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PREEMPTION OF STATE PRODUCT LIABILITY CLAIMS INVOLVING MEDICAL DEVICES: PREMARKET APPROVAL AS A SHIELD AGAINST LIABILITY

Robin Helmick Turner

Abstract: Under the Medical Device Amendments of 1976 (MDA), Congress established a complex scheme for regulating medical devices. Congress also included an express preemption provision in the Amendments that prohibits states from imposing different or additional requirements on devices. Much controversy has focused on whether the preemption provision operates to preempt plaintiffs' state product liability claims against medical device manufacturers. Although in *Medtronic, Inc. v. Lohr* the U.S. Supreme Court recently attempted to resolve the controversy, its ruling left open the question of whether manufacturers of devices subject to the most rigorous form of Food and Drug Administration scrutiny, known as premarket approval review, should be immune from product liability lawsuits. This Comment argues that the overall purpose behind the MDA, the *Lohr* decision, and the federal interpretative regulations support preempting product liability claims involving devices subject to premarket approval review. This Comment concludes that product liability claims should be preempted to the extent that such claims involve aspects of devices addressed by premarket approval rules.

An explosion in scientific knowledge in the late twentieth century has produced remarkable advancements in medical device technology. Medical devices such as CAT scanners, pacemakers, and kidney dialysis machines play a central role in diagnosing, treating, and preventing illness.¹ Currently, Americans spend approximately forty percent of their health care dollars on medical devices.² In 1976, Congress enacted the Medical Device Amendments ("MDA"),³ which established a complex regulatory system for medical devices. To prevent states from interfering with federal regulation of medical devices,⁴ Congress included an express preemption provision in the MDA.⁵ This provision prohibits states from imposing different or additional requirements on medical devices.⁶ The MDA's preemption provision, however, does not mention

1. See H.R. Rep. No. 94-853 (1976), reprinted in *An Analytical Legislative History of the Medical Device Amendments of 1976*, app. III (Daniel F. O'Keefe, Jr. et al. eds., 1976); see generally Rodney R. Munsey, *Trends and Events in FDA Regulation of Medical Devices Over the Last Fifty Years*, 50 *Food & Drug L.J.* 163 (1995).

2. Susan Bartlett Foote, *Managing the Medical Device Arms Race* 4 (1992).

3. Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified as amended at 21 U.S.C. §§ 353-395 (1994)).

4. H.R. Rep. No. 94-853, at 45.

5. 21 U.S.C. § 360k (1994).

6. 21 U.S.C. § 360k.

state product liability law,⁷ leading courts and commentators to vigorously debate whether it preempts plaintiffs' state product liability claims involving medical devices.⁸

In *Medtronic, Inc. v. Lohr*,⁹ the U.S. Supreme Court attempted to resolve the controversy by addressing whether the MDA's preemption provision bars plaintiffs from suing manufacturers of defective medical devices under common law theories of product liability.¹⁰ In *Lohr*, the Court held that none of the plaintiffs' claims were preempted by MDA rules.¹¹ *Lohr* raised more questions than it answered, however, because the Court's ruling depended heavily on an MDA loophole under which the device in question was marketed.¹² This loophole allowed the device manufacturer to avoid the most rigorous scrutiny of its product, known as premarket approval ("PMA") review.¹³ Instead, the manufacturer marketed its product rapidly, regulated by only basic MDA rules.¹⁴ Thus, *Lohr* failed to resolve the crucial issue of whether the Court's preemption analysis would have been different if the device had been subjected to the stringent PMA review process.

This Comment argues that the Congressional purpose underlying the preemption provision, the logic and reasoning of *Lohr*, and the Food and Drug Administration (FDA) regulations support preempting state product liability claims that involve aspects of devices addressed by PMA rules.

7. In this Comment, the phrase "product liability claims" encompasses state law actions sounding in negligence, strict liability, and warranty. Courts differ as to what plaintiffs' claims against device manufacturers should be called. Some courts refer to these claims as "common law claims," *see, e.g., Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240 (1996), whereas others use the term "state law damages actions," *see, e.g., Duvall v. Bristol-Myers-Squibb Co.*, 103 F.3d 324 (4th Cir. 1996). This Comment uses the term "product liability claims" because it indicates that these claims involve products, and it also recognizes that some product liability claims are not based on the common law, but rather on statutes such as the Uniform Commercial Code.

8. *See, e.g., Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1459 (9th Cir. 1995), *cert. denied*, 116 S. Ct. 2579 (1996) (ruling that MDA never preempts state product liability claims); Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 942-45 (1994) (same). *But see, e.g., King v. Collagen Corp.*, 983 F.2d 1130, 1139-40 (1st Cir. 1993) (holding that MDA preempts all of plaintiff's product liability claims); Mark Herrmann & Geoffrey J. Ritts, *Preemption and Medical Devices: A Response to Adler and Mann*, 51 Food & Drug. L.J. 1 (1996) (same).

9. 116 S. Ct. 2240 (1996).

10. *Id.* at 2245.

11. *Id.* at 2259.

12. *See id.* at 2247. The device in *Lohr* was subject to minimal FDA scrutiny known as section 510k review. *See infra* Part I.B.

13. *See* 21 U.S.C. § 360e (1994); *see also infra* Part I.B.

14. *See* 21 U.S.C. § 360(k) (1994); *see also infra* Part I.B.

Part I details the MDA's classification scheme and its history. Part II describes the MDA's preemption provision and how it has been interpreted by the FDA and by courts. Part III then argues that state product liability claims are within the scope of the MDA's preemption provision and that PMA rules should preempt state law. Finally, Part IV sets forth policy justifications for granting preemptive effect to PMA rules and concludes that the FDA is uniquely qualified to make decisions regarding device regulation.

I. THE MEDICAL DEVICE AMENDMENTS OF 1976

Throughout most of this century, medical devices have received minimal government scrutiny, resulting in thousands of injuries.¹⁵ Before 1976, the FDA did not have statutory authority to review devices before they reached the market.¹⁶ Consequently, many people were harmed by risky and faulty devices.¹⁷ Between 1960 and 1970, medical devices caused at least 10,000 injuries, including 731 deaths.¹⁸

In response to the public outcry over injuries resulting from dangerous devices such as the Dalkon Shield,¹⁹ Congress enacted the Medical Device Amendments of 1976²⁰ (MDA) to the Food, Drug, and Cosmetic Act of 1938.²¹ Congress's purpose in enacting the MDA was to ensure the safety and effectiveness of medical devices.²² A medical device is broadly defined as any item "which does not achieve its primary

15. 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).

16. David A. Kessler et al., *The Federal Regulation of Medical Devices*, 317 New Eng. J. Med. 357, 357 (1987).

17. Susan Bartlett Foote, *Loops and Loopholes: Hazardous Device Regulation Under the 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act*, 7 Ecology L.Q. 101, 102-03 (1978).

18. *Id.*

19. See H.R. Rep. No. 94-853, at 8 (1976), reprinted in *An Analytical Legislative History of the Medical Device Amendments of 1976*, app. III (Daniel F. O'Keefe, Jr. et al. eds., 1976). The Dalkon Shield is an intrauterine contraceptive device which, after only five years on the market, was linked to sixteen deaths and twenty-five miscarriages. *Id.*

20. Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified as amended at 21 U.S.C. §§ 353-395 (1994)).

21. Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-395 (1994)).

22. Preamble, Pub. L. No. 94-295, 90 Stat. 539 (1976); see also Adler & Mann, *supra* note 8, at 911 (arguing that "[t]he primary purpose of the Amendments was to expand consumer protection against dangerous devices").

intended purposes through chemical action.²³ This definition gives the FDA jurisdiction over more than 100,000 different medical devices in 1700 categories.²⁴

A. *Classification of Devices*

The MDA established a complex classification system for regulating devices according to their relative degree of risk.²⁵ Under the MDA, the FDA is required to assign all devices to one of three classes, dictating the level of regulatory controls placed on devices.²⁶

Class I and class II devices are low and medium risk devices that receive minimal FDA scrutiny before they are marketed. Examples of class I devices include tongue depressors and bed pans.²⁷ Class I devices are regulated by broad guidelines known as general controls,²⁸ which establish basic rules governing device labeling²⁹ and manufacturing quality control processes.³⁰ These general controls also apply to the other two classes of devices.³¹ Examples of class II devices include tampons and oxygen masks.³² Devices are categorized as class II when general controls are insufficient to ensure device safety and effectiveness.³³ Class II devices are subject to special controls such as performance standards,³⁴ which are device-specific standards established by the FDA that regulate the components, construction, and performance of devices.³⁵

23. 21 U.S.C. § 321(h) (1994).

24. General Accounting Office, *Medical Device Regulation: Too Early to Assess European System's Value as Model for FDA* (GAO/HEAS-96-65 1996) [hereinafter 1996 GAO Report].

25. Kessler et al., *supra* note 16, at 358.

26. 21 U.S.C. § 360c(a)(1) (1994).

27. *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1418 (5th Cir. 1993); Adler, *supra* note 15, at 512.

28. *See* 21 U.S.C. § 360c(a)(1)(A)(i).

29. 21 C.F.R. § 801.109(b)-(c) (1996).

30. 21 C.F.R. §§ 820.20-198 (1996).

31. 21 U.S.C. § 360j(f) (1994); 21 U.S.C. § 360c(a)(1)(A).

32. *Stamps*, 984 F.2d at 1418.

