring order and some predictability to the issue.

This Note will examine the development of the law interpreting the preemptive effect of compliance with the PMA process upon state common-law claims and discuss the divergence between the Seventh Circuit Court of Appeals and the Supreme Court of Illinois.

Part I of this Note will set out the development of federal regulation in the area of medical devices leading up to the enactment of the MDA. Part II will explain the PMA process by which the FDA initially evaluates the safety of medical devices before they are allowed onto the market for public use. Part III will discuss *Lohr*, the main Supreme Court decision addressing the preemption of state common-law claims against medical device manufacturers. Part IV examines the Seventh Circuit's interpretation of *Lohr*. Part V discusses the recent Supreme Court of Illinois decision in *Weiland* and notes the conflict between the Supreme Court of Illinois and the Seventh Circuit on the issue of preemption of state common-law claims by compliance with PMA requirements.

I. ENACTMENT OF THE MDA

Traditionally, individual states have been the main protectors of their citizens' health and safety.¹⁰ However, from the early part of the twentieth century Congress has displayed an increasing readiness to enact legislation to protect consumers from potentially harmful medical drugs and medical devices. The first major piece of congressional legislation was the Food and Drugs Act of 1906,¹¹ which constituted "a broad prohibition against the manufacture or shipment in interstate commerce of any adulterated or misbranded food or drug."¹² However, the Food and Drugs Act of 1906 did not contain any provision for the regulation of medical devices.¹³

manufacturer's compliance with the PMA process did not preempt state common-law claims).

8. 721 N.E.2d 1149 (Ill. 1999).

9. *Id.* at 1154.

10. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996). The Court noted that the "[s]tates traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." *Id.* (citing *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985)).

11. Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768, *repealed by* Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. § 301 (1994).

12. *Lohr*, 518 U.S. at 475 (citing Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768).

13. S. REP. NO. 94-33, at 2 (1976), *reprinted in* 1976 U.S.C.C.A.N. 1070, 1071. See generally Dennis R. Johnson, *The History of the 1906 Pure Food and Drugs Act and the Meat*

The absence of any provision for the regulation of medical devices was remedied by the enactment of the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA").¹⁴ FDCA "broadened the coverage of the 1906 Act to include misbranded or adulterated medical devices and cosmetics."¹⁵ This regulation was superior to the 1906 Act in that it allowed for the PMA of drugs.¹⁶ PMA was not extended to medical devices.¹⁷ At the time of FDCA's passage, Congress's major concern was the improper labeling of medical devices¹⁸ as "legitimate devices were relatively simple items which applied basic scientific concepts so that experts using them could recognize whether the device was functioning."¹⁹ The FDA turned its attention to the "hazards from legitimate medical devices around 1960."²⁰ This change in focus was a result of the rapid developments in the medical device industry following World War II that included inventions such as "heart pacemakers, kidney dialysis units, and artificial blood vessels and heart valves."²¹ The increased reliance on medical devices led to increasing consumer and regulatory concern.²² These concerns led Congress to enact the MDA²³ to protect the "[i]ncreasing numbers of patients [who] have been exposed to increasingly complex devices which pose serious risk if inadequately tested or improperly designed or used."²⁴

The MDA greatly strengthened the regulation of medical devices by giving the FDA the proactive power to review medical devices for safety and effectiveness before they entered the market.²⁵ Congress was mindful that it did not want to erect

Inspection Act, 37 FOOD DRUG COSM. L.J. 5 (1982).

14. Federal Food, Drug, and Cosmetic Act of 1938, ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-397 (1994 & Supp. IV 1998)).

15. *Lohr*, 518 U.S. at 475 (citing Federal Food, Drug, and Cosmetic Act of 1938 §§ 501-502, 21 U.S.C. §§ 350b-351 (1994 & Supp. IV 1998)).

16. *Id.*

17. *Id.*; S. REP. NO. 94-33, at 2, reprinted in 1976 U.S.C.C.A.N. at 1072.

18. S. REP. NO. 94-33, at 3, reprinted in 1976 U.S.C.C.A.N. at 1072.

19. *Id.* at 2-3, reprinted in 1976 U.S.C.C.A.N. at 1072.

20. *Id.* at 5, reprinted in 1976 U.S.C.C.A.N. at 1074.

21. *Id.*

22. *Lohr*, 518 U.S. at 475-76. The Dalkon Shield, an intrauterine contraceptive device, is an example of the types of medical devices that were causing some groups to call for greater regulation of the medical device industry. *Id.* "Touted as a safe and effective contraceptive, the Dalkon Shield resulted in a disturbingly high percentage of inadvertent pregnancies, serious infections, and even, in a few cases, death." *Id.* at 476 (citing Bruce A. Finck, *The Effectiveness of FDA Medical Device Regulation*, 7 U.C. DAVIS L. REV. 293, 297-301 (1974)); see also Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 MO. L. REV. 895, 911 n.83 (1994) (discussing the importance of the Cooper Committee, created by the Department of Health, Education & Welfare, in convincing Congress to enact medical device legislation).

23. Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended at 21 U.S.C. §§ 360c-360k, 379-379a (1994 & Supp. IV 1998)).

24. S. REP. NO. 94-33, at 5, reprinted in 1976 U.S.C.C.A.N. at 1075. For further discussion of the MDA, see Mary G. Boguslaski, *Classification and Performance Standards Under the 1976 Medical Device Amendments*, 40 FOOD DRUG COSM. L.J. 421 (1985).

25. Adler & Mann, *supra* note 22, at 910-11; Quentin F. Urquhart, Jr. & Robert E. Durgin, *Medtronic v. Lohr: Is There a Future for Preemption in Medical Device Cases?*, 64 DEF.

regulatory barriers so burdensome that they would discourage the development of medical devices that would benefit society.²⁶

The MDA breaks down medical devices into three main classes for regulatory purposes: class I devices, class II devices, and class III devices.²⁷ The FDA devised this system so that devices that posed potentially greater harm to the consumer would receive greater regulatory scrutiny.²⁸

A. Class I Devices

A device can qualify as a class I device in two ways.²⁹ The first method can be accomplished by showing that another section of the MDA is "sufficient to provide reasonable assurance of the safety and effectiveness of the device."³⁰ Alternatively, a device can qualify for class I certification if it "is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health"³¹ and "does not present a potential unreasonable risk of illness or injury."³²

Class I devices are thus "[d]evices . . . subject only to minimal regulation by 'general controls.'"³³ Devices that have been classified in class I include surgeon's gloves,³⁴ eye pads,³⁵ and ice bags.³⁶

COUNS. J. 45, 46 (1997).

26. S. REP. NO. 94-33, at 2, reprinted in 1976 U.S.C.C.A.N. at 1071 ("[A]s research makes new breakthroughs, an increasing number of sophisticated, critically important medical devices are being developed and used in the United States. . . . The Committee wants to encourage their research and development."); see also Scott W. Saylor & Steven M. Thomas, *Post-Decision Diagnosis: Medical Device Preemption Alive and Mostly Well After Medtronic, Inc. v. Lohr*, 6 ANNALS HEALTH L. 185, 186-87 (1997).

