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Medtronic, Inc. v. Lohr: Is Federal Pre-emption a Heartbeat away from Death under the Medical Device Amendments?

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I. INTRODUCTION

Lora Lohr "might not be alive today" if it were not for her pacemaker.[1] Her Medtronic pacemaker allowed her to have an active and healthy lifestyle despite her irregular heart condition.[2] That is, until one fateful day in December 1990 when her pacemaker lead[3] failed, allegedly causing "complete heart block" requiring "emergency surgery and replacement of her pacemaker."[4] In 1993, Lohr and her husband filed a civil suit in Florida state court.[5] They averred, in part, a negligence count alleging that Medtronic breached its "duty to use reasonable care in the design, manufacture, assembly, and sale of the subject pacemaker."[6] Medtronic removed the action to the federal district court and moved for summary judgment.[7] The district court eventually held that the Lohrs' causes of action were federally pre-empted and dismissed the entire action.[8] Amongst an uncertain legal landscape, the Lohrs would

1. *See* Brief for Petitioner Medtronic, Inc. at 24, Medtronic, Inc. v. Lohr, 116 S. Ct. 2240 (1996) (Nos. 95-754, 95-886), *available in* 1996 WL 88789 [hereinafter Brief for Petitioner].

2. *See generally id.* at 35.

3. *See* Brief for Cross-Petitioners Lora Lohr & Michael Lohr at 8, Medtronic, Inc. v. Lohr, 116 S. Ct. 2240 (1996) (Nos. 95-754, 95-886), *available in* 1996 WL 88460 [hereinafter Brief for Cross-Petitioners]. The lead delivers the electronic stimulus generated by the pacemaker to the heart, thus steadying the heartbeat. *See id.* at 7. Medtronic, Inc. reports over $1.7 billion in revenue from pacemakers, leads, and accessories, representing nearly a 50% market share. *See* MEDTRONIC, INC. 1995 ANNUAL SHAREHOLDERS REPORT 4, 6 (1996).

4. *See* Brief for Cross-Petitioners, *supra* note 3, at 8.

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

6. *Id.* (citations omitted).

7. *See id.*

8. *See id.* at 2249. The district court initially denied Medtronic's motion for summary judgment, but subsequently granted the motion on reconsideration in light of *Duncan v. Iolab Corp.*, 12 F.3d 194 (11th Cir. 1994). *See id.*

fight their case in the Court of Appeals for the Eleventh Circuit[9] and finally before the Supreme Court of the United States.[10]

The parties' conflicting interests highlight the importance of the Supreme Court's decision. For Mrs. Lohr and numerous consumers who rely on medical devices, federal pre-emption means that they bear the risk and cost of any subsequent injury resulting from the manufacturer's negligent acts or unreasonably dangerous defective product.[11] For Medtronic, Inc. and other similarly situated medical device manufacturers, numerous state tort actions could mean financial disaster,[12] or discourage future medical product research and development projects.[13]

This Note will explore the historical, judicial, and social ramifications of the Court's decision in *Medtronic, Inc. v. Lohr*. Part II[14] describes the history of the Federal Food, Drug and Cosmetic Act of 1938 (FDCA),[15] the Medical Device Amendments of 1976 (MDA),[16] federal

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9. Lohr v. Medtronic, Inc., 56 F.3d 1335 (11th Cir. 1995), *aff'd in part and rev'd in part*, 116 S. Ct. 2240 (1996).

10. *Medtronic*, 116 S. Ct. 2240. The Court noted that the courts of appeals were divided over the extent pre-emption affected common law claims under the Medical Device Amendments. *See id.* at 2250 n.6. *Compare* English v. Mentor Corp., 67 F.3d 477 (3d Cir. 1995) (finding pre-emption), *and Lohr*, 56 F.3d 1335 (finding pre-emption), *with* Feldt v. Mentor Corp., 61 F.3d 431 (5th Cir. 1995) (finding no pre-emption), Michael v. Shiley, Inc., 46 F.3d 1316 (3d Cir. 1995) (finding no pre-emption), *and* Kennedy v. Collagen Corp., 67 F.3d 1453 (9th Cir. 1995) (finding no pre-emption).

11. *See, e.g.*, Griffin v. Medtronic, Inc., 82 F.3d 79 (4th Cir. 1996), *cert. granted, vacated, and remanded*, 117 S. Ct. 939 (1997) (remanding case in light of the Supreme Court's *Medtronic* decision).

12. *See* Gina Kolata, *Details of Implant Settlement Announced by Federal Judge*, N.Y. TIMES, Apr. 5, 1994, at A16 (reporting $3.7 billion class-action settlement against three silicon breast implant manufacturers); *see also* Marcia Angell, *Shattuck Lecture—Evaluating the Health Risks of Breast Implants: The Interplay of Medical Science, the Law, and Public Opinion*, 334 N. ENG. J. MED. 1513, 1517 (1996) (noting that following the $4.2 billion settlement and over 20,000 individual lawsuits filed against them, Dow Corning, a major manufacturer of breast implants, was forced to file for bankruptcy protection) (citing Jay Mathews, *Breast Implant Maker Files for Bankruptcy*, WASH. POST, May 16, 1995, at A1).

13. *See* David M. Henry, *Pre-emption in* Medtronic *Pits MDA's Consumer Protection Purposes Against Goal of Encouraging Development of Medical Devices*, WEST'S LEGAL NEWS, May 23, 1996, *available in* 1996 WL 272691 (noting that the issue of pre-emption depends on balancing two competing interests—compensating an injured plaintiff and promoting medical device development—and may lean in favor of the medical devices industry).

14. *See infra* notes 21-147 and accompanying text.

15. Ch. 675, § 1, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-395 (1994)).

16. Pub. L. No. 94-295, § 1(a), 90 Stat. 539 (codified as amended in scattered sections of 15 U.S.C., 21 U.S.C., 42 U.S.C.).

pre-emption in general, and federal pre-emption under the MDA. Part III[17] presents the facts and judicial history of the case. In Part IV,[18] this Note critically analyzes Justice Stevens's plurality opinion and the concurring and dissenting opinions. Part V[19] discusses the judicial and social impacts of the case with particular attention to the implication for the biotechnology and medical device industries. Part VI[20] concludes by observing that various public policy concerns permeate the Court's pre-emption analysis and may signal a new approach for judicial decisionmaking.

II. HISTORICAL BACKGROUND

At issue in *Medtronic Inc. v. Lohr*[21] was whether the Medical Device Amendments of 1976 (MDA)[22] "pre-empts a state common-law negligence action against the manufacturer of an allegedly defective medical device."[23] The Supreme Court, in reaching its decision in *Medtronic*, necessarily required a thorough understanding of the historical development of food, drug, and medical device regulation in America as juxtiposed against the federal pre-emption doctrine.