33. 21 U.S.C. § 360c(a)(1)(B).

34. 21 U.S.C. § 360c(a)(1)(B). Other special controls include post-market surveillance and patient registries. 21 U.S.C. § 360c(a)(1)(B).

35. 21 U.S.C. § 360d(a)(2)(B)(i) (1994). At present, few performance standards have been issued by the FDA. *See* Kessler et al., *supra* note 16, at 361. Critics argue that the lack of performance standards for almost all class II devices results in two rather than three device classifications. *Id.*; Robert B. Leflar, *Public Accountability and Medical Device Regulation*, 2 Harv. J.L. & Tech. 1, 42-43 (1989).

Preemption of Product Liability Claims by the MDA

The FDA has categorized over eighty percent of the 1700 different types of devices as class I or class II.³⁶

Before manufacturers may market class I or class II devices, they must comply with relatively simple disclosure rules called section 510k notification.³⁷ Section 510k rules require manufacturers to submit an application to the FDA containing a description of the device, the class to which the device belongs, proposed labeling, and a description of the actions taken to comply with all applicable requirements.³⁸

Class III devices are subject to the most stringent MDA rules.³⁹ The FDA places a device into class III for one of two primary reasons. First, the FDA categorizes a device as class III if general and special controls are insufficient to ensure the safety and effectiveness of the device, and the device is life-sustaining or poses unreasonable safety risks.⁴⁰ Second, the MDA mandates that all devices introduced into the market after May 28, 1976 are automatically designated as class III, regardless of the risks they pose, unless they qualify under two limited exceptions: (1) the device is sufficiently similar to a class I or class II device marketed after the enactment of the MDA,⁴¹ or (2) the FDA places the device into a lower class because it is not a high-risk device.⁴² Class III devices constitute about twelve percent of all devices.⁴³ Before marketing a class III device, a manufacturer normally must obtain FDA approval of a device's safety and effectiveness, which is known as premarket approval (PMA).⁴⁴

36. General Accounting Office, *Medical Devices: FDA Review Time 3-4* (GAO/PEMD-96-2 1995) [hereinafter 1995 GAO Report].

37. 21 U.S.C. § 360(k) (1994). Section 510k notification is also called premarket notification. See Adler, *supra* note 15, at 513.

38. 21 U.S.C. § 360(k); 21 C.F.R. § 808.87 (1996).

39. Kessler et al., *supra* note 16, at 358.

40. 21 U.S.C. § 360c(a)(1)(C) (1994). A device may also be designated as a class III device if it is "for a use which is of substantial importance in preventing impairment of human health," or if it "presents a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C).

41. 21 U.S.C. § 360c(f)(1)(A).

42. 21 U.S.C. § 360c(f)(1)(B).

43. 1995 GAO Report, *supra* note 36, at 4. About three percent of all device types have not been classified. *Id.*

44. See 21 U.S.C. § 360e (1994).

B. *Premarket Approval and Substantial Equivalency*

Gaining PMA is often a costly and time-consuming process for manufacturers.⁴⁵ Before the FDA will grant PMA, it must be reasonably assured that a device is safe and effective in its design, manufacturing, and labeling.⁴⁶ PMA rules require manufacturers to submit an application to the FDA containing a full report of all clinical and laboratory tests regarding the device's safety and effectiveness,⁴⁷ a full statement of the components and design of the product,⁴⁸ a full description of the manufacturing process and the quality controls for manufacturing,⁴⁹ sample labeling instructions,⁵⁰ and other detailed information.⁵¹ The FDA thoroughly reviews all information contained in the application and determines whether the product should be marketed at all and under what conditions.⁵² If the FDA approves a device, manufacturers must comply with those design parameters submitted to the FDA in their PMA applications.⁵³

Despite Congress's concern over the safety and effectiveness of class III devices, most class III devices on the market have escaped PMA review because of the two exceptions provided by the MDA.⁵⁴ To

45. Adler, *supra* note 15, at 519; *see also* Kessler et al., *supra* note 16, at 359.

46. 21 U.S.C. § 360e(d)(2).

47. 21 U.S.C. § 360e(c)(1)(A).

48. 21 U.S.C. § 360e(c)(1)(B).

49. 21 U.S.C. § 360e(c)(1)(C).

50. 21 U.S.C. § 360e(c)(1)(F).

51. *See* 21 U.S.C. § 360e(c).

52. *See* 21 U.S.C. § 360e(d)(2) (outlining reasons for denying PMA); *see also* 21 U.S.C. § 360j(e) (1994) (authorizing FDA to restrict sale, distribution, or use of device to minimize its potential for harmful effects).

53. 21 C.F.R. § 814.80 (1996).

54. *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240, 2247 (1996). In addition to these two common exceptions, the MDA outlines other exceptions to the requirement that all class III devices must undergo PMA review. *See* 21 U.S.C. § 360j(m) (providing humanitarian exemption from PMA requirements for devices intended to benefit fewer than 4000 people in U.S.); 21 U.S.C. § 360j(g) and 21 C.F.R. §§ 812.1-150 (1996) (authorizing FDA to exempt certain investigational devices from PMA requirements for limited time to allow manufacturers to conduct clinical investigations of devices if manufacturers comply with other FDA rules to ensure safety of investigations). In light of *Lohr*, courts have attempted to determine whether FDA regulations promulgated under the investigational device exception (IDE) constitute preemptive federal requirements that displace plaintiffs' product liability claims. *See, e.g.,* *Martin v. Teletronics Pacing Sys., Inc.*, 105 F.3d 1090, 1099 (6th Cir. 1997) (ruling that plaintiff's claims against manufacturer of IDE device were preempted because such claims would thwart Congress's goal of encouraging development of new devices through IDE exception); *Berish v. Richards Med. Co.*, 937 F. Supp. 181, 185 (N.D.N.Y. 1996) (holding that IDE requirements displace state product liability claims). A more thorough

prevent market disruption,⁵⁵ Congress provided that all class III devices marketed prior to the MDA's enactment on May 28, 1976 are exempt from PMA requirements until the FDA specifically calls for their review.⁵⁶ The second exception to PMA review was created to prevent pre-MDA class III devices from gaining an unfair competitive advantage because of their temporary exemption from PMA requirements.⁵⁷ This exception, known as "substantial equivalency," allows manufacturers of class III devices marketed after May 28, 1976, to temporarily avoid the PMA process by demonstrating that their products are substantially similar to a pre-MDA device.⁵⁸ Manufacturers of substantially equivalent devices do not have to submit PMA applications until the FDA specifically calls the applications. Approximately eighty percent of all class III products are marketed as substantially equivalent devices, thus temporarily exempting such devices from PMA review.⁵⁹

Substantially equivalent devices are cleared through a modified section 510k process.⁶⁰ Manufacturers of these devices must submit a basic section 510k application with additional information reporting safety and effectiveness problems associated with the device.⁶¹ In about fifteen percent of these cases, the FDA also requires manufacturers to provide clinical and laboratory data to support their claims of substantial equivalence,⁶² thus making section 510k applications more akin to PMA applications. Nonetheless, significant differences between the two premarket clearance procedures persist and are illustrated by the fact that the FDA spends an average of 1200 hours on each PMA submission in

discussion of preemption of claims involving IDE devices, however, is outside the scope of this Comment because of the extensive differences between IDE and PMA review.

55. *Lohr*, 116 S. Ct. at 2247.

56. 21 U.S.C. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1) (1996). The FDA has not commenced the PMA process for most grandfathered class III devices. *Lohr*, 116 S. Ct. at 2247 n.3.

57. *Adler & Mann*, *supra* note 8, at 914.

58. 21 U.S.C. § 360c(i) (1994). The FDA considers a device to be substantially equivalent if it shares the same technology as the predicate device or, even if the technologies differ, if there is sufficient information demonstrating that the new device is as safe and effective as the previously marketed device and does not raise additional questions of safety or effectiveness. 21 U.S.C. § 360c(i).

59. H.R. Rep. No. 101-808, at 18, *reprinted in* 1990 U.S.C.C.A.N. 6305, 6312 (1990).

60. *See* 21 U.S.C. § 360c(i)(3)(A).

61. *See* 21 C.F.R. § 807.87(h)(2) (1996).

62. The Wilkerson Group, Inc., *Forces Reshaping the Performance and Contribution of the U.S. Medical Device Industry*, report prepared for Health Indus. Mfrs. Ass'n 70 (1995); *see also* *Adler*, *supra* note 15, at 516-17.

contrast to an average of twenty hours on a section 510k application.⁶³ One commentator has noted, “[t]he attraction of substantial equivalence to manufacturers is clear. A 510(k) . . . [application] requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly.”⁶⁴

II. PREEMPTION

The controversial aspect of the MDA has not been its classification system, but rather its express preemption provision.⁶⁵ Although commentators agree that the Supremacy Clause of the U.S. Constitution grants Congress the power to preempt state product liability claims, they disagree as to whether Congress intended to exercise this power in the MDA.⁶⁶

The Supremacy Clause provides that the laws of the United States “shall be the supreme Law of the Land.”⁶⁷ State laws that “interfere with, or are contrary to the laws of Congress” are invalid.⁶⁸ Under the Supremacy Clause, federal laws may preempt state laws through express preemption or implied preemption.⁶⁹ Express preemption occurs when Congress declares in a statute its intent to displace state law.⁷⁰ Implied preemption occurs when a court infers from a statute’s structure and purpose that Congress intended to preempt state law.⁷¹

Regardless of which type of preemption is involved, the Supreme Court has stated that two principles must guide a court’s preemption

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

64. Adler, *supra* note 15, at 516.

65. See *supra* note 8 and accompanying text.

66. See *id.*

67. U.S. Const. art. VI, cl. 2.

68. *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 211 (1824) (Marshall, C.J.).