27. 21 U.S.C. § 360c(a)(1)(A)-(C) (1994).

28. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476-77 (1996); *Duvall v. Bristol-Myers-Squibb Co.*, 103 F.3d 324, 327 (4th Cir. 1996); Adler & Mann, *supra* note 22, at 911-14; 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, 626 (1996).

29. 21 U.S.C. § 360c(a)(1)(A).

30. *Id.* § 360c(a)(1)(A)(i). For applicable sections, see 21 U.S.C. § 351 (1994 & Supp. IV 1998) ("Adulterated drugs and devices"); *id.* § 352 ("Misbranded drugs and devices"); 21 U.S.C. § 360f (1994) ("Banned devices"); 21 U.S.C. § 360i (1994 & Supp. IV 1998) ("Records and reports on devices"); *id.* § 360j ("General provisions respecting control of devices intended for human use").

31. 21 U.S.C. § 360c(a)(1)(A)(ii)(I) (1994).

32. *Id.* § 360c(a)(1)(A)(ii)(II).

33. *Lohr*, 518 U.S. at 476-77. "General controls relate to adulteration, misbranding, registration, premarket notification, good manufacturing practices, and reporting." Adler & Mann, *supra* note 22, at 913 n.88.

34. 21 C.F.R. § 878.4460 (2000).

35. *Id.* § 878.4440.

36. *Id.* § 880.6050.

B. Class II Devices

Class II devices are those for which “the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device.”³⁷ In addition, there must be enough “information to establish special controls . . . including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines . . . recommendations, and other appropriate actions as the Secretary deems necessary.”³⁸ For any class II devices that are “represented to be for a use in supporting or sustaining human life,” the Secretary must identify, examine, and provide assurance of any special controls “necessary to provide adequate assurance of the [device’s] safety.”³⁹ The FDA has classified tampons,⁴⁰ syringes,⁴¹ and neonatal incubators⁴² as class II devices.

C. Class III Devices

Class III devices are those that either “‘presen[t] a potential unreasonable risk of illness or injury’ or which are ‘purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health.’”⁴³ The FDA has classified pacemakers⁴⁴ and heart valves⁴⁵ as class III devices. Manufacturers of class III devices cannot market them unless they assure the FDA of the device’s safety and effectiveness by compliance with the PMA process.⁴⁶

II. THE PMA PROCESS

The PMA process has been described as rigorous.⁴⁷ A “[m]anufacturer[] must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1200 hours on each submission.”⁴⁸

37. 21 U.S.C. § 360c(a)(1)(B).

38. *Id.*

39. *Id.*

40. 21 C.F.R. § 884.5460. The FDA has taken the further step of requiring tampon manufacturers to follow specific labeling requirements and to conduct specific absorbency tests upon their products. *Id.* § 801.430. The specific labeling requirements have been held to preempt state common-law claims for failure to warn. *Papike v. Tambrands, Inc.*, 107 F.3d 737, 738 (9th Cir. 1997).

41. 21 C.F.R. § 880.5860.

42. *Id.* § 880.5400.

43. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996) (quoting 21 U.S.C. § 360c(a)(1)(C)).

44. 21 C.F.R. § 870.3610.

45. *Id.* § 870.3925.

46. 21 U.S.C. § 360e (1994 & Supp. IV 1998). For further discussion of the MDA classification scheme, see Adler & Mann, *supra* note 22, at 912-15.

47. *Lohr*, 518 U.S. at 477.

48. *Id.* (quoting *Medical Devices and Drug Issues: Hearings Before the Subcomm. on Health and the Env’t of the House Comm. on Energy and Commerce*, 100th Cong. 384 (1987) (statement of Rep. Benson, Deputy Dir., Ctr. for Devices and Radiological Health, Food, and Drug Admin., Dep’t of Health and Human Servs.)).

The submitted information must include: a report on all information (published or which should reasonably be known to the applicant) that would show the device's safety and effectiveness;⁴⁹ a statement of the device's components, ingredients, and principles of operation;⁵⁰ and a description of the facilities and quality controls involved in manufacturing, processing, packaging, and/or installing the device.⁵¹ In addition, the manufacturer may be required either to furnish a sample directly to the FDA or make a sample available for inspection at its place of business, if practicable,⁵² and furnish examples of the labels intended for use with the device.⁵³ The Secretary can augment these requirements with requests for more information if a determination is made that it is necessary.⁵⁴ Obviously, the full PMA process can be extremely expensive for manufacturers.⁵⁵ Therefore, manufacturers have not hesitated to take advantage of the available exceptions to the full PMA process.⁵⁶

A. Exceptions to the PMA Process

There are two exceptions to the PMA process. The first exception addresses the problem of what should be done with devices that were already on the market when the MDA was enacted. Obviously, it would have been impractical to withdraw those devices, so the FDA approved "a 'grandfathering' provision which allow[ed] pre-1976 devices to remain on the market without FDA approval until such time as the FDA initiates and completes the requisite PMA."⁵⁷ The FDA then turned to the

49. 21 U.S.C. § 360e(c)(1)(A) (1994).

50. *Id.* § 360e(c)(1)(B).

51. *Id.* § 360e(c)(1)(C).

52. *Id.* § 360e(c)(1)(E).

53. *Id.* § 360e(c)(1)(F).

54. *Id.* § 360e(c)(1)(G).

55. See David A. Kessler et al., *The Federal Regulation of Medical Devices*, 317 NEW ENG. J. MED. 357, 359 (1987).

56. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477-80 (1996) (noting that "[n]ot all, nor even most, Class III devices on the market today have received premarket approval because of two important exceptions to the PMA requirement"); Adler & Mann, *supra* note 22, at 914 n.98 (noting that in "1986, for example, 4,338 devices reached the market through the '510(k)' route while only 72 devices did so through the PMA process" (citing *Medical Devices and Drug Issues: Hearings Before the Subcomm. on Health and the Env't of the House Comm. on Energy and Commerce*, 100th Cong. 384 (1987) (statement of Rep. Benson, Deputy Dir., Ctr. for Devices and Radiological Health, Food, and Drug Admin., Dep't of Health and Human Servs.))). Putting a medical device through the full PMA process can cost from \$111,000 to \$828,000, while the exceptions cost from \$50 to \$2000. *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1369 n.1 (11th Cir. 1999) (citing *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1345 n.14 (11th Cir. 1995), *aff'd in part and rev'd in part*, 518 U.S. 470 (1996)). In *Lohr*, the Supreme Court noted that "[t]he attraction of substantial equivalence to manufacturers is clear. [Section] 510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly." *Lohr*, 518 U.S. at 479 (second alteration in original) (quoting 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, 516 (1988)).