A. A Brief History of Federal Regulation of Foods, Drugs & Medical Devices

1. The Pure Food and Drugs Act of 1906

In 1906, Congress passed the Pure Food and Drugs Act (1906 Act),[24] venturing for the first time to regulate the manufacture and distribution of drugs.[25] Among its prohibitions, the 1906 Act banned the manufacture and distribution of adulterated or misbranded food and drugs, and

17. *See infra* notes 148-55 and accompanying text.
18. *See infra* notes 156-97 and accompanying text.
19. *See infra* notes 198-259 and accompanying text.
20. *See infra* notes 260-63 and accompanying text.
21. 116 S. Ct. 2240 (1996).
22. Pub. L. No. 94-295, § 1(a), 90 Stat. 539 (codified as amended in scattered section of 21 U.S.C., 42 U.S.C.).
23. *Medtronic*, 116 S. Ct. at 2245.
24. Ch. 3915, 34 Stat. 768 (1906), *repealed by* Federal Drug and Cosmetic Act of 1938, 21 U.S.C. § 301 (1938).
25. *See* Dennis R. Johnson, *The History of the 1906 Pure Food and Drugs Act and the Meat Inspection Act*, 37 FOOD DRUG COSM. L.J. 5, 5 (1982).

the false or misleading labeling of food and drugs.[26] The 1906 Act vested enforcement in the Bureau of Chemistry (Bureau) an early forerunner of the Food and Drug Administration (FDA).[27] The Bureau had limited enforcement power, however, in that it could only seize non-conforming goods and press criminal charges after goods were already on the market.[28]

The Pure Food and Drugs Act's post-marketing regulatory scheme lacked many of the elements necessary to be effective.[29] First, rather than providing proactive protection, the 1906 Act operated only in response to a violation.[30] Manufacturers were not required to test their product prior to distribution, nor could the Bureau take any action until the product entered the stream of commerce.[31] Second, the 1906 Act only prohibited false statements about the identity or composition of drugs, not false statements as to the therapeutic effects of the drugs.[32] Finally, the 1906 Act failed to cover medical devices.[33] Despite Congress amending the Pure Food and Drug Act on several occasions,[34] the 1906 Act still lacked the essential conceptual framework of an effective and progressive regulatory process.[35]

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26. *See id.* at 6.

27. *See* Michael Brannon, *Organizing and Reorganizing the FDA*, *in* FOOD AND DRUG LAW 113, 115 (Richard M. Cooper ed., 1991).

28. *See id.*

29. *See* Charles J. Walsh & Alissa Pyrich, *Rationalizing the Regulation of Prescription Drugs and Medical Devices: Perspectives on Private Certification and Tort Reform*, 48 RUTGERS L. REV. 883, 890-92 (1996) (discussing the existing federal regulatory scheme under the Food, Drug, and Cosmetic Act (FDCA), the potential for privatization of certain aspects of drug and medical device regulation, and the need for products liability reform).

30. *See* Brannon, *supra* note 27, at 115.

31. *See* Julie C. Relihan, *Expediting FDA Approval of AIDS Drugs: An International Approach*, 13 B.U. INT'L L.J. 229, 234 (1995).

32. *See* United States v. Johnson, 221 U.S. 488, 496-97 (1911) (holding that the Pure Food and Drugs Act only prohibited false statements as to the identity of the drug).

33. *See* Rodney R. Munsey & Frank E. Samuel, Jr., *Medical Device Regulation, In Transition*, *in* SEVENTY-FIFTH ANNIVERSARY COMMEMORATIVE VOLUME OF FOOD AND DRUG LAW 350, 351 (Food and Drug Law Inst. ed., 1984).

34. *See* H.R. REP. No. 62-1138 (1912) (failed attempt to legislatively overturn the restrictions placed on enforcement in *United States v. Johnson*, 221 U.S. 488 (1911)).

35. *See* David F. Cavers, *The Food, Drug and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 LAW & CONTEMP. PROBS. 2, 20 (1939) (tracing the historical context giving rise to the adoption of the FDCA of 1938); Myron L. Marlin, *Treatment INDs: A Faster Route to Drug Approval?*, 39 AM. U. L. REV. 171, 177 (1989).

2. The Federal Food, Drug, and Cosmetic Act of 1938

For twenty-two years Congress struggled to find an effective regulatory system,[36] but no substantial change arose until public sentiment forced Congress to revamp federal food and drug regulations.[37] In 1937, public outrage reached a pinnacle when more than one hundred people tragically died from consuming Elixir Sulfanilamide, a drug never tested by its manufacturer prior to being sold.[38] In response to the Elixir Sulfanilamide incidents, Congress passed the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA).[39] The FDCA required all new drugs to be tested by their manufacturers and reviewed by the Federal Drug Administration (FDA) prior to being marketed.[40]

The FDCA addressed many of the areas lacking in its predecessor, the Pure Food and Drug Act. First, the FDCA was proactive rather than reactive.[41] Before a drug could be put on the market, the FDCA required a manufacturer to file a New Drug Application (NDA).[42] The NDA solicited medical and scientific information about the safety of the

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36. *See* Wallace F. Janssen, *The U.S. Food and Drug Law: How It Came; How It Works*, 35 FOOD DRUG COSM. L.J. 132, 132-36 (1980) (providing a brief account of the events leading to the adoption of the FDCA of 1938).

37. *See id.* at 135-36.

38. *See id.*; *see also* Walsh & Pyrich, *supra* note 29, at 893 & n.21 (citing REPORT OF THE SECRETARY OF AGRICULTURE ON DEATHS DUE TO ELIXIR SULFANILAMIDE, S. DOC. NO. 75-124, at 1-3 (1937)).

39. Ch. 675, § 1, 52 Stat. 1040 (1938) (current version at 21 U.S.C. §§ 301-395 (1994)).

40. *See id.* § 505(a), 52 Stat. at 1052 (current version at 21 U.S.C. § 355(a) (1994)). The FDCA originally defined a new drug as:

> (1) [a]ny drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended or suggested in the labeling thereof, . . . ; or (2) [a]ny drug the composition of which is such that such drug, as a result of investigations to determine its safety for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

See id. § 201, 52 Stat. at 1041-42 (current version at 21 U.S.C. § 321 (1994)).

41. *See* Janssen, *supra* note 36, at 136-37.

42. *See* Federal Food, Drug, and Cosmetic Act of 1938, § 505(a), 52 Stat. at 1052 (current version at 21 U.S.C. § 355(a) (1994)); *see also* Walsh & Pyrich, *supra* note 29, at 894-95.

drug for review by the FDA.[43] If the FDA found that the NDA provided insufficient information, the drug could not be sold.[44]

Second, the FDCA expanded the enforcement powers of the FDA to include the authority to inspect drug manufacturing facilities and seek court injunctions.[45] This added to the FDA's previous powers which included the authority to seize tainted products and pursue criminal prosecutions.[46]

Third, the FDCA also covered medical devices.[47] Although not as extensive in scope as the drug regulations, the FDCA's medical devices regulations prohibited manufacturers from distributing misbranded or adulterated medical devices in the market and placed restrictions on medical device labeling.[48] Yet, in its original form, the FDCA created only reactive protection for consumers of medical devices.[49] While the FDCA's drug provisions provided revolutionary premarket testing, medical devices could only be controlled after reaching the market.[50]

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43. *See* Walsh & Pyrich, *supra* note 29, at 894-95.

44. *See id.* Prior to 1962, if the FDA did not request additional information within a set period of time, the NDA would automatically become effective and the manufacture could begin marketing the product. *See* Note, *FDA Reform and the European Medicines Evaluation Agency*, 108 HARV. L. REV. 2009, 2012 (1995).

45. *See* Janssen, *supra* note 36, at 136.

46. *See id.*

47. *See id.* The FDCA originally defined medical devices as "instruments, apparatus, and contrivances, including their components, parts and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals." Food, Drug, and Cosmetic Act, ch. 675, § 201(h), 52 Stat. at 1040, 1041 (current version at 21 U.S.C. § 321(h) (1994)); *see* Munsey & Samuel, *supra* note 33, at 351; Gary E. Gamerman, Note, *Intended Use and Medical Devices: Distinguishing Nonmedical "Devices" from Medical "Devices" Under 21 U.S.C. § 321(h)*, 61 GEO. WASH. L. REV. 806, 816-20 (1993).

48. *See* Federal Food, Drug, and Cosmetic Act of 1938, § 201(n), 52 Stat. at 1041 (current version at 21 U.S.C. § 321(n) (1994)); *see also* Robert B. Leflar, *Public Accountability and Medical Device Regulation*, 2 HARV. J.L. & TECH. 1, 6 (1989).