69. See *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985) (observing that Congress may expressly preempt state law, or its intent to displace state law may be inferred).

70. *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977).

71. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). In the absence of an express preemption clause, preemption occurs where Congress passes an extensive statutory scheme that effectively occupies the field of regulation, *see, e.g.*, *Fidelity Fed. Sav. & Loan Ass’n v. de la Cuesta*, 458 U.S. 141, 153 (1982), or where state law actually conflicts with federal law, *see, e.g.*, *Pacific Gas & Elec. Co. v. State Energy Resources Conservation & Dev. Comm’n*, 461 U.S. 190, 204 (1983). A more thorough discussion of implied preemption is beyond the scope of this Comment because the MDA contains an express preemption clause. Where there is an express preemption clause that reliably indicates that Congress intends to preempt state law, there is no need to conduct implied preemption analysis. *Cipollone*, 505 U.S. at 517.

analysis.⁷² First, courts should presume that states' historic police powers are not superseded by federal law unless preemption is the "clear and manifest purpose of Congress."⁷³ Second, courts' decisions must be guided by the principle that "[t]he purpose of Congress is the ultimate touchstone' in every pre-emption case."⁷⁴

A. The MDA's Express Preemption Provision

The MDA contains an express preemption provision that prohibits states from establishing or enforcing:

any requirement—(1) which is different from, or in addition to, any [federal] requirement applicable under this chapter to the device, and (2) which relates to the safety and effectiveness of the device or to any other matter included in a [federal] requirement applicable to the device under this chapter.⁷⁵

This provision, codified as 21 U.S.C. § 360k(a), demands that three conditions be satisfied before a state law is preempted: (1) there is a federal requirement applicable to the device; (2) there is a state requirement that is different from, or in addition to, the federal requirement; and (3) the state requirement concerns the safety or effectiveness of a device or any other aspect of a device regulated by the MDA.

Much controversy has surrounded section 360k(a) and what types of federal rules and state laws qualify as requirements under it.⁷⁶ The legislative history of section 360k(a) provides little information regarding which state laws Congress intended the provision to preempt or which federal device rules should trigger preemption. The only relevant information about the preemption provision is contained in a House of Representatives report, which indicates that the purpose of section 360k(a) is to prevent interstate commerce from being "unduly burdened" by states imposing different or additional requirements on

72. See *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240, 2250 (1996).

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

74. *Id.* (quoting *Cipollone*, 505 U.S. at 516).

75. 21 U.S.C. § 360k(a) (1994). The FDA may grant exemptions to states that wish to establish or enforce laws that are more stringent than the federal laws governing medical devices. 21 U.S.C. § 360k(b).

76. See *supra* note 8 and accompanying text.

devices.⁷⁷ In the absence of information regarding the intended scope of the preemption provision, courts and the FDA have embarked on their own attempts to interpret the provision.

B. *The FDA's Interpretation of Section 360k(a)*

As the federal agency charged with implementing and enforcing the MDA,⁷⁸ the FDA has issued regulations interpreting section 360k(a).⁷⁹ These regulations significantly restrict the kind of state law that qualifies as a "state requirement," and they narrow the definition of a "federal requirement."⁸⁰

Under the FDA's interpretation of section 360k(a), a state requirement includes a "statute, ordinance, regulation, or [a] court decision."⁸¹ Not all state laws falling into one of these four categories, however, will be subject to preemption. The FDA excludes from its definition of state requirements "requirements of general applicability," which are laws that do not relate exclusively to medical devices.⁸² Nonetheless, this exclusion is not absolute. Although state laws of general applicability usually are not superseded, the regulations specify that when a law of general applicability "has the effect of establishing a substantive requirement . . . [that] is different from, or in addition to, a Federal requirement," it will be preempted.⁸³

FDA regulations also adopt a narrowing definition of preemptive "federal requirements" under section 360k(a).⁸⁴ The regulations specify two types of federal rules that trigger preemption.⁸⁵ First, "specific counterpart regulations" promulgated by the FDA that are applicable to a particular device qualify as federal requirements.⁸⁶ Second, "specific

77. H.R. Rep. No. 94-853, at 45 (1976), reprinted in *An Analytical Legislative History of the Medical Device Amendments of 1976*, app. III (Daniel F. O'Keefe, Jr. et al. eds., 1976).

78. 21 U.S.C. § 371(a) (1994). Although the MDA gave the Secretary of Health and Human Services authority to promulgate regulations under the Act, the Secretary subsequently delegated her authority to the FDA. *See Lohr*, 116 S. Ct. at 2249 n.5.

79. *See* 21 C.F.R. § 808.1 (1996).

80. *See* 21 C.F.R. § 808.1.

81. 21 C.F.R. § 808.1(b).

82. *See* 21 C.F.R. § 808.1(d).

83. 21 C.F.R. § 808.1(d)(6)(ii).

84. 21 C.F.R. § 808.1(d).

85. *See* 21 C.F.R. § 808.1(d).

86. 21 C.F.R. § 808.1(d).

... [federal rules] applicable to a particular device” that are included within the MDA itself also constitute federal requirements.⁸⁷

C. *Judicial Interpretation of the Scope of Section 360k(a)*

1. *Pre-Lohr Cases*

Until the 1990s, courts generally rejected the argument that the MDA preempted state product liability claims.⁸⁸ They viewed the MDA and its regulations as establishing the minimum, rather than the maximum, standard of care required by product liability law.⁸⁹ However, courts became more amenable to preemption arguments after *Cipollone v. Liggett Group, Inc.*⁹⁰ In *Cipollone*, the U.S. Supreme Court held that an express preemption clause in the Public Health Cigarette Smoking Act of 1969⁹¹ encompassed some state tort claims.⁹² Although *Cipollone* did not involve the MDA, courts faced with the issue of whether the MDA preempted state product liability claims relied on the decision because the preemption clause at issue mirrored the MDA’s preemption provision.⁹³

After *Cipollone*, courts adopted one of three different interpretations of section 360k(a).⁹⁴ First, the majority of federal courts held that the MDA preempted all state product liability claims.⁹⁵ Generally, these

87. 21 C.F.R. § 808.1(d).

88. Gary L. Wilson, *Listen to the FDA: The Medical Device Amendments Do Not Preempt Tort Law*, 19 Hamline L. Rev. 409, 412 (1996). Those instances in which courts did find preemption generally involved cases where the FDA had promulgated device-specific regulations such as performance standards for class II devices. *Id.*

89. *See* Adler & Mann, *supra* note 8, at 916.

90. 505 U.S. 504 (1992). In *Cipollone*, the son of a smoker sued a cigarette manufacturer under various product liability theories for his mother’s death. *Id.* at 508.

91. Pub. L. 91-222, 84 Stat. 87 (1970) (codified as amended at 15 U.S.C. §§ 1331–1340 (1994)). The express preemption bars states from imposing “requirement[s] or prohibition[s] based on smoking and health . . . with respect to the advertising or promotion of any cigarettes,” if a manufacturer has complied with the Act. 15 U.S.C. § 1334.

92. *Cipollone*, 505 U.S. at 523 (plurality opinion); *id.* at 549 (Scalia, J. and Thomas, J., concurring in judgment in part and dissenting in part).

93. *See, e.g.,* Mitchell v. Collagen Corp., 67 F.3d 1268, 1275–76 (7th Cir. 1995), *vacated*, 116 S. Ct. 2576 (1996) (*vacated and remanded for reconsideration in light of Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240 (1996)); King v. Collagen Corp., 983 F.2d 1130, 1134 (1st Cir. 1993).

94. *See* Anne-Marie Dega, Comment, *The Battle over Medical Device Regulation: Do the Federal Medical Device Amendments Preempt State Tort Law Claims?*, 27 Loy. U. Chi. L.J. 615, 633 (1996) (describing three general positions courts assumed).

95. *See, e.g.,* Martello v. CIBA Vision Corp., 42 F.3d 1167, 1168–69 (8th Cir. 1994) (ruling that product liability claims asserted against manufacturer of lens disinfection system were preempted),

courts reasoned that because the MDA establishes a comprehensive set of rules regulating devices, state product liability claims would necessarily impose requirements that were “different from or, in addition to,” MDA device rules, and thus such claims should be preempted under section 360k(a).⁹⁶ Second, in *Kennedy v. Collagen Corporation*,⁹⁷ the Ninth Circuit rejected the majority position and held that the MDA does not preempt any state product liability claims. Citing FDA regulations that state that section 360k(a) does not preempt laws of general applicability, the court concluded that the plaintiff’s state claims should not be preempted, because they were based on general theories of product liability.⁹⁸ Third, in *Feldt v. Mentor Corp.*,⁹⁹ the Fifth Circuit adopted a moderate approach and held that the MDA preempted some claims but not others. Focusing on the language in section 360k(a), the court announced the rule that only those state claims that attempt to regulate aspects of devices already governed by federal rules should be preempted, because only then do the state claims impose different or additional requirements within the meaning of section 360k(a).¹⁰⁰

2. Medtronic, Inc. v. Lohr

With much diversity in the decisions concerning the preemptive scope of the MDA, the issue was ripe for resolution by the U.S. Supreme Court. The Court answered this call when it granted certiorari in *Medtronic, Inc. v. Lohr*.¹⁰¹

cert. denied, 115 S. Ct. 2614 (1995); *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 541 (3d Cir. 1994) (finding product liability claims involving interocular lens were preempted); *Mendes v. Medtronic, Inc.*, 18 F.3d 13, 18–19 (1st Cir. 1994) (holding that plaintiff’s claims of negligent manufacture and distribution, failure-to-warn, and breach of express and implied warranty regarding pacemaker were all preempted); *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1420–21 (5th Cir. 1993) (holding that PMA rules preempt state law tort claims for defective design, inadequate warnings, and failure to warn); *King*, 983 F.2d 1130, 1139–40 (ruling that all of plaintiff’s state product liability claims against manufacturer of anti-wrinkle device were preempted).