57. *Lohr*, 518 U.S. at 478 (citing 21 U.S.C. § 360e(b)(1)(A), and 21 C.F.R. § 814.1(c)(1) (2000)).

problem of what to do to "prevent manufacturers of grandfathered devices from monopolizing the market while new devices clear the PMA hurdle."⁵⁸

In order to deal with this problem, the FDA allowed devices "that are 'substantially equivalent' to pre-existing devices to avoid the PMA process."⁵⁹ Medical device manufacturers who seek to meet MDA requirements in this fashion must submit a premarket notification or 510(k) notification to the FDA.⁶⁰ An FDA finding that the proposed device is substantially equivalent to an existing device allows the device to be marketed without having to go through the entire PMA process.⁶¹

B. Preemption of State Common-Law Claims

The major dispute in the field of medical device liability is the preemptive effect that courts should give to compliance with the PMA process.⁶² This necessitates an

58. *Id.*

59. *Id.* (citing 21 U.S.C. § 360e(b)(1)(B)); see also *Mitchell v. Collagen Corp.*, 126 F.3d 902, 905 (7th Cir. 1997); *Martin v. Teletronics Pacing Sys., Inc.*, 105 F.3d 1090, 1095-96 (6th Cir. 1997); *Reeves v. Acromed Corp.*, 103 F.3d 442, 445 (5th Cir. 1997); *Dunlap v. Medtronic Inc.*, 47 F. Supp. 2d 888, 893 (N.D. Ohio 1999); *Milkiewicz v. Baxter Healthcare Corp.*, 963 F. Supp. 1150, 1152 (M.D. Fla. 1996).

60. *Lohr*, 518 U.S. at 478.

61. *Id.* See generally 21 C.F.R. § 807.81 (2000) ("When a premarket notification submission is required."); *id.* § 807.85 ("Exemption from premarket notification."); *id.* § 897.87 ("Information required in a premarket notification submission."); *id.* § 807.90 ("Format of a premarket notification submission."); *id.* § 807.100 ("FDA action on a premarket notification."). Congress has authorized a third exception to the PMA process for devices for investigational use. 21 U.S.C. § 360j(g) (1994 & Supp. IV 1998); 21 C.F.R. § 812. Investigation has been defined as "research involving one or more subjects to determine the safety or effectiveness of a device." 21 C.F.R. § 812.3(h). This exception was approved in order "to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose." 21 U.S.C. § 360j(g)(1) (1994). The FDA will not approve an application for an investigational device exception ("IDE") if "the risks to the subjects are not outweighed by the anticipated benefits to the subjects and the importance of the knowledge to be gained, or informed consent is inadequate, or the investigation is scientifically unsound, or there is reason to believe that the device as used is ineffective." 21 C.F.R. § 812.30(b)(4). See generally *Chambers v. Osteonics Corp.*, 109 F.3d 1243, 1245 (7th Cir. 1997) (discussing the IDE exception); *Martin*, 105 F.3d at 1095 (same); *Lewis v. Intermedics Intraocular, Inc.*, 19 F. Supp. 2d 625, 627 (E.D. La. 1998) (noting that the FDA developed rules governing IDEs in general and for intraocular lenses in particular). For a more detailed discussion of the IDE exception, see Stephen D. Harris, *Preemption of State Tort Claims Under the Medical Device Amendments*, 24 COLO. LAW. 2217, 2219 (1995); Sayler & Thomas, *supra* note 26, at 204-06.

62. A number of courts have held that a manufacturer's compliance with the PMA process preempts state common-law claims. *E.g.*, *Richman v. W.L. Gore & Assocs., Inc.*, 988 F. Supp. 753, 758-59 (S.D.N.Y. 1997) (holding that state-law claims alleging that a manufacturer was negligent, careless, and reckless in manufacturing, design, construction, labeling, packaging, distribution, and sale of ligament were preempted by the MDA); *Kozma v. Medtronic, Inc.*, 925 F. Supp. 602, 605-06 (N.D. Ind. 1996) (holding that compliance with the PMA process

examination of the actual clause upon which manufacturers and courts have based their claims that compliance with the PMA process forestalls state common-law tort claims, which is contained in § 360k:

State and local requirements respecting devices

(a) General Rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement-

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.⁶³

preempted claims of defective design, failure to warn, and breach of implied warranties); *Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763, 771 (Cal. Ct. App. 1996) (noting that in approving a product through the PMA process, the FDA imposed federal requirements specific to that device preempting state common-law claims); *Mears v. Marshall*, 944 P.2d 984, 993 (Or. Ct. App. 1997) (“Without question, [the PMA process completed by Zyderm] established requirements that governed nearly every aspect of Zyderm’s commercial existence, [therefore preempting state common-law claims.]”); *Fry v. Allergen Med. Optics*, 695 A.2d 511, 514-17 (R.I. 1997) (concluding that the PMA process imposed strict federal requirements on a manufacturer and therefore that state common-law claims were preempted); *Wutzke v. Schwaegler*, 940 P.2d 1386, 1391 (Wash. Ct. App. 1997) (“The general consensus is that the rigorous process of the PMA results in approval of a device’s design that rises to the level of specific federal requirements.”).

Other courts have held that compliance with the PMA process does not preempt state common-law claims. *E.g.*, *Lakie v. SmithKline Beecham*, 965 F. Supp. 49, 54 (D.D.C. 1997) (“The fact that the PMA process requires certain information and mandates certain procedures from manufacturers does not transform the PMA process *itself* into a specific federal requirement which triggers preemption and protects a manufacturer from suit.” (emphasis in original)); *Comeau v. Heller*, 945 F. Supp. 7, 12 (D. Mass. 1996) (“The Supreme Court was well aware of the distinction between a PMA-approved device and a § 510(k)-approved device yet it failed to limit the *Medtronic* holding to the latter.”); *Walker v. Johnson & Johnson Vision Prods., Inc.*, 552 N.W.2d 679, 684 (Mich. Ct. App. 1996) (disagreeing with “most federal and state courts that have considered similar arguments [and] have concluded that the [PMA] process satisfies the FDA’s preemption rule and preempts state common law claims”); *Sowell v. Bausch & Lomb, Inc.*, 656 N.Y.S.2d 16, 20 (N.Y. App. Div. 1997) (stating that “while a PMA review is considerably more rigorous and detailed than the premarket notification at issue in *Medtronic*,” it does not preempt state common-law claims).

63. 21 U.S.C. § 360k(a). Subsection (b) allows a state or one of its political subdivisions to apply for an exception to preemption when compelling local conditions require a more stringent requirement:

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if-

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under

The above provision further necessitates an inquiry into federal preemption doctrine. Federal preemption of state law is based upon the Supremacy Clause of the Constitution:

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.⁶⁴

Preemption of state law has been described as “complicated and not readily predictable. It is . . . a matter of statutory interpretation and is highly text-specific, turning on the language, structure and purpose of the federal regulatory scheme at issue. Precedent decided under one statute must therefore be used with caution when interpreting a different statute.”⁶⁵ The *Lohr* Court noted that in interpreting § 360k we should be “informed by two presumptions about the nature of preemption.”⁶⁶ First, because of the states’ historic preeminence in regulating the health and safety of their citizens, “we ‘start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.’”⁶⁷ Second, “[t]he purpose of Congress is the ultimate touchstone’ in every pre-emption case.”⁶⁸ “As a result, any understanding of the scope of a pre-emption statute must rest primarily on ‘a fair understanding of congressional purpose.’”⁶⁹

The MDA is an example of express preemption.⁷⁰ Express preemption occurs “when Congress explicitly provides language indicating that it wishes state laws to be displaced.”⁷¹ However, as noted above,⁷² even with explicit preemptive language, “interpreting congressional intent remains the key challenge since the ‘purpose of Congress is the ultimate touchstone’ in determining preemption.”⁷³

this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

Id. § 360k(b).