49. *See* Leflar, *supra* note 48, at 6; Munsey & Samuel, *supra* note 33, at 351; Gamerman, *supra* note 47, at 820.

50. *See* Walsh & Pyrich, *supra* note 29, at 895.

3. The Medical Device Amendments of 1976

Since 1938, Congress has amended the FDCA over twenty times.[51] Not until 1976, however, did Congress address perceived shortcomings of the FDCA in regulating medical devices by enacting the Medical Device Amendments of 1976 (MDA).[52] Specifically, Congress desired to protect consumers from "increasingly complex devices which pose[d] serious risk if inadequately tested or improperly designed or used,"[53] without, however, stifling medical innovation.[54] Realizing the unique attributes of the medical devices industry,[55] Congress rejected merely extending the same regulations applied to drug manufacturers and in-

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51. *See* PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW 13 (2d ed. 1991) (noting that the general trend in the amendments was to expand the coverage and increase the substantive authority granted to the FDA). Between 1938 and 1962, three amendments significantly altered the character of the regulatory scheme under the FDCA: the Food Additives Amendment of 1958, Pub. L. No. 85-929, § 1, 72 Stat. 1784 (codified as amended in scattered sections of 21 U.S.C.); the Color Additive Amendments of 1960, Pub. L. No. 86-618, 74 Stat. 397 (codified as amended in scattered sections of 21 U.S.C.); and the Drug Amendments of 1962, Pub. L. No. 87-781, § 1, 76 Stat. 780 (1962). *See id.* The Drug Amendments of 1962 again represented a response to public tragedy. *See* Janssen, *supra* note 36, at 137. Researchers had discovered a link between the use of thalidomide (a drug used to relieve morning sickness) and serious birth defects. *See id.* The 1962 Amendments expanded the FDA's role by requiring a premarket determination that all drugs were safe and effective for their intended purpose. *See* 21 U.S.C. § 355(b) (1994). Further, drug manufacturers were prohibited from conducting human clinical tests without prior FDA approval. *See id.*

52. Pub. L. No. 94-295, § 1(a), 90 Stat. 539 (1976) (codified as amended in scattered sections of 15 U.S.C., 21 U.S.C., 42 U.S.C.) (stating that the purpose of the amendments is "to provide for the safety and effectiveness of medical devices intended for human use").

53. S. REP. NO. 94-33, at 5 (1975), *reprinted in* 1976 U.S.C.C.A.N. 1070, 1075.

54. *See id.* at 2.

55. *See* H.R. REP. NO. 94-853, at 12 (1976); *see also* King v. Collagen Corp., 983 F.2d 1130, 1138 (1st Cir. 1993) (Aldrich, J., concurring) (citing the legislative history of the MDA and noting that Congress intended to provide protection to users of medical devices and encourage research).

> The legislative history . . . shows the principal emphasis to be on the protection of the individual user. But it also shows the intent to "encourage . . . research and development" and "permit new and improved devices to be marketed without delay." Perfection is impossible and a few individuals may be denied full protection at the cost of benefiting the rest.

Id. (Aldrich, J., concurring) (quoting S. REP. NO. 94-33, at 2, 14, *reprinted in* 1976 U.S.C.C.A.N. at 1071, 1083).

stead created a flexible system dependent on the risks and benefits of the device.[56]

The MDA classifies devices into three categories based on the device's risk to the public.[57] Class I devices pose "no unreasonable risk of illness or injury . . . and are subject only to minimal regulation by 'general controls.'"[58] Class II devices pose a "potentially more harmful" risk to the public and "must comply with federal performance regulations known as 'special controls.'"[59] Class III devices "'present a potential[ly] unreasonable risk of illness or injury' or . . . 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.'"[60] Prior to distribution to consumers, class III devices must undergo an extensive premarket approval (PMA) process administered by the FDA.[61]

The FDA, however, does not require all Class III devices to pass premarket approval.[62] The MDA provides for two key exceptions: (1) pre-1976 devices pending FDA approval (i.e., "grandfathered" devices),[63] and (2) devices that are "substantially equivalent" to pre-existing devices.[64] Under the "grandfathered" exception, any device, including

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56. *See* H.R. REP. NO. 94-853, at 12. The House elaborated:

> [T]he Committee has developed a balanced regulatory proposal intended to assure that the public is protected from unsafe and ineffective medical devices, that health professionals have more confidence in the devices they use or prescribe, and that innovations in medical device technology are not stifled by unnecessary restrictions. [The bill] . . . would prohibit . . . the marketing of a new device until the safety and effectiveness of the device has been established . . . . [The bill] reflects the need to develop innovative new devices, consistent with the need to protect the subjects of device research.

Id.

57. *See* 21 U.S.C. § 360a (1994); *see generally* Walsh & Pyrich, *supra* note 29, at 918-21 (describing the classification system of medical devices under the MDA).

58. Medtronic, Inc. v. Lohr, 116 S. Ct. 2240, 2246 (1996) (quoting 21 U.S.C. § 360c(a)(1)(A) (1994)). Examples of Class I devices include tongue depressors and Band-Aids. *See* 21 U.S.C. § 360c(a)(1)(A).

59. *Medtronic*, 116 S. Ct. at 2246 (quoting 21 U.S.C. § 360c(a)(1)(B)). Examples of Class II devices include oxygen masks and tampons. *See* 21 U.S.C. § 360c(a)(1)(B).

60. *Medtronic*, 116 S. Ct. at 2246 (quoting 21 U.S.C. § 360c(a)(1)(C)). Class III devices include pacemakers (at issue in *Medtronic*), breast implants, and intrauterine contraceptive devices. *See* 21 U.S.C. § 360c(a)(1)(C).

61. *See Medtronic*, 116 S. Ct. at 2246-47 (noting that the FDA spends an average of 1200 hours reviewing each Class III application during the premarket approval (PMA) process).

62. *See* 21 U.S.C. § 360e(b)(1)(A)-(B) (1994).

63. *See* 21 U.S.C. § 360e(b)(1)(A).

64. *See* 21 U.S.C. § 360e(b)(1)(B).

Class III devices, on the market prior to the effective date of the MDA need not undergo premarket approval.[65] Under the "substantially equivalent" exception, a medical device marketed after the MDA's effective date avoids the rigorous premarket approval process if the device is "substantially equivalent" to either a Class III "grandfathered" device or any Class I or Class II device.[66]

Devices qualifying under either exception need only comply with the less rigorous FDA premarket notification approval (PNA) requirements.[67] Significantly, under the premarket notification process, the FDA does not evaluate the device's safety or effectiveness.[68] Rather, the FDA inquiry merely determines whether or not the device in question is "substantially equivalent" to a pre-existing device.[69] Some commentators contend that exempting devices from the more thorough review of the premarket approval process has become the rule rather than the exception.[70]

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65. *See* 21 U.S.C. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c) (1) (1997). Medical devices qualifying under this exception avoid premarket FDA scrutiny for 30 months after the FDA classifies the device in Class III, or 90 days after the FDA calls for premarket approval applications for the particular type of device. *See* 21 U.S.C. § 351(f)(2)(B) (1994); 21 U.S.C. § 360e(b).

66. *See* 21 U.S.C. §§ 360c(f)(1)(A), 360e(b)(1)(B); *see also* Jonathan S. Kahan, *Premarket Approval Versus Premarket Notification: Different Routes to the Same Market*, 39 FOOD DRUG COSM. L.J. 510, 515-18 (1984) (noting the less stringent premarket notification requirements under the "substantially equivalent" exception).

67. *See* 21 U.S.C. § 360e(b)(1)(A)-(B).