96. See cases cited *supra* note 95.

97. 67 F.3d 1453 (9th Cir. 1995) (holding that none of claims asserted against manufacturer of anti-wrinkle treatment that had undergone PMA review were preempted).

98. *Id.* at 1458–59.

99. See, e.g., *Feldt v. Mentor Corp.*, 61 F.3d 431 (5th Cir. 1995) (ruling that inadequate warning and labeling claims against manufacturer of substantially equivalent device that had undergone section 510k review were preempted by general controls, but that defective design claims were not preempted because there were no federal design requirements imposed on device), *vacated*, 116 S. Ct. 2575 (1996) (remanded for reconsideration in light of *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240 (1996)).

100. *Id.* at 435.

101. 56 F.3d 1335 (11th Cir. 1995), *aff’d in part and rev’d in part*, 116 S. Ct. 2240 (1996).

Preemption of Product Liability Claims by the MDA

In *Lohr*, a recipient of a pacemaker, Lora Lohr, and her husband sued the manufacturer of the pacemaker after it allegedly failed, causing complete heart block.¹⁰² The pacemaker was a class III product marketed as a substantially equivalent device, which had undergone section 510k review.¹⁰³ The plaintiffs' complaint contained negligence and strict liability counts alleging defective design, manufacturing, and labeling.¹⁰⁴ The defendant, Medtronic, asserted that federal device rules preempted all of the Lohrs' claims.¹⁰⁵ In a 4-1-4 decision, the Court held that the MDA's purpose and legislative history, as well as the FDA's interpretative regulations, mandated that none of the Lohrs' claims be preempted.¹⁰⁶

A majority of the Court determined that common law actions impose state requirements within the meaning of section 360k(a).¹⁰⁷ This majority was comprised of the four dissenting justices¹⁰⁸ and Justice Breyer, who concurred in part and concurred in the judgment of the plurality.¹⁰⁹ These five justices declared that state product liability claims are within the scope of section 360k(a).¹¹⁰ They reasoned that *Cipollone* required product liability claims to be included within the definition of a state requirement because they could find no basis upon which to distinguish the language in section 360k(a) from the preemption provision at issue in *Cipollone*.¹¹¹ According to the justices, "requirement" easily encompasses obligations that take the form of common law rules given that "[state] regulation can be as effectively exerted through an award of damages as through some form of preventative relief."¹¹² Insofar as the MDA preempts a state requirement embodied in a positive enactment of law, the justices concluded that it also preempts state common law claims that would impose requirements

102. *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240, 2248 (1996).

103. *Id.*

104. *Id.*

105. *Id.*

106. *Id.* at 2258 (majority opinion); *id.* at 2261 (Breyer, J., concurring).

107. *Id.* at 2259 (Breyer, J., concurring); *id.* at 2263 (O'Connor, J., dissenting).

108. Justice O'Connor wrote the dissenting opinion and was joined by Chief Justice Rehnquist and Justices Scalia and Thomas.

109. *Lohr*, 116 S. Ct. at 2259 (Breyer, J., concurring).

110. *Id.*

111. *Id.* (Breyer, J., concurring); *id.* at 2262-63 (O'Connor, J., dissenting).

112. *Id.* at 2259 (Breyer, J., concurring) (quoting *Cipollone v. Liggett Group Inc.*, 505 U.S. 504, 521 (1992)); *id.* at 2262 (O'Connor, J., dissenting) (same).

that are different from, or in addition to, requirements imposed under the MDA.¹¹³

A different majority of the Court, however, concluded that none of the Lohrs' claims were preempted by federal device rules because neither section 510k notification rules nor general controls governing all devices qualified as preemptive federal requirements under section 360k(a).¹¹⁴ With respect to the plaintiffs' defective design claims, the Court found that section 510k review does not constitute an FDA finding of safety and effectiveness that could preempt state requirements involving the pacemaker's design.¹¹⁵ According to the Court, section 510k rules do not preempt state-imposed design requirements because the design of substantially equivalent devices "has never been formally reviewed under the MDA for safety or efficacy."¹¹⁶ Rather, FDA approval of a section 510k application only ensures that a product is "no more dangerous and no less effective than" a pre-1976 device.¹¹⁷ In the absence of federal design requirements, the Court held that liability claims premised on the theory that a manufacturer should have employed a different product design do not impose different or additional state requirements.¹¹⁸

Relying on the FDA's interpretation of section 360k(a), this same majority found that the general controls governing manufacturing quality control processes and device labeling—the only other significant rules applicable to the pacemaker—did not preempt the plaintiffs' claims based on allegedly defective manufacturing or labeling.¹¹⁹ Quoting FDA regulations, the Court declared that state requirements are preempted only when the "FDA has established 'specific counterpart regulations or . . . [there are] other specific requirements applicable to a particular device'" under the MDA.¹²⁰ According to the Court, general controls do not qualify under either of these preemptive categories because they "reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of

113. *Id.* at 2260 (Breyer, J., concurring); *id.* at 2263 (O'Connor, J., dissenting).

114. *Id.* at 2258. This majority was comprised of Justice Stevens, author of the principle opinion, who was joined by Justices Kennedy, Souter, and Ginsburg, and Justice Breyer, who concurred in part and concurred in the judgment.

115. *Id.* at 2254.

116. *Id.*

117. *Id.*

118. *Id.* at 2255.

119. *Id.* at 2258.

120. *Id.* at 2257 (quoting 21 C.F.R. § 808.1(d) (1995)).

device regulation which the statute or regulations were designed to protect from contradictory state requirements.”¹²¹

Although divided on the issue of whether product liability claims constitute state requirements within the meaning of section 360k(a), the justices unanimously agreed that product liability claims alleging violations of the MDA are not preempted.¹²² Quoting FDA regulations, the Court explained section 360k(a) ““does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under”” the MDA.¹²³ The Court explained that when plaintiffs premise liability on a manufacturer’s failure to comply with federal device rules, the claims are identical to MDA requirements and thus should not be preempted.¹²⁴ Even when a state’s tort law requires a plaintiff to prove not only that a manufacturer failed to comply with federal law, but also that the violation was the result of negligent conduct, the Court observed that the plaintiff’s claim does not constitute a different or additional requirement under the MDA.¹²⁵

3. *Post-Lohr Cases*

In spite of the Court’s attempt to resolve the circuit split concerning the preemptive scope of section 360k(a), *Lohr*’s narrow holding left many questions unanswered.¹²⁶ Although *Lohr* conclusively established that section 510k rules and general controls do not preempt state product liability claims, the Court failed to address whether PMA rules preempt product liability claims. Most post-*Lohr* courts have held that PMA rules do not preempt product liability claims.¹²⁷ Nonetheless, courts have failed to agree on a single rationale for rejecting preemption.

121. *Id.* at 2244.

122. *See id.* at 2256 (majority opinion); *id.* at 2264 (dissenting opinion).

123. *Id.* at 2256 (quoting 21 C.F.R. § 808.5 (1995)).

124. *Id.* at 2255.

125. *Id.*

126. *See, e.g.,* *Green v. Dolsky*, 685 A.2d 110, 115–17 (Pa. 1996) (stating that although *Lohr* answered some questions regarding section 510k rules, decision does not provide sufficient guidance for analyzing preemptive scope of PMA rules), *cert. denied*, 117 S. Ct. 1432 (1997).