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

65. William W. Schwarzer, *Federal Preemption—a Brief Analysis*, in 2 CIVIL PRACTICE AND LITIGATION IN FEDERAL AND STATE COURTS § H-6, at 1 (Sol Schreiber et al. eds., 8th ed. 1998).

66. *Lohr*, 518 U.S. at 485.

67. *Id.* (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

68. *Id.* (quoting *Retail Clerks Int’l Ass’n, Local 1625 v. Schermerhorn*, 375 U.S. 96, 103 (1963) (alteration in original)).

69. *Id.* at 485-86 (emphasis in original) (quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 530 n.27 (1992)).

70. *Id.* at 484.

71. Adler & Mann, *supra* note 22, at 900.

72. See *supra* text accompanying note 69.

73. Adler & Mann, *supra* note 22, at 900 (quoting *Retail Clerks Int’l Ass’n, Local 1625*

One of the major decisions in developing the concept of federal preemption of state products liability laws was *Cipollone v. Liggett Group, Inc.*⁷⁴ *Cipollone* involved the interpretation of section 5(b) of the Federal Cigarette Labeling and Advertising Act of 1965 ("1965 Act").⁷⁵ Section 5(b) provided that "[n]o 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."⁷⁶ The Public Health Cigarette Smoking Act of 1969 ("1969 Act") amended this section.⁷⁷ The preemption clause was amended to 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 provisions of this Act."⁷⁸

Brought against a cigarette manufacturer, *Cipollone* involved five basic claims under New Jersey law.⁷⁹ For the purposes of this Note, we are most interested in how the Court dealt with the plaintiff's claims for failure to warn based on the theories that Liggett was negligent either in the manner in which it advertised cigarettes or for its failure to provide adequate warnings regarding the consequences of smoking.⁸⁰ The Court held that "insofar as claims under either failure-to-warn theory require a showing that respondents' post-1969 advertising or promotions should have included additional, or more clearly stated, warnings, those claims are preempted."⁸¹ The Court stated that while the 1965 Act had preemptive force against state positive law but not state common-law claims,⁸² the 1969 Act did preempt certain state common-law tort claims as a result of the changes Congress made in the statute's language.⁸³ The Court noted that "the later Act bars not simply 'statement[s]' but rather 'requirement[s] or prohibition[s] . . . imposed under State law'"⁸⁴ and that the "later Act reaches beyond statements 'in the advertising' to obligations 'with respect to the advertising or promotion' of cigarettes."⁸⁵

The Court then refused to hold that common-law rules did not constitute a

v. Schermerhorn, 375 U.S. 96, 103 (1963)).

74. 505 U.S. 504 (1992).

75. Federal Cigarette Labeling and Advertising Act of 1965 § 5(b), 15 U.S.C. §1334(b) (1994).

76. *Id.*

77. Public Health Cigarette Smoking Act of 1969 § 2, 15 U.S.C. § 1334(b) (1994).

78. *Id.* The required warning was "WARNING: THE SURGEON GENERAL HAS DETERMINED THAT SMOKING IS DANGEROUS TO YOUR HEALTH." *Cipollone*, 505 U.S. at 508 (emphasis in original). This warning was later amended to a series of four rotating warnings. *Id.* at 508 n.1.

79. *Id.* at 509.

80. *Id.*

81. *Id.* at 524.

82. *Id.* at 519-20.

83. *Id.* at 520-31.

84. *Id.* at 520 (alterations in original) (quoting Public Health Cigarette Smoking Act of 1969 § 2, 15 U.S.C. § 1334 (1994)).

85. *Id.* (quoting Federal Cigarette Labeling and Advertising Act of 1965 § 5(b), 15 U.S.C. §1334(b) (1994), and Public Health Cigarette Smoking Act of 1969 § 2, 15 U.S.C. § 1334 (1994), respectively).

“requirement” under the 1969 Act.⁸⁶ Rather, it said “[n]o requirement or prohibition” sweeps broadly and suggests no distinction between positive enactments and common law.⁸⁷ The Court went on to state “[a]s we noted in another context, ‘[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy.’”⁸⁸

In justifying its position, the Court recapitulated that the presumption against preemption obligated it to read the preemption statute narrowly.⁸⁹ This required a narrow reading of the statute’s language to determine whether “the legal duty that is the predicate of the common law damages action constitutes a ‘requirement or prohibition based on smoking and health . . . imposed under State law with respect to . . . advertising or promotion.’”⁹⁰ *Cipollone*’s resolution of the preemption issue was recognized by the dissents as an unsatisfactory resolution of the matter.⁹¹

Beyond all the judicial rhetoric about the proper mode of analysis with which to examine the 1969 Act, the proper approach is that of Justice Stevens.⁹² He confronted a statute that was explicit in preempting state requirements that conflicted with the federal government’s requirement for the labeling of cigarettes.⁹³ From the plain language of the statute, it can be easily inferred that common-law decisions finding that cigarette companies were negligent in their compliance with federal requirements would necessarily interfere with the federal requirement. Singling out a single aspect of cigarette manufacturing for regulation, Congress preempted common-law claims in that area, while leaving consumers with a variety of other state common-law claims to fall back on such as breach of warranty,⁹⁴ fraudulent misrepresentation,⁹⁵ and conspiracy to misrepresent or conceal material facts concerning the health hazards of smoking.⁹⁶

In examining the application of the preemption doctrine to the medical device field, we should be mindful of the essentially commonsense nature of Justice Stevens’s

86. *Id.* at 521.

87. *Id.* (alteration in original) (quoting Public Health Cigarette Smoking Act of 1969 § 2, 15 U.S.C. § 1334 (1994)).

88. *Id.* (quoting *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 247 (1959)).

89. *Id.* at 523.

90. *Id.* at 524 (alteration in original) (quoting Public Health Cigarette Smoking Act of 1969 § 2, 15 U.S.C. § 1334 (1994)).

91. *See id.* at 543-44 (Blackmun, J., concurring in part, concurring in the judgment in part, and dissenting in part) (“I can only speculate as to the difficulty lower courts will encounter in attempting to implement today’s decision.”); *see also id.* at 555-56 (Scalia, J., dissenting) (agreeing with Justice Blackmun that the lower courts will have difficulty in implementing the decision).

92. For further discussion of *Cipollone*, see Mary P. Benz & Derek J. Meyer, *Express Federal Preemption: Where Is It After Cipollone?*, 59 DEF. COUNS. J. 491 (1992); Thomas C. Galligan, Jr., *Products Liability—Cigarettes and Cipollone: What’s Left? What’s Gone?*, 53 LA. L. REV. 713 (1993); Michael D. Green, *Cipollone Revisited: A Not So Little Secret About the Scope of Cigarette Preemption*, 82 IOWA L. REV. 1257 (1997).

93. *See supra* note 78 and accompanying text.

94. *Cipollone*, 505 U.S. at 526-27.