68. *Compare* 21 C.F.R. § 814.45(c) (describing premarket approval process), *with* 21 C.F.R. § 807.100(b) (describing the premarket notification process). Congressional investigation has quantified this disparate level of scrutiny noting that the FDA spends an average of 1200 hours reviewing a Class III application during the PMA process while spending only 20 hours during premarket notification approval (PNA) process. Medtronic Inc. v. Lohr, 116 S. Ct. 2240, 2246-47 (1996) (citing *Medical Devices and Drug Issues: Hearings Before the Subcommittee on Health & the Environ. of the House Comm. on Energy & Commerce*, 100th Cong. 384 (1987) (statement of James S. Benson, Deputy Director of the Center for Devices and Radiological Health)); Kahan, *supra* note 66, at 512-14.

69. *See* 21 C.F.R. § 807.100(b).

70. *See* Robert Adler, *The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 FOOD DRUG COSM. L.J. 511 (1988); Lawrence S. Makow, Note, *Medical Device Review at the Food and Drug Administration: Lessons From Magnetic Resonance Spectroscopy and Biliary Lithotripsy*, 46 STAN. L. REV. 709 (1994) (noting that exemption is faster and more common).

Overall, the MDA represents an elaborate regulatory system protecting consumers nation-wide from potentially life-threatening medical devices while balancing the unique concerns of the medical device industry.[71]

B. General Overview of Federal Pre-emption

In crafting a comprehensive regulatory scheme governing the medical device industry, Congress desired to establish a single standard for

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71. *See* King v. Collagen Corp., 983 F.2d 1130, 1138 (1st Cir. 1993) (Aldrich, J., concurring); *see also supra* notes 51-56 and accompanying text (discussing the purpose of the MDA). *Cf.* 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, 622-25 (1996). After reviewing the legislative history, Dega concludes that "the primary goal of the [MDA] remain[s] to protect public health and safety." *Id.* at 625. *Compare* United States v. Bacto-Unidisk, 394 U.S. 784, 798 (1969) ("[T]he Act's overriding purpose [is] to protect the public health."), *with* United States v. Diapulse Corp., 457 F.2d 25, 27-28 (2d Cir. 1972) (explaining that the primary purpose of the FDCA, of which the MDA is a part, is to protect the public from unsafe products and "the safeguarding of the public health by enforcement of certain standards of purity and effectiveness"). However, the *Bacto-Unidisk* and *Diapulse Corp.* decisions pre-date the adoption of the MDA in 1976 and thus cannot stand for the proposition that the "primary goal" of the MDA is to protect public health and safety. Furthermore, a careful reading of the cited cases indicates that the courts' use of the words "the Act" referred to the FDCA and the legislative history of the Food, Drug, and Cosmetic Act of 1938, not the Medical Device Amendments of 1976. In *Bacto-Unidisk*, the Court stated:

> But we are all the more convinced that we must give effect to congressional intent in view of the well-accepted principle that remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with *the Act's overriding purpose to protect the public health*, and specifically, § 507's purpose to ensure that antibiotic products marketed serve the public with "efficacy" and "safety."

Bacto-Unidisk, 394 U.S. at 798 (emphasis added).

Finally, Dega mischaracterizes Justice Aldrich's concurrence in *King*, the only post-MDA authority cited above the district court level. Read in its proper context, Justice Aldrich indicated that the legislative history points to a balanced consideration of protection of the individual user versus protection of society as a whole. *See King*, 983 F.2d at 1138 (citing S. REP. NO. 94-33, at 2, 6, 14 (1975), *reprinted in* 1976 U.S.C.C.A.N. 1070, 1071, 1075, 1083). Justice Aldrich stated:

> Concededly, the U.S. Code Congressional and Administrative News, 94th Congress, Second Session, Vol. 3, pp. 1070 *et seq.*, Medical Device Amendments of 1976, shows the principal emphasis to be on the protection of the individual user. *But it also shows the intent to "encourage . . . research and development" and "permit new and improved devices to be marketed without delay." Perfection is impossible and a few individuals may be denied full protection at the cost of benefitting the rest.*

King, 983 F.2d at 1138 (emphasis added) (citations omitted).

ensuring the safety of medical devices.[72] Also desiring to relieve the industry of burdensome state regulatory requirements, Congress turned to the doctrine of federal pre-emption.[73]

Under the Supremacy Clause of the United States Constitution, "the Laws of the United States . . . shall be the supreme Law of the Land."[74] Accordingly, the laws Congress enacts necessarily supersede state statutes[75] or local ordinances.[76] Under certain circumstances, federal laws also can pre-empt state common-law actions.[77] However, courts scrutinize federal legislation to ensure that Congress evinced a "clear and manifest" intent to pre-empt state common-law actions.[78]

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72. *See supra* notes 51-56 and accompanying text (discussing the purpose of the MDA).

73. *See* 21 U.S.C. § 360k (1994); *see also infra* note 126 (providing the complete text of § 360k).

74. U.S. CONST. art. VI, cl. 2 ("This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; . . . 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.").

75. *See, e.g.*, Schneidewind v. ANR Pipeline Co., 485 U.S. 293, 300 (1988) (holding that a state statute regulating issuance of long-term securities of natural gas pipeline companies was pre-empted by federal Natural Gas Act); Michigan Canners & Freezers Ass'n v. Agricultural Mktg. & Bargaining Bd., 467 U.S. 461, 478 (1984) (holding that a state agricultural marketing statute was pre-empted by federal Agricultural Fair Practices Act).

76. *See, e.g.*, City of Burbank v. Lockheed Air Terminal, Inc., 411 U.S. 624, 640 (1973) (stating that a municipal airport curfew was pre-empted by FAA regulation).

77. *See, e.g.*, International Paper Co. v. Ouellette, 479 U.S. 481, 500 (1987) (holding that private nuisance action against out-of-state polluters was pre-empted by federal Clean Water Act); Arkansas La. Gas Co. v. Hall, 453 U.S. 571, 582-84 (1981) (holding calculation of damages under state contract doctrines was pre-empted by Natural Gas Act); Chicago & N.W. Transp. Co. v. Kalo Brick & Tile Co., 450 U.S. 311, 331-32 (1981) (holding that state tort claim based on abandonment of services was pre-empted by Interstate Commerce Act); Old Dominion Branch No. 496, National Ass'n of Letter Carriers v. Austin, 418 U.S. 264, 270-73 (1974) (holding that state-law libel claims were pre-empted by National Labor Relations Act); Sperry v. Florida *ex rel.* Fla. Bar, 373 U.S. 379, 385 (1963) (holding that state enforcement of licensing requirements was pre-empted by federal determination); San Diego Bldg. Trades Council v. Garmon, 359 U.S. 236, 245 (1959) (holding that state tort-law action against labor union for unfair labor practice was pre-empted by National Labor Relations Act).

78. *See* Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947) (finding state police powers not pre-empted by federal acts absent a "clear and manifest" intent from Congress).

A court can find the requisite congressional intent in three general scenarios.[79] First, Congress may expressly intend to pre-empt state law as evidenced by the actual language of the statute (i.e., "express" pre-emption).[80] Second, Congress may enact a regulatory scheme so pervasive as to displace all forms of state regulation in the same field (i.e., "federal occupation-of-the-field" pre-emption).[81] Third, Congress may enact a federal law to achieve a particular objective that would be prohibited, impaired, or frustrated by the enforcement of a conflicting state law (i.e., "actual conflict" pre-emption).[82]

1. Express Pre-emption

Congress must provide specific statutory language reflecting a "clear and manifest" intent to pre-empt when it intends to pre-empt a state regulation within a particular realm.[83] For instance, in *Rice v. Santa Fe Elevator Corp.*,[84] the Supreme Court held that the United States Warehouse Act (Warehouse Act)[85] pre-empted the enforcement of Illinois laws against federally licensed warehouse operators.[86] The Court focused on a 1931 amendment to the Warehouse Act. Although the Ware-

79. *See* Pacific Gas & Elec. Co. v. State Energy Resources Conservation & Dev. Comm'n, 461 U.S. 190, 203-04 (1983) (listing various ways in which pre-emption may occur).