127. *See, e.g.,* *Armstrong v. Optical Radiation Corp.*, 50 Cal. App. 4th 580, 595 (Cal. Ct. App. 1996) (finding that PMA rules trigger preemption, but rejecting preemption on grounds that state product liability laws are laws of general applicability); *Kernats v. Smith Indus. Med. Sys., Inc.*, 669 N.E.2d 1300, 1308–09 (Ill. App. Ct. 1996) (ruling that although PMA rules are preemptive federal requirements, state product liability law was not preempted because it was not specifically developed with respect to medical devices), *appeal denied*, 675 N.E.2d 634 (Ill. 1996), *petition for cert. filed*, 65 U.S.L.W. 3632 (U.S. Mar. 4, 1997) (No. 96-1405); *Walker v. Johnson & Johnson Vision Prods.*,

Most post-*Lohr* courts reject preemption on the ground that product liability claims do not qualify as state requirements within the meaning of section 360k(a).¹²⁸ Notwithstanding similar outcomes, these courts have employed different rationales for refusing to treat product liability claims as state requirements.¹²⁹ For instance, the California Court of Appeals relied on FDA regulations¹³⁰ to find that product liability law is a law of general applicability that is exempt from preemption. However, in *Kernats v. Smith Industries Medical Systems, Inc.*,¹³¹ the Illinois Court of Appeals furnished another reason for rejecting preemption of product liability claims. Quoting the majority opinion in *Lohr*, the court declared that state product liability claims are not preempted by PMA rules because product liability law is not "specifically developed with respect to medical devices," and thus its generality leaves it outside the scope of laws Congress intended to be preempted.¹³²

However, in *Walker v. Johnson & Johnson Vision Products, Inc.*,¹³³ the Michigan Court of Appeals rejected preemption on the basis that PMA rules are not preemptive federal requirements within the meaning of section 360k(a). The court interpreted FDA regulations and *Lohr* to require that federal rules be device specific to preempt state law.¹³⁴ It then concluded that because the PMA rules apply to all non-exempt class III devices, PMA rules are not device specific, and thus they do not preempt product liability claims.¹³⁵

In *Green v. Dolsky*,¹³⁶ the Supreme Court of Pennsylvania adopted a minority position, finding that PMA requirements preempt state product

Inc., 552 N.W.2d 679, 684-85 (Mich. Ct. App. 1996) (rejecting preemption of product liability claims on grounds that PMA rules are not device specific, and state product liability law is law of general applicability and thus not within scope of section 360k(a)); *Connelly v. Iolab Corp.*, 927 S.W.2d 848, 853 (Mo. 1996) (applying form of conflict preemption analysis to find that plaintiff's product liability claims survive preemption because manufacturer was physically unable to comply with requirements imposed by state claims and those imposed by MDA rules), *cert. dismissed*, 65 U.S.L.W. 3815 (U.S. June 4, 1997) (No. R46-011); *Sowell v. Bausch & Lomb, Inc.*, 656 N.Y.S.2d 16, 20 (N.Y. Sup. Ct. 1997) (rejecting preemption in case of contact lens that had undergone PMA review because PMA rules are not device specific). *But see Green*, 685 A.2d at 117-18 (finding that PMA rules preempt certain types of state product liability claims).

128. *See, e.g., Armstrong*, 50 Cal. App. 4th at 595-96; *Kernats*, 669 N.E.2d at 1308-09.

129. *See cases cited supra* note 128.

130. *Armstrong*, 50 Cal. App. 4th at 595.

131. 669 N.E.2d 1300, 1309 (Ill. App. Ct. 1996); *accord Sowell*, 656 N.Y.S.2d at 19-23.

132. *Id.* at 1309 (quoting *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240, 2258 (1996)).

133. 552 N.W.2d 679, 684 (Mich. Ct. App. 1996).

134. *Id.* at 685.

135. *Id.* at 684.

136. 685 A.2d 110, 117-18 (Pa. 1996).

liability claims. In *Dolsky*, the plaintiff sued her doctor and Collagen Corporation after she allegedly developed an auto immune reaction after receiving an injection of Zyderm.¹³⁷ Without discussion, the court assumed that state product liability claims are within the scope of the section 360k(a) and that PMA rules constitute preemptive federal requirements.¹³⁸ Ultimately, the court held that all of the plaintiff's discernible product liability claims were preempted because they would have required a judge or jury "to substitute a reasonableness analysis characteristic of negligence claims for the judgment of the FDA in approving the . . . particular product in the course of its premarket approval process."¹³⁹ The *Dolsky* court concluded that product liability actions are preempted to the extent that they invade the field of PMA review.¹⁴⁰

III. PMA RULES SHOULD PREEMPT PRODUCT LIABILITY CLAIMS THAT INVOLVE ASPECTS OF DEVICES ADDRESSED BY PMA RULES

The *Lohr* decision leaves ample room for courts to treat PMA rules as federal requirements that preempt state product liability claims. The U.S. Supreme Court's rationale for refusing to grant preemptive effect to section 510k rules and general controls supports preemption in the context of devices subject to PMA rules.¹⁴¹ Moreover, finding that PMA rules preempt product liability claims is consistent with interpretative regulations promulgated by the FDA.¹⁴² In the wake of *Lohr*, however, only certain product liability claims should be preempted.¹⁴³ Determining which claims are displaced by PMA rules requires careful analysis of the product defect underlying the state law claim, the nature of the PMA rules governing the device, and the purpose of the MDA.¹⁴⁴

137. *Id.* at 113.

138. *See id.* at 117.

139. *Id.*

140. *Id.*

141. *See infra* Part III.B.1.

142. *See infra* Part III.B.2.

143. *See supra* Part II.C.2 (discussing how *Lohr* Court unanimously agreed that claims alleging violations of MDA were not preempted).

144. *See Feldt v. Mentor Corp.*, 61 F.3d 431, 435-37 (5th Cir. 1995) (using similar approach to determine whether federal rules governing substantially similar device preempted state product liability claims).

Before a court may hold that PMA rules preempt a plaintiff's state product liability claim, it must resolve three issues. First, the court must decide whether product liability claims are within the intended scope of section 360k(a). Second, the court must determine whether PMA rules trigger preemption of state product liability claims. Third, the court must establish which state claims PMA rules preempt.

A. State Product Liability Claims Should Be Treated as State Requirements Within the Meaning of Section 360k(a)

A majority of the Court in *Lohr* found that state product liability claims may be preempted under the MDA.¹⁴⁵ Nonetheless, several post-*Lohr* courts have ignored this finding and have instead held that product liability claims are outside the scope of section 360k(a).¹⁴⁶ To reach this conclusion, courts misinterpret a section in the majority opinion in *Lohr* and misconstrue FDA regulations.

1. Courts Have Misinterpreted Lohr as Excluding Product Liability Claims from Preemption

Courts that place state product liability claims outside the intended scope of section 360k(a) have invariably relied upon one passage in the principal opinion in *Lohr*.¹⁴⁷ In this passage, the four plurality justices, joined by Justice Breyer, rejected preemption on the grounds that not only were the federal rules governing the pacemaker not sufficiently specific to warrant preemption, but also because the plaintiffs' state claims "were not specifically developed 'with respect to' medical devices."¹⁴⁸ The Court reasoned that because the legal obligations underlying the plaintiffs' state claims apply to all product manufacturers, the claims did not interfere with a specific federal interest advanced by the MDA and thus should not be preempted.¹⁴⁹ Several post-*Lohr* courts have cited this passage to support the proposition that product liability

145. See *supra* Part II.C.2.

146. See cases cited *supra* note 127.

147. See *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240, 2258 (1996).

148. *Id.*

149. *Id.*

claims are never preempted by federal device rules because such claims are never developed specifically with respect to medical devices.¹⁵⁰

Although five justices joined the section of the opinion containing this passage,¹⁵¹ it cannot be considered the opinion of the Court because it is inconsistent with Justice Breyer's separate opinion. This passage imposes a condition that cannot be satisfied because theories of product liability are never formulated exclusively with respect to medical devices.¹⁵² Rather, they develop gradually and apply to all types of products.¹⁵³ Thus, if the condition were imposed, no product liability claims would ever be preempted under the MDA. But this result cannot be reconciled with Justice Breyer's explicit finding in his separate opinion that product liability claims are preempted to the same extent as positive enactments of law.¹⁵⁴ Because Justice Breyer wrote a separate opinion to highlight his disagreement with the plurality concerning product liability claims,¹⁵⁵ and because without Justice Breyer's vote the passage is supported by only four other justices, the condition the passage imposes does not in fact constitute the law of the land and should not be relied upon by courts. Instead, Justice Breyer's and the four dissenting justices' declaration that product liability claims are within the intended scope of the preemption provision constitutes the opinion of the Court.¹⁵⁶

2. *Courts Have Failed To Carefully Analyze FDA Regulations Regarding Preemption of State Laws*

Courts holding that state product liability claims are outside the scope of the MDA not only misconstrue *Lohr*, but also incorrectly interpret

150. See, e.g., *Armstrong v. Optical Radiation Corp.*, 50 Cal. App. 4th 580, 595 (Cal. Ct. App. 1996); *Walker v. Johnson & Johnson Vision Prods., Inc.*, 552 N.W.2d 679, 686 (Mich. Ct. App. 1996).

151. *Lohr*, 116 S. Ct. at 2245.

152. See generally W. Page Keeton et al., *Prosser and Keeton on the Law of Torts* §§ 95–96, at 677–90 (5th ed. 1984) (describing different theories of product liability and how they developed).

153. *Id.*

154. *Lohr*, 116 S. Ct. at 2260.

155. See *id.* at 2259–60.

156. See *Papike v. Tambrands, Inc.*, 107 F.3d 737, 741 (9th Cir. 1997) (declaring that Ninth Circuit's earlier holding in *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995), *cert. denied*, 116 S. Ct. 2579 (1996), that state product liability claims are never preempted under MDA could not "survive in light of the concurring and dissenting opinions in [*Lohr*]").