95. *Id.* at 527-29.

96. *Id.* at 530-31.

decision. As a matter of policy, courts should look for detailed congressional consideration of an issue before they find that Congress intended to take people's common-law rights away. Thus, Congress can either explicitly reserve an area of regulation for itself as it did in the Airline Deregulation Act⁹⁷ or enact a statute that by its nature intimates that Congress desired the statute to be regulated exclusively by Congress. The 1969 Act, which contains no explicit preemption of state common-law claims, can be more reasonably seen in this regard as a measure that reserved the field of cigarette labeling regulations to Congress.

The only Supreme Court decision dealing with the preemptive scope of the MDA is *Lohr*.⁹⁸ *Lohr* was originally tried in the Eleventh Circuit⁹⁹ and is informative because it forms the basis for the Seventh Circuit's decision in *Mitchell*¹⁰⁰ and the Illinois Supreme Court's decision in *Weiland*.¹⁰¹

III. MEDTRONIC, INC. V. LOHR

In 1987, Lora Lohr received a Medtronic pacemaker equipped with a Model 4011 pacemaker lead.¹⁰² Three years after she received the pacemaker, it failed, the occurrence of which necessitated emergency surgery.¹⁰³ After her physician identified the lead as the likely cause of the failure, Mr. and Mrs. Lohr filed suit in a Florida state court.¹⁰⁴ They alleged both a negligence claim for failure to use reasonable care in the design, manufacture, assembly, and sale of the pacemaker and a strict liability claim asserting that the device was defective and unreasonably dangerous to foreseeable users.¹⁰⁵ Medtronic removed the case to federal court where it moved for summary judgment based on the theory that all the Lohrs' claims were preempted by the MDA.¹⁰⁶ After initially denying Medtronic's application for summary judgment, the district court reviewed its finding in light of a decision of the Court of Appeals for the Eleventh Circuit and dismissed all the Lohrs' claims.¹⁰⁷

The court of appeals reversed in part and affirmed in part, leading the Supreme Court to grant certiorari because "the Courts of Appeals are divided over the extent to which state common-law claims are pre-empted by the MDA."¹⁰⁸ The pacemaker at issue in *Lohr* had been approved through section 510(k)'s expedited process, which

97. 49 U.S.C. § 41713(b)(1) (1994) (preempting states from enforcing any "law, regulation, or other provision having the force and effect of law related to a price, route, or service of an air carrier").

98. *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

99. *Lohr v. Medtronic, Inc.*, 56 F.3d 1335 (11th Cir. 1995), *aff'd in part and rev'd in part*, 518 U.S. 470 (1996).

100. *Mitchell v. Collagen*, 126 F.3d 902 (7th Cir. 1997).

101. *Weiland v. Teletronics Pacing Sys., Inc.*, 721 N.E.2d 1149 (Ill. 1999).

102. *Lohr*, 518 U.S. at 480.

103. *Id.* at 480-81.

104. *Id.* at 481.

105. *Id.*

106. *Id.* Medtronic pointed specifically to 21 U.S.C. § 360k(a) (1994); *see supra* note 62 and accompanying text.

107. *Lohr*, 518 U.S. at 482-83.

108. *Id.* at 484.

permitted the approval of devices that were substantially equivalent to those on the market.¹⁰⁹ This fact is of critical importance because it meant that the Court's holding did not deal with devices that passed through the complete PMA process, leaving courts to pore over *Lohr*'s text to try to decipher how they should decide those cases.¹¹⁰

Lohr features a seven-part decision of which Justice Stevens announced the Court's judgment and delivered the opinion of the Court with regard to parts I, II, III, V, and VII.¹¹¹ Stevens was joined in these parts by Justices Breyer, Ginsburg, Kennedy, and Souter.¹¹² Justice Breyer did not join parts IV and VI, stating that he did not feel the issue that part IV addressed was relevant, and that he did not agree with part VI's contention that "future incidents of MDA pre-emption of common law claims will be 'few' or 'rare.'"¹¹³ Justice O'Connor filed an opinion concurring in part and dissenting in part, in which Justices Rehnquist, Scalia, and Thomas joined.¹¹⁴

Parts I and II are uncontroversial aspects of the *Lohr* case. Part I developed the history of medical regulation, detailing the limitations of previous legislation and the pressures that helped motivate Congress to enact the MDA.¹¹⁵ In addition, it examined the structure of the MDA, especially the abbreviated section 510(k) process under which the Medtronic pacemaker was approved.¹¹⁶ Part II reviewed the procedural history of the case and introduced § 360k, under which Medtronic claimed that all state common-law claims asserted against it were preempted.¹¹⁷

Part III set out the Court's basis for its analysis of preemption issues.¹¹⁸ The Court reiterated its respect for the concept of federalism, declaring that state causes of action should not be "cavalierly pre-empt[ed]" without a showing of the "clear and manifest purpose of Congress," and that this concern for the states' police powers should be used to "narrow[ly] interpret[]" any such "invalidation of state law."¹¹⁹ The

109. *Id.* at 480; *see supra* notes 58-61 and accompanying text.

110.

[T]he Supreme Court's disposition of *Lohr* provides little more than a rudimentary analytical framework to guide our resolution of Medtronic's preemption claims in this court because *Lohr* involved the 510k process rather than the PMA process, and because the Court fractured in an all but irreconcilable manner over the extent to which section 360k(a) would ever preempt a general state common law tort claim.

Goodlin v. Medtronic, Inc., 167 F.3d 1367, 1371 (11th Cir. 1999).

111. *Lohr*, 518 U.S. at 474.

112. *See id.* at 474, 509.

113. *Id.* at 508 (Breyer, J., concurring in part and concurring in judgment) (quoting the opinion of the Court in *Lohr*, 518 U.S. at 502).

114. *Id.* at 509 (O'Connor, J., concurring in part and dissenting in part).

115. *Id.* at 475-80.

116. *Id.*

117. *Id.* at 480-84.

118. *Id.* at 484-86.

119. *Id.* at 485 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)) (noting the objection of Justice Scalia that the presumption against the curtailment of the states' police powers "should apply only to the question whether Congress intended any pre-emption at all, as opposed to questions concerning the *scope* of its intended invalidation of state law" (emphasis in original)).