80. *See Pacific Gas & Elec. Co.*, 461 U.S. at 203; *see infra* notes 83-98 and accompanying text (discussing express pre-emption).

81. *See Pacific Gas & Elec. Co.*, 461 U.S. at 203-04; *see infra* notes 99-101 and accompanying text (discussing federal occupation of the field pre-emption).

82. *See Pacific Gas & Elec. Co.*, 461 U.S. at 204. *See generally* Elaine M. Martin, Note, *The Burger Court and Pre-emption Doctrine: Federalism in the Balance*, 60 NOTRE DAME L. REV. 1233, 1235-36 (1985) (distinguishing express, conflict, and occupation-of-the-field pre-emption). *But see* Hines v. Davidowitz, 312 U.S. 52, 67 (1941) (commenting that "none of these expressions provides an infallible constitutional test or an exclusive constitutional yardstick. In the final analysis, there can be no one crystal clear distinctly marked formula").

83. *See Rice*, 331 U.S. at 230 (citing Napier v. Atlantic Coast Line R.R., 272 U.S. 605, 611 (1926); Allen-Bradley Local v. Wisconsin Employment Relations Bd., 315 U.S. 740, 749 (1942)) ("[W]e 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."); *see also* Shaw v. Delta Air Lines, Inc., 463 U.S. 85, 106-08 (1983) (holding that state disability benefits law was not pre-empted by ERISA); Railway Employees' Dep't v. Hanson, 351 U.S. 225, 232 (1956) (discussing express congressional intent); South Carolina v. Katzenbach, 383 U.S. 301, 324-25 (1966) (stating Fifteenth Amendment language specific enough); Exxon Corp. v. City of New York, 548 F.2d 1088, 1091 (2d Cir. 1977) (finding explicit pre-emption language).

84. 331 U.S. 218.

85. Ch. 313, 39 Stat. 486 (1916) (codified as amended at 7 U.S.C. §§ 241-273 (1994)).

86. *See Rice*, 331 U.S. at 236-37.

house Act initially "provide[d] that although the Secretary of Agriculture 'is authorized to cooperate with State officials charged with the enforcement of State laws relating to warehouses, warehousemen' and their personnel,"[87] Congress nevertheless added the language "'the power, jurisdiction, and authority conferred upon the Secretary of Agriculture under the act shall be exclusive with respect to all persons securing a license hereunder so long as said license remains in effect.'"[88] Relying on the amendment's legislative history for guidance,[89] the Court found that Congress adopted the amended language in order to remedy past difficulties associated with a "dual system of regulation."[90] The Court concluded that Congress intended to displace state authority over all federally licensed warehouse operators.[91]

In *Fidelity Federal Savings & Loan Association v. de la Cuesta*,[92] the Court extended the express pre-emption doctrine to regulations promulgated by a federal agency.[93] In *Fidelity*, the Court addressed the issue of whether a Federal Loan Bank Board regulation concerning "due-on-sale" clauses superseded a conflicting state common law doc-

87. *Id.* at 223-24 (quoting language as originally enacted, Ch. 313, § 29, 39 Stat. 486 (current version at 7 U.S.C. § 269 (1994))).

88. *Id.* at 224 (quoting Act Mar. 2, 1931, ch. 366, § 9, 46 Stat. 1465 (1931) (current version at 7 U.S.C. § 269)).

89. *See id.* at 233-34 (citing S. REP. No. 1775, 71-3, at 2 (1931); H.R. REP. No. 4, 71-1, at 1 (1929)); H.R. REP. No. 2314, 70-2, at 4 (1928). The Court noted that the Secretary of Agriculture testified that "'[t]he amendment suggested relative to section 29 aims to make the Federal warehouse act [sic] independent of any State legislation on the subject.'" *Id.* at 223-24 n.4 (quoting *Hearing Before Senate Committee on Agriculture and Forestry on H.R. 7*, 71st Cong. 10 (3d Sess. 1929)).

90. *See id.* at 234.

91. *See id.* at 235-36.

92. 458 U.S. 141 (1982).

93. *See id.* at 170; *see also* Capital Cities Cable, Inc. v. Crisp, 467 U.S. 691, 700 (1984) (holding application of Oklahoma's alcoholic beverages advertising ban to out-of-state cable signals carried by Oklahoma cable operators pre-empted by FCC's statutory authority); Free v. Bland, 369 U.S. 663, 667-68 (1962) (holding inconsistent Texas community property law pre-empted by Treasury Regulations which created a right of survivorship in U.S. Savings Bonds); Public Utils. Comm'n v. United States, 355 U.S. 534, 544-45 (1958) (holding that California Public Utilities Commission's approval of common carrier rates were not required by United States procurement agents); Leslie Miller, Inc. v. Arkansas, 352 U.S. 187, 189-90 (1956) (holding Arkansas statute requiring state license to contract in Arkansas did not apply to federal contractor constructing on an Air Force base in Arkansas due to federal regulation of federal contractors).

trine limiting the use of due-on-sale clauses.[94] The Court found that, under the Home Owners' Loan Act of 1933,[95] Congress intended to grant the Board authority over federal savings and loan associations.[96] The Court concluded that regulations promulgated by the Board evinced a clear desire to displace state law concerning the due-on-sale clauses.[97] Accordingly, the Court held that the Board's regulation expressly pre-empted the conflicting state law.[98]

2. Federal Occupation-of-the-Field Pre-emption

The federal and state governments, at times, regulate the same area of law. When the federal regulatory scheme becomes so pervasive, however, it may displace all state regulatory action in the same area.[99] Displacement may occur in one of two manners. First, the federal regulatory interest may dominate to such an extent as to justify federal occupation-of-the-field.[100] Alternatively, a federal regulatory scheme may be so pervasive as to completely occupy a particular field, thus negating any state regulations in that field.[101]

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94. *See Fidelity*, 458 U.S. at 144.

95. 12 U.S.C. § 1461 (1994).

96. *See Fidelity*, 458 U.S. at 159-67.

97. *See id.* at 158.

98. *See id.* at 170.

99. *See, e.g.*, Amalgamated Ass'n of St., Elec. Ry. & Motor Coach Employees v. Lockridge, 403 U.S. 274, 296 (1971) (holding employment-related complaint was within the National Labor Relations Board's exclusive jurisdiction); Guss v. Utah Labor Relations Bd., 353 U.S. 1, 10-11 (1957) (holding National Labor Relations Board had exclusive jurisdiction over labor relations affecting interstate commerce); Napier v. Atlantic Coast Line R.R., 272 U.S. 605, 612-13 (1926) (holding state legislation was precluded by the Boiler Inspection Act, which regulated locomotive equipment on interstate highways); Pennsylvania R.R. v. Public Serv. Comm'n, 250 U.S. 566, 569 (1919) (holding Pennsylvania law requiring a certain platform on train cabooses "invade[d] a subject of regulation fully occupied by Congress"); Southern Ry. v. Railroad Comm'n, 236 U.S. 439, 447 (1915) (holding Indiana law requiring grab-ons and hand-holds on railroad cars used in interstate commerce was superseded by the Safety Appliance Act).

100. *See* San Diego Bldg. Trades Council v. Garmon, 359 U.S. 236 (1959) (holding that the National Labor Relations Board's dominant interest in regulating labor relations effectively ousted a state court from awarding damages for a union's unfair labor practices).