FDA regulations.¹⁵⁷ FDA regulations specify that laws of general applicability are not generally preempted under section 360k(a).¹⁵⁸ Based on this language, some courts make the cursory determination that state product liability claims are not preempted.¹⁵⁹

By ending their inquiry here, these courts fail to consider two other important sections in the regulations that support preemption of some state claims.¹⁶⁰ First, the regulations specify that state requirements may take the form of court decisions.¹⁶¹ Because court decisions are the vehicle by which product liability claims impose requirements, the characterization of court decisions as state requirements strongly suggests that product liability claims are within the scope of the MDA.¹⁶² Second, the regulations state an exception to the rule that laws of general applicability escape preemption.¹⁶³ This exception provides that when laws of general applicability have “the effect of establishing a substantive requirement for a specific device,” they are preempted to the same extent as other state laws.¹⁶⁴ Product liability claims fall under this exception because they effectively establish substantive requirements for specific devices.¹⁶⁵ A majority of the *Lohr* Court explicitly recognized this point when they declared that “[state] regulation can be as effectively exerted through an award of damages as through some form of preventative relief.”¹⁶⁶ Because product liability claims do in fact impose substantive duties, they should be treated as a state requirement and should be preempted to the extent that they impose different or additional requirements.¹⁶⁷

157. See, e.g., *Armstrong v. Optical Radiation Corp.*, 50 Cal. App. 4th 580, 595 (Cal. Ct. App. 1996); *Walker v. Johnson & Johnson Vision Prods., Inc.*, 552 N.W.2d 679, 684–85 (Mich. Ct. App. 1996).

158. 21 C.F.R. § 808.1(d)(1) (1996).

159. See, e.g., *Armstrong*, 50 Cal. App. 4th at 595; *Walker*, 552 N.W.2d at 684–85.

160. See 21 C.F.R. § 808.1(b), (d)(6)(ii).

161. 21 C.F.R. § 808.1(b).

162. See Herrmann & Ritts, *supra* note 8, at 16–18.

163. See 21 C.F.R. § 808.1(d)(6)(ii).

164. 21 C.F.R. § 808.1(d)(6)(ii).

165. See Herrmann & Ritts, *supra* note 8, at 17.

166. *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240, 2259 (1996) (Breyer, J., concurring); *id.* at 2262 (O'Connor, J., dissenting) (quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521 (1992)).

167. See *infra* Part III.C for a discussion of which product liability claims PMA rules preempt.

B. PMA Rules Should Be Treated as Preemptive Federal Requirements

Once a court finds that state product liability claims are within the scope of section 360k(a), it must determine whether PMA rules trigger preemption of those claims. However, this issue is not easily resolved because neither *Lohr* nor the FDA regulations explicitly address whether PMA rules constitute federal requirements within the meaning of section 360k(a). Nonetheless, the *Lohr* Court's reasoning for refusing to grant preemptive effect to section 510k rules and general controls supports treating PMA rules as preemptive federal requirements. Moreover, under FDA regulations interpreting section 360k(a), PMA rules logically qualify as preemptive federal requirements.

I. Lohr's Reasoning Supports Treating PMA Rules as Preemptive Federal Requirements

Noting that the purpose of a statute is the “touchstone” in every preemption case,” the *Lohr* Court found that section 510k rules and general controls do not preempt state law because a contrary finding would be inconsistent with the overall purpose of the MDA as well as the specific purpose of the preemption provision.¹⁶⁸ The Court observed that the overall purpose of the MDA is to protect consumers from unsafe and ineffective medical devices.¹⁶⁹ However, section 510k rules merely ensure equivalency and not the safety of devices.¹⁷⁰ The Court reasoned that treating section 510k rules as preemptive federal requirements would have the perverse effect of leaving the safety of substantially equivalent devices less regulated than they were before the passage of the MDA.¹⁷¹ Before Congress granted the FDA the authority to regulate devices, the Court observed that the safety of devices was at least regulated by product liability lawsuits.¹⁷² For this reason, the Court concluded that Congress did not intend for section 510k rules to preempt state product liability law.¹⁷³

168. *Lohr*, 116 S. Ct. at 2254–55.

169. *Id.*; see also *supra* note 22.

170. *Lohr*, 116 S. Ct. at 2254.

171. *Id.* at 2255.

172. *Id.*

173. *Id.*

The Court also found that the specific purpose of the preemption provision was not furthered by treating 510k rules and general controls as preemptive federal requirements.¹⁷⁴ According to the Court, federal rules should preempt state law only when those rules promote specific federal interests.¹⁷⁵ Using this criterion, the Court explained that section 510k rules and general controls do not trigger preemption because these rules “reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which . . . [the preemption provision was] designed to protect from potentially contradictory state requirements.”¹⁷⁶

When the Court’s reasoning is applied to devices subject to PMA rules, preemption is appropriate. PMA rules advance the overall purpose of the MDA because the PMA process is directly concerned with a device’s safety and effectiveness.¹⁷⁷ PMA applications must be extremely detailed to give the FDA enough data to make informed safety determinations.¹⁷⁸ If the FDA is not satisfied with a PMA application, it may require a manufacturer to submit additional information or conduct further testing, or the FDA may refuse to approve a device entirely.¹⁷⁹ Even after the FDA grants premarket approval of a device, it may either conditionally or permanently revoke its approval, thus forcing the device off of the market.¹⁸⁰ Given the overall purpose of the MDA, and the PMA process’s focus on safety, it is appropriate to treat PMA rules as preemptive federal requirements.

Moreover, treating PMA rules as preemptive federal requirements is consistent with the notion of limiting the scope of the preemption provision to only those state laws that interfere with specific federal interests.¹⁸¹ During PMA review, the FDA makes complex scientific and policy decisions, assessing whether the benefits of devices outweigh the known risks.¹⁸² Rather than “reflecting entirely generic concerns about

174. *Id.* at 2258.

175. *Id.*

176. *Id.*

177. *See, e.g.*, 21 U.S.C. § 360e(d)(2) (1994) (authorizing FDA to deny approval of PMA application absent showing of reasonable assurance that device is safe and effective).

178. *See, e.g.*, 21 U.S.C. § 360e(c) (describing extensive information that PMA application must contain).

179. *See* 21 C.F.R. §§ 814.44–45 (1996).

180. 21 C.F.R. § 814.46 (outlining FDA procedures for revoking PMA of device).

181. *See Lohr*, 116 S. Ct. at 2258.

182. *See* 21 C.F.R. § 860.7(b)(3) (1996) (describing factors FDA must consider in assessing whether to grant PMA).

device regulation generally,” the difficult choices that the FDA makes about each device that is subject to PMA review are exactly the kind of federal regulations that the preemption provision was designed to protect from potentially contradictory state requirements.¹⁸³

2. *FDA Regulations Support Finding that PMA Rules Preempt Product Liability Claims*

Because the *Lohr* Court adopted the FDA’s definition of a federal requirement,¹⁸⁴ courts should rely on FDA regulations to determine whether PMA rules qualify as federal requirements. Although FDA regulations do not state explicitly whether PMA rules trigger preemption, the FDA’s definition of a preemptive federal requirement logically encompasses PMA rules. Under the regulations, federal rules qualify as federal requirements if either (1) they are specific rules enacted by Congress that are applicable to a particular device, or (2) they are specific counterpart regulations promulgated by the FDA that are applicable to a particular device.¹⁸⁵ Although the categories differ in that each encompasses requirements originating from different sources, both categories require that rules be device specific to trigger preemption.¹⁸⁶

Under this definition, PMA rules do not fall under the first category because those PMA rules enacted by Congress are not device specific.¹⁸⁷ Instead, PMA rules apply to all non-exempt class III devices.¹⁸⁸ Congress left the task of crafting device-specific rules to the FDA.¹⁸⁹

PMA rules, however, do qualify as federal requirements under the second category because of the way the FDA tailors PMA review to each particular device.¹⁹⁰ PMA rules require manufacturers to submit in a

183. See Roger W. Bivans, Note, *Substantially Equivalent? Federal Preemption of State Common-Law Claims Involving Medical Devices*, 74 Tex. L. Rev. 1087, 1110 (1996) (arguing that PMA process “is more than a broad procedural framework” but instead involves extensive testing and review of devices, and thus PMA rules should be treated as preemptive federal requirements).

184. *Lohr*, 116 S. Ct. at 2257.

185. 21 C.F.R. § 808.1(d) (1996).

186. See *Duvall v. Bristol-Myers-Squibb Co.*, 103 F.3d 324, 330 (4th Cir. 1996) (observing that *Lohr* Court’s interpretation of FDA regulations dictates that federal rules be device specific to preempt state law).

187. In fact, no particular device is singled out for individual treatment in the MDA.

188. See *supra* Part I.B.

189. See *supra* note 78.

190. See John D. Burnside, Comment, *Kennedy v. Collagen Corp.: Falling from the Medical Device Amendments’ Federal Preemption Garden*, 28 Ariz. St. L.J. 949, 971 (1996) (observing that

PMA application detailed information regarding the product's design, manufacturing, marketing, labeling, packaging, and distribution.¹⁹¹ After the FDA approves a PMA application, manufacturers must comply with those design, labeling, and production parameters specified in the application.¹⁹² Because manufacturers are constrained in the changes they may make after the FDA grants PMA, the FDA-approved application operates as a specific counterpart regulation that is uniquely applicable to that particular device, and thus PMA rules constitute federal requirements.

C. *A Framework for Identifying Which Product Liability Claims PMA Rules Preempt*

After a court has determined that product liability claims qualify as state requirements and PMA rules trigger preemption, it must identify which claims PMA rules preempt. *Lohr* makes clear that PMA rules preempt only those state laws that impose different or additional requirements.¹⁹³ Product liability claims impose different or additional requirements when claims are based on allegations that a manufacturer should have done something more or different than required by PMA rules.¹⁹⁴ Put another way, PMA rules should preempt state product liability claims when such claims involve aspects of devices already addressed by PMA rules.¹⁹⁵ Therefore, the task is to identify what aspects of devices PMA rules address, and then to identify the extent to which state claims invade the domain of PMA rules.