Court also noted that “understanding of the scope of a pre-emption statute must rest primarily on ‘a fair understanding of *congressional purpose*’”¹²⁰ in addition to “the language of the pre-emption statute and the ‘statutory framework’ surrounding it”¹²¹ and “the ‘structure and purpose of the statute as a whole.’”¹²²

Part IV of the opinion has no authority over lower courts because it only attracted four votes.¹²³ It does show, however, the position of four justices in that they rejected Medtronic’s argument that the plain language of § 360k preempted any common-law claims against a medical device manufacturer whose product had been approved.¹²⁴ Stevens’s opinion stated that it was “‘difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct,’”¹²⁵ especially since Congress decided the industry needed more “stringent regulation.”¹²⁶ Stevens supported this opinion by examining the MDA’s legislative history and finding no mention of any desire to exempt the medical device industry from common-law duties.¹²⁷ The Court sought to distinguish the definition of “requirement” from its use in *Cipollone*, in which it was deemed to include state common-law damage claims.¹²⁸

In part V of the opinion, the Court examined the Lohrs’ claims.¹²⁹ The Court focused on the nature of the section 510(k) process.¹³⁰ The section 510(k) process concentrates on whether a device is the equivalent of a pre-1976 device.¹³¹ Because this process did not place any requirements directing the pacemaker to “take any particular form for any particular reason,” there was no federal requirement as required by § 360k to preempt state law.¹³² All nine justices supported this decision: compliance with the abbreviated section 510(k) process would have no preemptive effect upon state common law.¹³³ The remainder of part V clarified that a plaintiff could sue to enforce compliance with the FDA’s own requirements because that “does not amount to the additional or different ‘requirement’ that is necessary under [§ 360k]; . . . rather, it merely provides another reason for manufacturers to comply with identical existing ‘requirements’ under federal law.”¹³⁴

Finally, under part V, the Court considered the Lohrs’ claims for negligent

120. *Id.* at 485-86 (quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 530 n.27 (1992) (emphasis in original)).

121. *Id.* at 486 (quoting *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 111 (1992) (Kennedy, J., concurring in part and concurring in judgment)).

122. *Id.* (quoting *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 98 (1992)).

123. *Id.* at 474.

124. *Id.* at 486-91.

125. *Id.* at 487 (quoting *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984)).

126. *Id.*

127. *Id.* at 491.

128. *Id.* at 488-90.

129. *Id.* at 492-502.

130. *Id.*

131. *Id.* at 492-93.

132. *Id.* at 493-94.

133. *Id.* at 494-95, 513.

134. *Id.* at 495.

manufacturing and labeling.¹³⁵ This is a more interesting area since the section 510(k) process contains regulations governing labeling and “Good Manufacturing Practices.”¹³⁶ Stevens and Breyer looked to the FDA regulations that mandate that “state requirements are pre-empted ‘only’ when the FDA has established ‘specific counterpart regulations or . . . other specific requirements applicable to a particular device.’”¹³⁷ The general requirements present under § 360k were held to be not specific enough to constitute a federal requirement, and therefore the state common-law claims were not preempted.¹³⁸

Justice Stevens went on to state that general state law duties, such as using due care to avoid foreseeable danger in products and “inform[ing] users and purchasers of potentially dangerous items of the risks involved in their use,” were not specifically developed with regard to medical devices.¹³⁹ Therefore, “their generality leaves them outside the category of requirements that § 360k envisioned to be ‘with respect to’ specific devices such as pacemakers.”¹⁴⁰ This language seems to be at odds with Justice Breyer’s concurrence even though he joined in part V.¹⁴¹ Justice Breyer evinced agreement with Justice O’Connor’s opinion in which she stated that common-law duties could easily be construed as requirements that would conflict with the language of § 360k.¹⁴² However, in explaining his position that state common-law claims could *sometimes* be preempted, Breyer used an example that featured an express MDA regulation requiring a particular device to have a particular feature.¹⁴³ This is not identical to the general common-law duties that Justice Stevens discussed above. The FDA has passed few measures that go to the detail of prescribing what size wire a pacemaker should use.¹⁴⁴ Instead, the MDA process tests generally for a device’s fitness for the marketplace and does not put any specific requirements upon a particular device such as the regulation of the size of wires.¹⁴⁵ Justice Breyer found further support for his position in the FDA’s regulation interpreting the preemptive scope of § 360k.¹⁴⁶

135. *Id.* at 497-502.

136. *Id.* at 497.

137. *Id.* at 498 (quoting 21 C.F.R. § 808.1(d) (2000)).

138. *Id.* at 501-02.

139. *Id.* at 501.

140. *Id.* at 502.

141. *Id.* at 503-08.

142. *Id.* at 503-04.

143. *See id.* at 504. Justice Breyer used the example of a federal MDA regulation with respect to a particular hearing aid component that requires a two-inch wire. *Id.* He stated that just as a state regulation that mandated a one-inch wire would be preempted so should a court decision imposing a duty that involved the use of a one-inch wire. *Id.* Otherwise, allowing the court decision to stand would result in an “anomalous result.” *Id.*

144. One example of specific regulation is the condition that tampon labeling (a class II device) adhere to the requirements set out by the FDA. *See* 21 C.F.R. § 801.430(d) (2000).

145. *See Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1376-77 (1999). In discussing the nature of the FDA regulations at issue in the PMA process, the *Goodlin* court stated that “the restrictions Medtronic proffers in this case are entirely general in nature, and the FDA has not promulgated them with respect to [a] ‘particular device’ . . . or even with respect to the class of specific devices at issue.” *Id.* at 1377.

146. *See* 21 C.F.R. § 808.1(d). The FDA’s regulation provides:

The importance of Breyer's position lies in the fact that any plaintiff seeking to avoid preemption of their common-law claims must gain his vote in order to prevail. Justice Breyer has signaled that he will find that a common-law action is preempted if it conflicts directly with a particular PMA regulation on a particular device, thus rejecting the position that a common-law cause of action can never be preempted by § 360k.¹⁴⁷

IV. SEVENTH CIRCUIT INTERPRETATION OF *LOHR*

The Seventh Circuit discussed the preemptive effect of PMA compliance in *Mitchell*.¹⁴⁸ In *Mitchell*, the Seventh Circuit reconsidered its previous holding that the MDA preempted some of a plaintiff's state common-law claims.¹⁴⁹ The Supreme Court had remanded *Mitchell* in light of its holding in *Lohr*.¹⁵⁰

In the original trial, the Mitchells alleged various common-law claims including strict liability, negligence, fraud, mislabeling, misbranding, adulteration, and breach of warranty.¹⁵¹ The plaintiff had developed serious medical complications after being injected with a collagen-based product, classified as a class III medical device, manufactured by the defendant.¹⁵² The trial court granted summary judgment to Collagen on the grounds that these claims were preempted by the MDA based on § 360k.¹⁵³ The appellate court affirmed the trial court decision, although it based its findings not only on the defendant's preemption defense but also on the basis that the Mitchells had failed to produce enough evidence to defeat summary judgment.¹⁵⁴

Upon reconsideration of the case following remand by the Supreme Court, the Seventh Circuit affirmed its decision in *Mitchell*.¹⁵⁵ The Seventh Circuit first noted that *Lohr* involved a medical device that had not gone through the full PMA process, but rather had gone through the abbreviated 510(k) process that was concerned with whether a device was substantially equivalent to a pre-1976 device.¹⁵⁶ Also, the Seventh Circuit described *Lohr* as "contain[ing] several ambiguities that impair our ability to perceive with absolute clarity the path that the Court has chosen for us to

State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.

Id.

147. See *Lohr*, 518 U.S. at 502-03.

148. *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997), *aff'g* 67 F.3d 1268 (7th Cir. 1995).

149. *Id.* at 904.

150. *Id.*

151. *Id.* at 906.

152. *Id.* at 905.

153. *Id.* at 906.

154. *Id.* at 906-07.

155. *Id.* at 915.