101. *See* Schneidewind v. ANR Pipeline Co., 485 U.S. 293 (1988) (holding that Federal Energy Regulatory Commission's pervasive authority over the financial activities of natural gas companies effectively precluded state regulation of gas company rates and facilities). *But see* Hillsborough County v. Automated Med. Lab., Inc., 471 U.S. 707 (1985) (finding that FDA's comprehensive regulation of blood products alone was not enough to exclude more extensive state regulation).

3. Actual Conflict Pre-emption

When a federal statute or regulation conflicts with state law, the federal statute or regulation prevails.[102] A conflict may arise in one of three ways: (1) when state law requires action that federal law prohibits, or vice versa;[103] (2) when a state law diminishes or interferes with the exercise of a federal right;[104] or (3) when state law frustrates the objectives of federal law without openly conflicting with it.[105]

4. *Cipollone v. Liggett Group, Inc.*

In 1992, the Court in *Cipollone v. Liggett Group, Inc.*[106] addressed the issue of whether the Federal Cigarette Labeling and Advertising Act of 1965 (FCLAA)[107] and the Public Health Cigarette Smoking Act of 1969 (PHCSA)[108] pre-empted various state common law tort

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102. *See, e.g., Fidelity*, 458 U.S. at 153.

103. *See* McDermott v. Wisconsin, 228 U.S. 115, 137 (1913) (holding that FDA labeling requirement made it impossible to comply with state labeling statute and thus the state law was pre-empted).

104. *See* Wissner v. Wissner, 338 U.S. 655 (1950) (holding that state community property law that diminishes right to military insurance policies is pre-empted).

105. *See* International Paper Co. v. Ouellette, 479 U.S. 481 (1987) (holding pre-emptive effect where state law designed to protect water pollution interfered with federal methods of achieving the same goal); Michigan Canners & Freezers Ass'n v. Agricultural Mktg. & Bargaining Bd., 467 U.S. 461 (1984) (finding pre-emptive effect where state organizing of agricultural growers would frustrate federal regulatory intentions of safeguarding growers' choice of marketing products). *But see* Silkwood v. Kerr-McGee Corp., 464 U.S. 238 (1984) (upholding state court award of punitive damages against nuclear power plant despite potential interference with Nuclear Regulatory Commission's punitive system of civil fines).

106. 505 U.S. 504 (1992).

107. Pub. L. No. 89-92, 79 Stat. 282 (1965) (codified as amended at 15 U.S.C. §§ 1331-1341 (1994)). The pre-emption language in the Federal Cigarette Labeling and Advertising Act of 1965 (FCLAA) provides in part as follows:

> (a) No statement relating to smoking and health, other than the statement required by section 4 of this Act, shall be required on any cigarette package.
> (b) No statement relating to smoking and health shall be required in the advertising of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.

Id. at § 5(a)-(b), 1965 U.S.C.C.A.N. (79 Stat.) 300.

108. Pub. L. No. 91-222, 84 Stat. 87 (1970) (codified as amended at 15 U.S.C. §§ 1331-1340 (1994)). The Public Health Cigarette Smoking Act of 1969 (PHCSA) amended the pre-emption provision in § 5(b) of the FCLAA to read as follows: "(b)

claims.[109] First, the Court held that the FCLAA did not pre-empt any state law damages claim.[110] Further, the Court held that the PHCSA expressly pre-empted a state tort claim for improper warning labels on cigarette advertising.[111] Finally, the Court held that the PHCSA did not necessarily pre-empt state claims for breach of express warranty, misrepresentation, or conspiracy.[112]

In *Cipollone*, the plaintiffs, a husband, and his wife who died of lung cancer, alleged that various cigarette companies failed to provide adequate warnings about the risks of smoking, that they expressly warranted their products as not dangerous to the health of consumers, and that they attempted to neutralize the effects of statutorily required warnings.[113] The plaintiffs further alleged that the cigarette companies ignored medical evidence about the dangers of smoking and conspired to prevent such medical evidence from reaching the general public.[114] The cigarette companies contended that the FCLAA and the PHCSA pre-empted all the state tort claims.[115]

Justice Stevens, writing for a plurality of the Court, postulated that the Court's analysis should be guided by the fact that "'the historic police powers of the States [are] not to be superseded by . . . Federal Act[s] unless that [is] the clear and manifest purpose of Congress.'"[116] Thus, "'"[t]he purpose of Congress is the ultimate touchstone of pre-emption analysis."'"[117] Justice Stevens found that when a statute contains an express pre-emption provision, implied theories of pre-emption

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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." *Id.* at § 5(b), 1970 U.S.C.C.A.N. (84 Stat.) 95.

109. *See Cipollone*, 505 U.S. at 508.

110. *See id.* at 519-20.

111. *See id.* at 524.

112. *See id.* at 525-30. The Supreme Court summarized its holding stating:

> The 1965 Act [FCLAA] did not pre-empt state-law damages actions; the 1969 Act [PHCSA] pre-empts petitioner's claims based on a failure to warn and the neutralization of federally mandated warnings to the extent that those claims rely on omissions or inclusions in respondents' advertising or promotions; the 1969 Act does not pre-empt petitioner's claims based on express warranty, intentional fraud and misrepresentation, or conspiracy.

Id. at 530-31.

113. *See id.* at 509-10.

114. *See id.*

115. *See id.* at 510.

116. *Id.* at 516 (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)) (alterations in original).

117. *Id.* (quoting Malone v. White Motor Corp., 435 U.S. 497, 504 (1978) (quoting Retail Clerks v. Schermerhorn, 375 U.S. 96, 103 (1963)).

should not be controlling.[118] In other words, when Congress intends to define a particular area for pre-emption, all other areas presumptively should be excluded from pre-emption.[119]

Justice Stevens examined whether the FCLAA expressly prohibited any "'requirement or prohibition based on smoking and health . . . imposed under State law with respect to . . . advertising or promotion.'"[120] Applying the principles propounded, Justice Stevens concluded in the affirmative, reasoning that the duty to warn is "a state-law 'requirement . . . with respect to . . . advertising or promotion.'"[121] Accordingly, the warning claims were pre-empted to the extent that they penalized the cigarette companies for failing to provide warnings over and above those required by federal law.[122] Justice Stevens found, however, that the breach of warranty, fraudulent misrepresentation, and conspiracy claims did not have the same effect and therefore should not be pre-empted.[123]

C. Federal Pre-emption and the Medical Device Amendments

Similar to the Federal Cigarette Labeling and Advertising Act at issue in *Cipollone*,[124] Congress also explicitly provided for federal pre-emption under the Medical Device Amendments.[125] Specifically, 21 U.S.C. § 360k provides that the MDA pre-empts any state and local "requirement (1) which is different from, or in addition to, any requirement applicable under the [MDA], and (2) which relates to the safety or ef-

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118. *See id.* at 517. Justice Stevens wrote:

> When Congress has considered the issue of pre-emption and has included in the enacted legislation a provision explicitly addressing that issue, and when that provision provides a reliable indicium of congressional intent with respect to state authority, there is no need to infer congressional intent to pre-empt state laws from the substantive provisions of the legislation.

Id. (citations omitted).

119. *See id.*

120. *Id.* at 524 (quoting Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, § 5(b), 84 Stat. 87 (1970) (codified as amended at 15 U.S.C. §§ 1331-1340 (1994))).

121. *Id.* (quoting Public Health Cigarette Smoking Act of 1969 § 5(b)).

122. *See id.* at 524-25.

123. *See id.* at 525-31.

124. *See supra* notes 106-23 and accompanying text (discussing the *Cipollone* case).