Although product liability laws vary among states,¹⁹⁶ there are essentially three theories of recovery available to injured plaintiffs:

PMA process qualifies as specific requirement applicable to particular device because FDA makes specific finding of safety and effectiveness for each device under examination).

191. See *Armstrong v. Optical Radiation Corp.*, 50 Cal. App. 4th 580, 594 (Ct. App. 1996).

192. 21 C.F.R. § 814.80 (1996). When a manufacturer alters its product, it must notify the FDA. 21 C.F.R. § 814.39(b). Any changes that adversely affect the safety or effectiveness of a device must be specifically approved by the FDA. 21 C.F.R. §§ 814.39(a)-(b).

193. See *supra* Part II.C.2.

194. See *Green v. Dolsky*, 685 A.2d 110, 118 (Pa. 1996) (arguing that to "allow a strict liability claim for a product specifically approved by the FDA would be to impose 'requirements' which are different from those of the FDA . . .").

195. See *Feldt v. Mentor Corp.*, 61 F.3d 431, 435-37 (5th Cir. 1995) (applying same analysis in case of a substantially similar device to determine whether general controls and section 510k rules preempted plaintiff's product liability claims).

196. Henry Grabowski, *Product Liability in Pharmaceuticals: Comments on Chapters Eight and Nine*, in *The Liability Maze: The Impact of Liability Law on Safety and Innovation* 363 (Peter W. Huber & Robert E. Litan eds., 1991).

(1) breach of warranty, express or implied; (2) negligence; and (3) strict liability.¹⁹⁷ Below is an overview of which claims the PMA rules should preempt.

Breach of express and implied warranty claims should not be treated uniformly for preemption purposes. Because express warranties are not created by state law, but instead arise through promises made by private parties,¹⁹⁸ they do not run afoul of the section 360k(a) prohibition on states establishing or enforcing requirements relating to devices.¹⁹⁹ Accordingly, neither PMA rules nor any other federal requirements should preempt express warranty claims. On the other hand, state law imposes implied warranties even when contracting parties have made no express promises.²⁰⁰ One such warranty is the implied warranty of fitness of purpose, which establishes a duty on merchants to supply products that are suited for their intended purpose.²⁰¹ A claim for breach of an implied warranty of fitness requires a court to find that a product is unsuitable for the purpose for which it was marketed.²⁰² When a court rules on a breach of implied warranty claim involving a device to which the FDA granted PMA, the court, in effect, substitutes its judgment regarding a device's safety for the FDA's determination that the device was safe for its intended use. Therefore, PMA rules should preempt claims of breach of implied warranty of fitness.

Although strict liability and negligence actions differ significantly, in the final analysis both types of claims should be treated similarly for preemption purposes. Negligence actions focus on how a defendant's failure to exercise reasonable care resulted in a plaintiff's injury.²⁰³ In

197. See Keeton et al., *supra* note 152, at 694.

198. See U.C.C. § 2-313 (1994) (describing different ways that sellers may create express warranties).

199. *Kernats v. Smith Indus. Med. Sys., Inc.*, 669 N.E.2d 1300, 1310 (Ill. App. Ct. 1996) (finding that breach of express warranty claims are not preempted under MDA because requirements are not imposed under state law, but imposed by warrantor), *appeal denied*, 675 N.E.2d 634 (Ill. 1996), *petition for cert. filed*, 65 U.S.L.W. 3632 (U.S. Mar. 4, 1997) (No. 96-1405).

200. See U.C.C. §§ 2-313, -315 (1994) (creating implied warranties that goods must meet minimal standard according to trade, and must be fit for particular purpose that purchasers intended if seller is aware of this purpose).

201. U.C.C. § 2-315 ("Where the seller . . . has reason to know . . . [the] purpose for which the goods are required . . . there is . . . an implied warranty that the goods shall be fit for such purpose."). The U.C.C. also establishes an implied warranty of merchantability, which requires that goods conform to industry standards. See U.C.C. § 2-314 (1994).

202. See U.C.C. § 2-315.

203. Kathleen A. Touby, *Product Liability and the Device Industry*, 43 Food Drug Cosm. L.J. 55, 61 (1988).

contrast, strict liability actions focus on the product itself and whether it is unreasonably dangerous.²⁰⁴ Nonetheless, under either theory plaintiffs must prove that a product is defective,²⁰⁵ and under both theories the types of product defects are largely the same.²⁰⁶ Because the type of product defect involved in a claim will dictate those aspects of a device that a court's judgment will regulate, strict liability and negligence claims should be analyzed in the same manner.

Under either a negligence or a strict liability theory, products may be defective in three primary ways: (1) there is a flaw in the product that makes it more dangerous than intended;²⁰⁷ (2) the product information fails to warn or lacks a sufficient warning about a risk inherent in the way the product is designed;²⁰⁸ and (3) a product's design is defective and dangerous.²⁰⁹ PMA rules preempt claims involving all three defects because PMA rules address all of those aspects of the devices associated with these product defects

PMA rules should preempt claims alleging that a device's flaw was created or not discovered during the manufacturing process, because PMA rules require manufacturers to submit a description of the methods, facilities, and controls used for manufacturing devices.²¹⁰ PMA rules should preempt this type of claim because the FDA determines whether the manufacturing processes and controls specified in a PMA application are sufficient to guard against the creation of flaws and are adequate to ensure the discovery of those flaws that are created.²¹¹ Allowing a plaintiff to maintain a negligence or strict liability action against a manufacturer that has complied with FDA regulations subjects a manufacturer to additional state requirements in an area already regulated by PMA rules.

204. Keeton et al., *supra* note 152, at 695.

205. Charles J. Walsh & Marc S. Klein, *The Conflicting Objectives of Federal and State Tort Law Drug Regulation*, 41 Food Drug Cosm. L.J. 171, 172 (1986).

206. See Keeton et al., *supra* note 152, at 685 (describing three types of product defects under negligence theory); *id.* at 695-97 (outlining almost identical types of product defects under strict liability).

207. *Id.* at 685, 695.

208. *Id.* at 685, 697.

209. *Id.* at 688, 698. Courts use different tests for assessing whether a product's design is hazardous in negligence and strict liability actions. *Id.*

210. See 21 U.S.C. § 360e(c)(1)(C) (1994); 21 C.F.R. § 814.20(b)(4)(v) (1996).

211. See 21 C.F.R. § 814.20(b)(4)(v) (requiring that PMA application adequately explain quality control processes so that FDA can make knowledgeable assessment of controls).

Preemption of Product Liability Claims by the MDA

Likewise, PMA rules should also preempt defective warning claims because the FDA reviews specimens of proposed labeling and product information submitted in all PMA applications.²¹² When the FDA is not satisfied with draft warning information, it may condition final approval of a device on the manufacturers' willingness to include changes as specified by the FDA.²¹³ Because premarket approval of a device involves close scrutiny of device labels,²¹⁴ defective warning claims impose different or additional requirements and thus should be preempted.

Finally, PMA rules should preempt defective design claims because the FDA reviews the design of a product during PMA review²¹⁵ and grants approval only after determining that the probable health benefits of the device outweigh the probable risks.²¹⁶ Therefore, a defective design claim should be preempted because it requires a court to substitute its cost-benefit analysis for that of the FDA concerning the utility of marketing a product.

Although PMA rules should preempt most product liability claims, plaintiffs will not necessarily be without recourse in state court. The *Lohr* Court made clear that plaintiffs' state product liability claims alleging violations of MDA rules were not preempted because such claims are not different from, or in addition to, federal device requirements.²¹⁷ Consequently, when a plaintiff's state law claims are predicated on an allegation that a defect resulted from a manufacturer violating PMA rules, such as a manufacturer's failure to comply with those quality control processes specified in its PMA application, such a claim would survive preemption.²¹⁸

212. See 21 U.S.C. § 360e(c)(F); 21 C.F.R. § 814.20(b)(10).

213. See 21 C.F.R. § 814.44(d).

214. See 21 U.S.C. § 360e(c)(1)(F) (requiring manufacturers to submit to FDA draft labeling instructions); 21 C.F.R. § 860.7 (1996) (mandating that device reviewers consider whether device labels are adequate before reviewers may grant PMA).

215. 21 U.S.C. § 360e(c)(B); 21 C.F.R. § 814.20.

216. 21 C.F.R. § 860.7(b)(3).

217. See *supra* Part II.C.2.

218. See *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240, 2255 (1996).

IV. POLICY CONSIDERATIONS SUPPORT PREEMPTING PRODUCT LIABILITY CLAIMS THAT INTERFERE WITH PMA RULES

PMA rules and product liability law share common goals of deterring the production and sale of devices that fail to conform to a certain standard of safety.²¹⁹ However, these two methods of device regulation accomplish their shared goals in very different ways. Federal rules prospectively regulate devices by establishing uniform national standards against which scientists evaluate the safety of devices.²²⁰ In contrast, state product liability claims retrospectively regulate devices and potentially subject manufacturers to a different set of rules in each state.²²¹ Moreover, in state product liability lawsuits, judges and juries rather than experts make safety determinations.²²² Given the complexity and importance of medical devices to human health, and the FDA's unique qualifications to make decisions regarding device regulation, courts should not regulate devices subject to PMA rules.²²³ When courts attempt to co-regulate devices, their activities are at best redundant; at worst, they subject manufacturers to contradictory and unclear standards, they risk making medical devices less affordable and available, and they threaten to frustrate the federal regulation of devices.