156. *Id.* at 907.

follow.”¹⁵⁷

In analyzing *Lohr*, the *Mitchell* court noted that four members of the Court would find that general state common-law judgments could never be “requirements” as mandated by the MDA’s preemption statute while four other Justices concluded explicitly that state common-law decisions were “requirements.”¹⁵⁸ The Seventh Circuit then noted that “Justice Breyer supplied the determining vote in establishing the Court’s holding.”¹⁵⁹ This determination is open to question since the *Lohr* Court did not need to go beyond its conclusion that the abbreviated section 510(k) process did not constitute a federal requirement in order to make its decision. Therefore, the language concerning § 360k was not necessary to the holding and should be considered dicta, especially since Justice Breyer did not explicitly join the four members of the Court who advanced that idea.¹⁶⁰

However, Justice Breyer’s separate opinion does indicate he found himself in basic agreement with Justice O’Connor.¹⁶¹ He qualifies this agreement by stating “[o]ne can reasonably read the word ‘requirement’ as including the legal requirements that grow out of the application, *in particular circumstances*, of a State’s tort law.”¹⁶² The language “*in particular circumstances*” indicates that Justice Breyer thought that state common-law judgments would not always preempt federal law. Breyer’s refinement of his position through his joining in part V of the *Lohr* decision¹⁶³ should be interpreted as questioning the *Mitchell* decision that the PMA process can be considered a federal requirement¹⁶⁴ and supporting the conclusion of the *Weiland* court that the PMA is not a federal requirement.¹⁶⁵ As discussed above, Justice Breyer’s interpretation can be read as resting on particular federal requirements for a particular device rather than relying on the general PMA process.¹⁶⁶

After concluding that state common-law claims could constitute requirements under § 360k, the *Mitchell* court then considered whether the PMA process could be termed a requirement under § 360k. The Seventh Circuit distinguished the PMA process from the abbreviated “substantially equivalent” process by “emphasiz[ing] that the PMA process imposed requirements that directly affected the safety and effectiveness of the product.”¹⁶⁷ The FDA could be said to have “weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.”¹⁶⁸ Therefore, the Seventh Circuit

157. *Id.* at 910.

158. *See id.* at 908-11.

159. *Id.* at 908.

160. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 509-14 (1996) (O’Connor, J., joined by Rehnquist, C.J., Scalia, Thomas, JJ., concurring in part and dissenting in part).

161. *See id.* at 503.

162. *Id.* at 503-04 (emphasis added).

163. *See supra* note 143 and accompanying text.

164. *See Mitchell*, 126 F.3d at 911.

165. *See Weiland v. Teletronics Pacing Sys., Inc.*, 721 N.E.2d 1149, 1151 (Ill. 1999).

166. *See supra* note 147 and accompanying text.

167. *Mitchell*, 126 F.3d at 911.

168. *Id.* (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 501 (1996)).

concluded that the PMA process is a specific federal requirement and that

in order to determine whether a common law cause of action is preempted by the action of the FDA, it is necessary to examine the state law cause of action at a sufficiently precise level of generality to determine whether the final judgment of the state court would impose on the manufacturer a burden incompatible with the requirements imposed by the FDA.¹⁶⁹

The *Mitchell* court then applied its findings to the claims before it, using the test laid out in *Lohr*. Under § 360k, in order for a state common-law decision to be preempted there needs to be “a conflict between the state and federal regulations of the medical devices which threatens to interfere with a specific federal interest.”¹⁷⁰

The Mitchells’ claim for strict liability was held to be preempted because “[a]pproval by the FDA constitutes approval of the product’s design . . . [and] [a] state court judgment premised on a contrary determination . . . would constitute . . . a requirement ‘different from, or in addition to,’ the standard required by federal authority.”¹⁷¹ The court held that the Mitchells’ negligence, mislabeling, misbranding, fraudulent misrepresentation, implied warranty, and adulteration claims were preempted for similar reasons.¹⁷²

In dismissing the Mitchells’ claims, the Seventh Circuit did note that a complaint that alleged that a manufacturer negligently adhered to the PMA process’s standards would not be preempted since a state court judgment to that effect “would not set up a requirement ‘different from or in addition to,’ those established by the FDA. . . . [but rather] simply would enforce the standard embodied in the federal PMA.”¹⁷³ In addition, the court noted that an express warranty claim created by the parties’ bargain would not necessarily interfere with the PMA process.¹⁷⁴ The court does not explain why a state court enforcement of an express warranty would not amount to a different requirement than the PMA process.

In holding that state courts cannot enforce conditions “different from, or in addition to” federal PMA requirements, it does not seem obvious why the Seventh Circuit should allow state courts to have this exception. Certainly, the *Mitchell* court provides no evidence in the form of legislative history to show that Congress intended the MDA to preempt common-law claims unless manufacturers found it beneficial to override that preemption. It may be that the *Mitchell* court saw express warranties as a method to provide for some measure of consumer protection while protecting manufacturers from most common-law torts. However, it does not seem reasonable to believe that a patient in need of a pacemaker is going to be in a position to bargain

169. *Id.* at 912.

170. *Id.* at 913 (quoting *Hernandez v. Coopervision, Inc.*, 691 So. 2d 639, 641 (Fla. Dist. Ct. App. 1997)).

171. *Id.*

172. *Id.* at 913-15. In assessing the claim for breach of implied warranty, the court stated that “an implied warranty claim is based on the accepted standards of design and manufacture of the products. In the case of a product that has gone through the PMA process, these criteria are set by the FDA.” *Id.* at 915. Therefore, if a court entered a judgment of breach of implied warranty then it would be interfering with the PMA process. *Id.*

173. *Id.* at 914.

174. *See id.* at 915.

with a manufacturer in order to receive such assurances.

The U.S. Supreme Court should address, and the Seventh Circuit should reexamine, the issue of whether the PMA process preempts state common-law claims. At the federal level there is a split between the Seventh and Eleventh Circuits,¹⁷⁵ and recently the Supreme Court of Illinois has stated that it believes the *Mitchell* decision was “wrongly decided.”¹⁷⁶ A discussion of the *Weiland* decision will show that it comports better with congressional purpose and Justice Breyer’s opinion in *Lohr*.

V. *WEILAND V. TELELECTRONICS PACING SYSTEMS, INC.*

The plaintiff in *Weiland* alleged claims for breach of warranty and defective design and manufacture against the manufacturer of two pacemakers he received in subsequent operations.¹⁷⁷ Both pacemakers were alleged to have malfunctioned, causing Weiland to need surgery.¹⁷⁸ The trial court granted Telectronics summary judgment on the grounds that § 360k preempted state claims that sought “to impose requirements on the manufacturer that relate to the safety and effectiveness of a class III device that are different from and in addition to the requirements imposed by the medical device amendment[s].”¹⁷⁹ On appeal, the court looked to *Lohr*, *Mitchell*, and *Kernats v. Smith Industries Medical Systems, Inc.*¹⁸⁰ for guidance.¹⁸¹

The Illinois Appellate Court had previously stated in *Kernats* that “the PMA process is a specific federal requirement.”¹⁸² However, *Kernats* also held that “[t]he [*Lohr*] Court held that common-law claims challenging the manufacturing and labeling of medical devices were not preempted by the MDA because they were simply ‘general obligations’ imposed by the state on manufacturers; they were not state requirements specifically developed ‘with respect to’ medical devices.”¹⁸³ After an extensive discussion of *Mitchell* and the relevant case law, the *Weiland* court overruled *Kernats* on the issue of whether state common-law claims constituted requirements under § 360k.¹⁸⁴ While the Illinois Appellate Court recounted a sweeping number of cases holding that state common-law claims should be treated as requirements for § 360k purposes, it did not give much of a normative reason for choosing to overrule *Kernats*. The court did, however, state that the “decisions of the Federal courts interpreting a Federal act” are binding on Illinois courts to ensure that

175. Compare *id.* (holding that PMA approval is a specific requirement for preemptive purposes), with *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999) (holding that the PMA process does not constitute a federal requirement).