125. *See* 21 U.S.C. § 360k (1976).

fectiveness of the device or to any other matter included in a requirement applicable to the device under the [MDA]."[126]

Just as the Justices of the Supreme Court could not find consensus in *Cipollone*,[127] the courts of appeals have disagreed on whether and to what extent the Medical Device Amendments pre-empt state common law actions.[128] Three distinct interpretations of the MDA's pre-emptive powers have emerged from the circuit courts. Depending on the circuit, a court may find that the MDA pre-empts *all* state tort claims,[129] *some* state tort claims,[130] or *no* state tort claims.[131]

The circuits which hold that the MDA pre-empts all state common law claims[132] find that the MDA's pre-emption clause[133] pre-empts a

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126. *Id.* § 360k(a)(1)-(2). Section 360k provides in full:

> 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.
> (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 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.

127. *Cipollone*, 505 U.S. 504 (1992) (plurality opinion).

128. *See* Dega, *supra* note 71, at 633-46 (describing the split in the circuits over MDA pre-emption).

129. *See* Talbott v. C.R. Bard, Inc., 63 F.3d 25 (1st Cir. 1995) (holding that the MDA pre-empts all state tort claims), *cert. dismissed*, 116 S. Ct. 1892 (1996).

130. *See* Lohr v. Medtronic, Inc., 56 F.3d 1335 (11th Cir. 1995) (holding that the MDA pre-empts some state tort claims), *aff'd in part and rev'd in part*, 116 S. Ct. 2240 (1996).

131. *See* Kennedy v. Collagen Corp., 67 F.3d 1453 (9th Cir. 1995) (holding that the MDA does not pre-empt any state tort claims).

132. *See, e.g.*, Martello v. CIBA Vision Corp., 42 F.3d 1167 (8th Cir. 1994) (holding

state "requirement" that "establishes a new substantive requirement for [a] device in a regulated area."[134] These courts reason that 21 U.S.C.

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that the MDA pre-empts state product liability claims); Gile v. Optical Radiation Corp., 22 F.3d 540 (3d Cir. 1994) (holding that the MDA pre-empts product liability and negligence claims); Mendes v. Medtronic, Inc., 18 F.3d 13 (1st Cir. 1994) (holding that the MDA pre-empts negligent manufacture, distribution, failure to warn, and breach of implied warranty claims); Stamps v. Collagen Corp., 984 F.2d 1416 (5th Cir. 1993) (holding that the MDA pre-empts defective design, inadequate warnings, and negligent failure to warn claims); King v. Collagen Corp., 983 F.2d 1130 (1st Cir. 1993) (holding that the MDA pre-empts all state tort claims.).

133. 21 U.S.C. § 360k(a) (1994). See *supra* note 126, for the complete text of § 360k.

134. *King*, 983 F.2d at 1134-35 (citing 21 C.F.R. § 808.1(d)(6)(ii) (1995)). FDA regulations interpreting the pre-emptive effect of § 360k of the Medical Device Amendments provide:

> (d) 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. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:
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> . . .
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> (6) (i) Section 521(a) does not preempt State or local requirements respecting general enforcement, e.g., requirements that State inspection be permitted of factory records concerning all devices, registration, and licensing requirements for manufacturers and others, and prohibition of manufacture of devices in unlicensed establishments. However, Federal regulations issued under sections 519 and 520(f) of the act may impose requirements for records and reports and good manufacturing practices beyond those prescribed in State or local requirements. If there is a conflict between such regulations and State or local requirements, the Federal regulations shall prevail.
>
> (ii) Generally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices. Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the prohibition will be pre-empted if the requirement is different from, or in addition to, a Federal requirement established under the act. In determining whether such a requirement is pre-empted, the determinative factor is how the requirement is interpreted and enforced by the State or local government and not the literal language of the statute, which may be identical to a provision in the act.

21 C.F.R. § 808.1(d)(6)(i)-(ii).

§ 360k provides for broad pre-emption that encompasses all state tort actions that are "different from, or in addition to" the MDA.[135] These courts, therefore, conclude that any successful claim must be pre-empted, equating a judgment to a state-created requirement differing or surpassing FDA regulations on the manufacturer.[136]

Other circuits have adopted a different approach, resulting in the pre-emption of only some state tort claims.[137] These courts interpret 21 U.S.C. § 360k to include state common law actions within the meaning of the term "requirement."[138] Contrary to the teachings of *Cipollone*[139] which limit statutory interpretation to the plain meaning of the statute, some courts look to the FDA's regulations for guidance.[140] Courts seeking guidance from 21 C.F.R. § 808.1(d)[141] of the FDA regulations conclude that a state tort action is only pre-empted if the tort action conflicts with the MDA or FDA regulations pertaining to a particular process, procedure, or device.[142] Thus, pre-emption is evoked only when the state tort claim would create a requirement that

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135. 21 U.S.C. § 360k (1995); *See Stamps*, 984 F.2d at 1421; 21 C.F.R. § 808.1(b) (1996).

136. *See King*, 983 F.2d at 1135-36.

137. *See, e.g.*, Mitchell v. Collagen Corp., 67 F.3d 1268 (7th Cir. 1995) (holding that the MDA pre-empts express warranty claim, if properly established, but does not pre-empt implied warranty, mislabeling, and fraud claims); Lohr v. Medtronic, Inc., 56 F.3d 1335 (11th Cir. 1995) (holding that the MDA pre-empted two state tort claims, but did not pre-empt two others), *aff'd in part and rev'd in part*, 116 S. Ct. 2240 (1996); Feldt v. Mentor Corp., 61 F.3d 431 (5th Cir. 1995) (holding that the MDA does not pre-empt design defect claims against manufacturers, but does pre-empt marketing defect, manufacturing defect, and inadequate warning claims); Michael v. Shiley, Inc., 46 F.3d 1316 (3d Cir. 1995) (holding that the MDA does not pre-empt express warranty and fraud in advertising claims, but does pre-empt negligence, strict liability, breach of implied warranty, and fraud claims).

138. *See Lohr*, 56 F.3d at 1342.

139. 505 U.S. at 517; *see supra* notes 106-23 and accompanying text (discussing the *Cipollone* case).

140. *See Lohr*, 56 F.3d at 1344. Giving deference to the agency's interpretations, the Eleventh Circuit focused on § 808.1(d) of the FDA regulations and interpreted the term requirement to mean "specific requirement." *See id.* at 1344-45 (citing Hillsborough County v. Automated Medical Lab., Inc., 471 U.S. 707, 712-14 (1985) (finding regulations promulgated by a federal agency are to be given deference in interpreting statutory meaning)).

141. 21 C.F.R. § 808.1(d) (1996).

142. *See Lohr*, 56 F.3d at 1346. The Eleventh Circuit held that the MDA did not pre-empt a negligent design claim because neither the statute nor the FDA regulations "establish[ed] any specific design requirements . . . conflict[ing] with the state law claim." *See id.* at 1349. The court concluded, however, that FDA regulation of manufacturing and labeling practices required pre-emption of state claims for negligent manufacturing and failure to warn claims in that successful claims would be "different from or in addition to" the FDA requirements. *See id.* at 1350-51.

is "different from or in addition to" the MDA requirements or the FDA regulations.[143]

Finally, a small but growing number of courts have held that the MDA can *never* pre-empt a state tort claim.[144] By adhering strictly to the plain meaning of 21 U.S.C. § 360k of the MDA, these courts hold that Congress did not intend a "requirement" to include a state common law action.[145] Additionally, these courts use the FDA regulations to bolster their position that Congress did not intend to pre-empt state tort actions.[146]

Against this background, the Supreme Court decided *Medtronic, Inc. v. Lohr*.[147]

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143. *See id.* at 1350-51.