Preemption of product liability claims by PMA rules is not only consistent with the overall purpose of the MDA, but it also furthers the specific purpose of the MDA's preemption clause.²²⁴ Congress included an express preemption provision in the MDA to ensure that manufacturers are not unduly burdened by dual regulation of devices by both the states and the federal government.²²⁵ Product liability actions frustrate this purpose because manufacturers must comply with each state's product liability law to avoid liability losses, even though they have completed the stringent PMA process and the FDA has determined that their products are reasonably safe and effective. Given the exacting

219. Foote, *supra* note 2, at 138.

220. *Id.*

221. *Id.*

222. *Id.*

223. *But see* Adler & Mann, *supra* note 8, at 945 (arguing that FDA alone cannot adequately protect consumers from dangerous devices).

224. *See* H.R. Rep. No. 94-853, at 45 (1976), reprinted in *An Analytical Legislative History of the Medical Device Amendments of 1976*, app. III (Daniel F. O'Keefe, Jr. et al. eds., 1976); *see also supra* Part II.A.

225. *See* H.R. Rep. No. 94-853, at 45.

nature of PMA review and the hardships it imposes on manufacturers, treating PMA rules as preemptive federal requirements that displace product liability claims furthers Congress's objective of reducing the unnecessary regulatory burdens on manufacturers.

Commentators advance two main policy arguments for imposing liability on manufacturers of defective consumer products.²²⁶ First, liability promotes product safety because damage awards provide an incentive to manufacturers to make products safer to avoid liability losses.²²⁷ Second, product liability spreads a plaintiff's losses among those who benefit from a product.²²⁸ Manufacturers who are forced to pay damage awards can pass on the costs to their other customers in the form of higher sales prices.²²⁹ Nonetheless, these policy arguments are not as compelling in the case of PMA devices as in the context of other consumer goods.

Manufacturers of devices that are subject to PMA review have strong incentives to make products safe regardless of liability concerns. In contrast to manufacturers of minimally regulated products, device manufacturers must ensure that their products meet stringent FDA standards.²³⁰ Even minor safety problems will lead the FDA to postpone premarket approval of a product until the agency's concerns are allayed.²³¹ Because approval delays impose significant costs on manufacturers, estimated between \$15,000 and \$1 million per month,²³² and often lead smaller companies to borrow money, lay off employees, or decide not to develop new products in the future,²³³ device

226. Laura K. Jortberg, Note, *Who Should Bear the Burden of Experimental Medical Device Testing: The Preemptive Scope of the Medical Device Amendments Under Slater v. Optical Radiation Corp.*, 43 DePaul L. Rev. 963, 981 (1994).

227. The Wilkerson Group, Inc., *supra* note 62, at 99.

228. Jortberg, *supra* note 226, at 981.

229. *Id.* at 983.

230. See, e.g., Edward M. Basile, *Improving FDA's Product Approval Process for Medical Devices*, 41 Food Drug Cosm. L.J., 287, 290 (1986) (describing costs to manufacturers of approval delays).

231. See *Regulating Innovation: FDA's Medical Device Approval Process: Hearing Before the Subcomm. on Investigations and Oversight of the House Comm. on Science, Space, and Technology*, 103d Cong. 146 (1993) (statement of Dr. Susan Alpert, Acting Director, Office of Device Education, FDA) (responding to criticism from device manufacturers that FDA reviewers delay device approval by requesting irrelevant information from manufacturers).

232. Basile, *supra* note 230, at 290 (citing Tucker & Blozan, *PMA Applications for Post-Amendment Devices: A Look at the Current Process*, MDDI Reports, June 1985, at 94).

233. *Id.* at 291.

manufacturers are likely to make their products as safe as possible even if product liability actions are preempted.

Moreover, product liability actions are a flawed method of ensuring safety because they send a vague signal to manufacturers. Product liability law fails to adequately convey to manufacturers how to be more careful or how careful they should be.²³⁴ Although manufacturers of many consumer goods may be able to alter their behavior in response to product liability lawsuits because needed safety modifications are obvious, this is not the case for manufacturers of many medical devices subject to PMA review because of the complexity and sensitivity of many of these devices.²³⁵ Modifications to such devices may produce unintended and unforeseeable consequences, which might render devices even more unsafe. Consequently, manufacturers of PMA devices are less capable of improving product safety in response to lawsuits than manufacturers of other consumer goods.

Spreading injured plaintiffs' losses also is not necessarily desirable in the case of medical devices. Large damage awards can force manufacturers to remove vital products from the market to minimize liability exposure,²³⁶ or the awards may drive some companies out of business.²³⁷ In fact, in the 1980s, as childhood vaccine manufacturers faced increased liability exposure, a drastic decline in the number of manufacturers threatened to cause a worldwide shortage of vaccines for polio, measles, mumps, and rubella.²³⁸ If the current liability laws operate unchecked, we risk delaying or making unavailable life-saving medical devices.²³⁹

234. See Peter W. Huber & Robert E. Litan, *Overview*, in *The Liability Maze*, *supra* note 196, at 1, 5.

235. Although some relatively simple devices are categorized as class III devices, the classification scheme was designed to ensure that the most complex and vital devices are subject to PMA review. See H.R. Rep. No. 94-853, at 35 (1976), reprinted in *An Analytical Legislative History of the Medical Device Amendments of 1976*, app. III (Daniel F. O'Keefe, Jr. et al. eds., 1976) (describing how Congress wanted to require premarket approval for devices that are of particular importance to human health).

236. See Foote, *supra* note 2, at 148-49.

237. The Wilkerson Group, Inc., *supra* note 62, at 105 (describing how worst case scenarios factor heavily into decision making).

238. Charles F. Hagan, *Vaccine Compensation Schemes*, 45 Food Drug Cosm. L.J. 477, 479 (1990). Concerned about the effects of state product liability law on the supply of vaccines, Congress enacted the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa (1994), which established a national trust fund to compensate children injured by vaccines if they choose to forego suits against vaccine manufacturers. *Id.* at 479-80.

239. See Herrmann & Ritts, *supra* note 8, at 13-14 (arguing that social costs of product liability lawsuits in case of medical devices are much more severe than for other products).

The threat of large damage awards not only forces existing products off the market, but such awards also have a chilling effect on product development and innovation.²⁴⁰ For example, many device manufacturers will not invest money in the research and development of devices that have high potential liability costs such as anesthesiology, intrauterine contraceptive devices, and many pediatric applications of existing technologies.²⁴¹ When it is not cost-effective for manufacturers to develop new devices, consumers pay the price in unnecessary and unrelieved suffering.²⁴²

Finally, product liability actions allow judges and juries to second-guess the FDA's scientific and policy decisions.²⁴³ This is improper given that Congress granted the FDA authority to review the safety and effectiveness of medical devices and make complex policy choices concerning whether a device should be marketed at all, and under what conditions.²⁴⁴ The FDA is staffed with scientific experts who are more qualified than judges or juries to assess product safety.²⁴⁵ Moreover, the FDA is better equipped than courts to make policy decisions regarding medical devices because it can more accurately weigh the overall benefit to society against the potential harms of marketing a product.²⁴⁶ Given the comprehensiveness and rigor of the PMA process, courts should defer to the specific scientific and policy judgments made by the FDA.²⁴⁷

V. CONCLUSION

In *Lohr*, the U.S. Supreme Court failed to resolve the question of whether premarket approval of a device shields a manufacturer from liability actions. Because PMA devices are vital to human health, and their availability and affordability has severe consequences for many

240. See, e.g., Foote, *supra* note 2, at 7–8 (citing adverse impact of liability on contraception research and development).

241. The Wilkerson Group, Inc., *supra* note 62, at 106.

242. See, e.g., Pennington P. Landen, *Federal Preemption and the Drug Industry: Can Courts Co-Regulate?*, 43 Food Drug Cosm. L.J. 85, 119 (1988) (observing that “spectre of liability—despite FDA approval—chills the manufacturer’s incentive to develop new products”).

243. Jortberg, *supra* note 226, at 984.

244. 21 C.F.R. § 860.7 (1996) (describing considerations FDA must make in assessing whether product should receive premarket approval).

245. See Jortberg, *supra* note 226, at 985.

246. See Walsh & Klein, *supra* note 205, at 193 (observing that in context of federal drug rules, courts are ill-equipped to make complex risk-utility judgments about whether drugs should be marketed at all).

247. See *id.*

Americans, this question is too important to leave unanswered. Congress included an express preemption clause in the MDA to ensure that state laws do not interfere with the uniform federal regulation of medical devices. PMA rules establish a comprehensive process by which the FDA rigorously scrutinizes nearly every aspect of a device's labeling, design, and manufacturing. Allowing plaintiffs to sue manufacturers of devices governed by PMA rules, despite manufacturers' full compliance with the rules, thwarts the purpose behind the preemption provision of freeing manufacturers from duplicative state requirements. Moreover, both the reasoning of *Lohr* and FDA interpretive regulations support preempting product liability claims that attempt to regulate aspects of devices already addressed by PMA rules. Consequently, courts should treat PMA rules as preemptive federal requirements that displace state product liability claims to the extent that such claims impose requirements on devices that are different from, or in addition to, PMA rules.