176. *Weiland v. Telectronics Pacing Sys., Inc.*, 721 N.E.2d 1149, 1154 (Ill. 1999).

177. *Id.* at 1150-51.

178. *Id.*

179. *Weiland v. Telectronics Pacing Sys., Inc.*, 704 N.E.2d 854, 855 (Ill. App. Ct. 1998), *aff'd*, 721 N.E.2d 1149 (Ill. 1999).

180. 669 N.E.2d 1300 (Ill. App. Ct.), *appeal denied*, 675 N.E.2d 634 (Ill. 1996).

181. See *Weiland*, 704 N.E.2d at 855-56.

182. *Kernats*, 669 N.E.2d at 1308.

183. *Id.* at 1309 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 501-02 (1996)).

184. *Weiland*, 704 N.E.2d at 861 (“We disagree, however, with the *Kernats* court as to whether the state law claims create requirements different from or in addition to the federal requirements so as to find preemption.”).

the act is uniformly applied.¹⁸⁵

The Illinois Supreme Court approached the issue of state common-law preemption by first stating that “for a federal ‘requirement’ to have preemptive effect under section 360k . . . it must be a *specific* requirement which applies to a *particular* device and focuses on the safety and effectiveness of that device.”¹⁸⁶ While the court did accept that the PMA process related to a device’s safety and effectiveness, it did not accept that the PMA process imposed a federal requirement.¹⁸⁷ *Weiland* stated that PMA signifies “only a finding that the manufacturer’s proposal to market a device has reasonably assured the FDA of the device’s safety and effectiveness.”¹⁸⁸ This is similar to the point made by the Eleventh Circuit in *Goodlin* that “[t]he PMA process permits the FDA to regulate the introduction and sale of medical devices to assure their minimal safety for public consumption—it does not appear to address the appropriate standards of liability once the product enters the marketplace.”¹⁸⁹ Furthermore, “[t]he design of the pacemakers at issue in this case originated solely with the manufacturer of the device, not the FDA. The FDA did not require the pacemakers to take any particular form for any particular reason.”¹⁹⁰ The *Weiland* court then stated that preemption would occur where the “FDA determines that particular design or manufacturing specifications for pacemakers are warranted.”¹⁹¹ It is obvious that the *Weiland* court has interpreted Justice Breyer’s concurrence in *Lohr* to mandate that a federal requirement be specific to a particular device in order for preemption to occur. This is indicated by the use of an example similar to that used by Justice Breyer in *Lohr*.¹⁹² The *Weiland* example indicated that “if the FDA promulgated a rule requiring all manufacturers to use ceramic insulators for pacemakers, section 360k would preempt plaintiff’s claim in this case that [Telectronics’s] pacemakers were defective because ceramic insulators are susceptible to cracking.”¹⁹³ The *Weiland* court concluded its opinion by holding that “the FDA’s premarket approval of a Class III medical device does not establish a specific federal requirement which preempts plaintiff’s state common law claims.”¹⁹⁴

The holding of *Weiland* indicates a split between the Seventh Circuit Court of Appeals and the Illinois Supreme Court. This ongoing disagreement concerning whether the PMA process should be treated as a “requirement” for preemptive

185. *Id.* (quoting *Busch v. Graphics Color Corp.*, 662 N.E.2d 397, 403 (Ill. 1996)). The Illinois Supreme Court addressed this position in its opinion:

This court need not follow Seventh Circuit precedent interpreting a federal statute where, as here, the Supreme Court has not ruled on the question presented, there is a split of authority among the federal circuit courts of appeals, and, we believe, the case from the Seventh Circuit was wrongly decided.

Weiland v. Telectronics Pacing Sys., Inc., 721 N.E.2d 1149, 1154 (Ill. 1999).

186. *Id.* at 1151 (emphasis in original).

187. *See id.* at 1152.

188. *Id.* (quoting *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1375 (11th Cir. 1999)).

189. *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1378 (11th Cir. 1999).

190. *Weiland*, 721 N.E.2d at 1152.

191. *Id.*

192. *See supra* note 143 and accompanying text.

193. *Weiland*, 721 N.E.2d at 1153.

194. *Id.*

purposes needs to be addressed by the Court. The *Weiland* court is correct in its interpretation of Justice Breyer's position in *Lohr*.¹⁹⁵ In addition, *Goodlin* sets out sound reasons to support a finding that the PMA process does not constitute a federal requirement absent a showing of a particular regulation of a particular device.¹⁹⁶ The most notable reason set out in *Goodlin* was the lack of remedies available to consumers if the preemption defense was allowed to stand.¹⁹⁷ As the court noted:

Reading the PMA process to impose specific federal requirements that enjoy preemptive effect under section 360k, therefore, would deprive all persons suffering injury as a result of a defective device—the very class of persons that Congress intended to protect by enacting the MDA—of “most, if not all relief.”¹⁹⁸

The court concluded that “[i]t is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.”¹⁹⁹

CONCLUSION

There is no need to leave consumers without any judicial recourse. Justice Breyer pointed the way to a resolution of the issue in his *Lohr* concurrence. The PMA process should only have preemptive effect when it imposes a specific regulation upon a specific device, for example, such as when the FDA requires tampons to be labeled in a specific manner. In this regard, the public can be assured that preemption of common-law claims is being traded for the sake of detailed regulation of a particular device, rather than for compliance with a program that only assures minimal public safety. The U.S. Supreme Court should revisit the issue of MDA preemption and look to the Eleventh Circuit and the Supreme Court of Illinois, rather than the Seventh Circuit for its guidance.

195. See *supra* note 192 and accompanying text.

196. See *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1378-81 (11th Cir. 1999). The court noted that the MDA's legislative history indicated a congressional desire to provide extra protection to consumers by promoting regulation before a device entered the marketplace. See *id.* at 1378. This congressional desire was consistent with reducing the regulatory burden on manufacturers before they entered the marketplace. *Id.* *Goodlin* also remarked upon the fact that the medical device industry did not attempt to assert the preemption defense until fifteen years after the passage of the MDA. The court found it unlikely that “the industry would have ignored its immunity under the MDA for so long after the statute's enactment if Congress, in fact, had intended to provide immunity in 1976.” *Id.* at 1381.

197. See *id.* at 1379.

198. *Id.*

199. *Id.* (quoting *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984)).