144. *See, e.g.*, Mulligan v. Pfizer, Inc., 850 F. Supp. 633 (S.D. Ohio 1994) (holding that the MDA did not pre-empt the strict liability, negligence, and breach of implied warranty claims of a user of a prosthetic knee device); Oja v. Howmedica, Inc., 848 F. Supp. 905 (D. Colo. 1994) (finding that the MDA did not pre-empt a products liability claim under state law for an allegedly defective hip replacement device); Desmarais v. Dow Corning Corp., 712 F. Supp. 13 (D. Conn. 1989) (concluding that the MDA did not pre-empt the state-based claim of failure to warn with regard to breast implants); Callan v. G.D. Searle & Co., 709 F. Supp. 662 (D. Md. 1989) (holding that a plaintiff's state tort claims were not pre-empted as a result of her injuries sustained due to use of an intrauterine device); Kociemba v. G.D. Searle & Co., 680 F. Supp. 1293 (D. Minn. 1988) (concluding that the state law products liability claim of an intrauterine device user was not pre-empted by the MDA); Larsen v. Pacesetter Sys., Inc., 837 P.2d 1273 (Haw. 1992) (concluding that an implied warranty claim for injuries caused by defective pacemaker was not pre-empted by the MDA); Haudrich v. Howmedica, Inc., 642 N.E.2d 206 (Ill. App. Ct. 1994) (ruling that the MDA did not pre-empt a common law products liability claim against a knee implant manufacturer), *aff'd*, 662 N.E.2d 1248 (Ill. 1996); Fogal v. Steinfeld, 620 N.Y.S.2d 875 (N.Y. Sup. Ct. 1994) (holding that the defective design, breach of warranty, and failure to warn claims against a pacemaker manufacturer were not pre-empted).

145. *See* Kennedy v. Collagen Corp., 67 F.3d 1453, 1457 (9th Cir. 1995) (holding that the MDA does not pre-empt any state common law claims including negligence, strict liability, breach of warranty, battery, conspiracy and loss of consortium). The Ninth Circuit noted that precedent dictated a presumption against finding pre-emption. *See id.* Further, the court determined that Congress failed to define a "state requirement" subject to pre-emption and noted the absurd results under other courts' interpretations of 21 U.S.C. § 360k. *See id.* at 1457-59.

146. *See id.* at 1459. Deferring to the FDA interpretation of 21 U.S.C. § 360k, the Ninth Circuit found that 21 C.F.R. § 808.1(d) did not pre-empt generally applicable requirements, but rather only "specific requirements." *See id.* at 1459. The court concluded that a state tort action constituted a generally applicable law and, therefore, could not be pre-empted by the MDA. *See id.*

147. 116 S. Ct. 2240 (1996).

III. SUMMARY OF FACTS

In 1987, doctors surgically implanted a pacemaker in the chest of Lora Lohr.[148] Three years later, the pacemaker failed, allegedly causing Lohr to suffer severe injuries that required her to undergo emergency surgery to replace her pacemaker.[149] Medtronic, Inc., the manufacturer of Lohr's pacemaker, received FDA approval to place the Class III device in the marketplace after only cursory review.[150] Lohr, and her husband, filed a civil suit in Florida state court pleading four theories of liability: three under negligence (design, manufacturing, failure to adequately warn) and one under strict liability (defective device, unreasonably dangerous at time of sale).[151] Medtronic removed the case to the federal district court and filed a motion for summary judgment, arguing that 21 U.S.C. § 360k(a) of the MDA pre-empted all state law claims.[152] The district court eventually agreed with the defendant and dismissed the action.[153] The Eleventh Circuit reversed in part and affirmed in part, holding that the MDA pre-empted the Lohrs' negligent manufacturing and warning claims, but that the strict liability and negligent design claims were not pre-empted.[154] On cross-petitions, the United States

148. *See* Brief for Cross-Petitioners, *supra* note 3, at 1.

149. *See id.* at 2.

150. *See id.* at 7-8; *supra* notes 60-70 and accompanying text (discussing premarket approval of Class III devices under the MDA). Medtronic's pacemaker and leads qualified as "substantially equivalent" devices requiring review under the less rigorous premarket notification requirements of § 510(k). *See Medtronic*, 116 S. Ct. at 2246-47 (citing *Hearings before the Subcommittee on Health and the Environment of the House Committee on Energy & Commerce*, 100th Cong. 384 (1987)) (noting that the FDA spends an average of 1200 hours reviewing Class III application during the PMA process, while only 20 hours on average in the premarket notification review). Further, statistics indicate that over 80% of all Class III medical devices on the market in 1990 did not go through the rigorous PMA process. *See id.* at 2247.

151. *See id.* at 2248. Specifically, Lohr "alleged that Medtronic had designed, manufactured, and assembled its pacemaker in an unreasonably dangerous manner and that the pacemaker was prone to sudden catrostraphic failure. [Lohr] further alleged that Medtronic had failed to warn Ms. Lohr or her physicians of the product's threatening tendency to life-threatening failure." Brief for Cross-Petitioners, *supra* note 3, at 8-9. The district court dismissed a breach of warranty cause of action finding that Lohr failed to state a claim under Florida law. *See Medtronic*, 116 S. Ct. at 2248.

152. *See id.*

153. *See id.* The district court initially denied Medtronic's motion for summary judgment, but subsequently granted the motion on reconsideration in light of *Duncan v. Iolab Corp.*, 12 F.3d 194 (11th Cir. 1994). *See id.* at 2249.

154. *See id.*; Lohr v. Medtronic, Inc., 56 F.3d 1335, 1352 (11th Cir. 1995). In pre-empting *some* of Lohr's state tort claims, the Eleventh Circuit followed the holdings and rationale of three other circuits. *See Lohr*, 56 F.3d at 1352; *supra* notes 124-46 and accompanying text (discussing the holdings of pre-emption cases under the MDA in the Third, Fifth, Seventh, and Eleventh circuits). Following the rationale of these

circuits, the Eleventh Circuit focused on two threshold questions, namely: (1) what constitutes a "State requirement," and (2) what constitutes a "requirement" under the MDA? *See Lohr*, 56 F.3d at 1342 (citing 21 U.S.C. § 360k (1994)). First, the court found that a "state requirement" under 21 U.S.C. § 360k included state common law tort actions. *See id.* (citing Duncan v. Iolab Corp., 12 F.3d 194 (11th Cir. 1995) (holding various state tort claims pre-empted by the MDA)).

Next, the Eleventh Circuit turned to what constituted an "MDA requirement" under 21 U.S.C. § 360k. *See id.* at 1343. The court relied on the interpretation of 21 U.S.C. § 360k in the FDA regulations for guidance to determine the meaning of requirement. *See id.* Finding that the *Cipollone* decision did not prohibit it from relying on an agency's interpretation of a pre-emption clause, the court stated:

> While the opinion speaks only of "the express language" of the statutes, neither of the statutes examined in *Cipollone* had regulations interpreting its pre-emptive scope and nothing in the opinion indicates that the issue of pre-emption regulations was ever raised or considered . . . . We are therefore unable to conclude that *Cipollone* created an express pre-emption rule which forecloses our examination of the FDA's regulations.

Id. at 1343-44. The Eleventh Circuit opined that the principle of giving deference to an agency's regulatory interpretation of a statute was "well established." *See id.* at 1344 (citing NationsBank N.A. v. Variable Annuity Life Ins. Co., 513 U.S. 251 (1995); Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 841-43 (1984)). Accordingly, the Eleventh Circuit found the FDA's pre-emption regulations reasonable and worthy of deference. *See id.* at 1345. Unfortunately, the FDA pre-emption regulation provided only modest clarification. *See id.* Following the holdings of the First, Third, Fifth, and Eighth Circuits, the court rejected a finding that specific requirement meant a "device-specific requirement." *See id.* at 1346. Rather, the court held that "pre-emption-triggering requirements should, in some way, be 'restricted by nature' to a particular process, procedure, or device and should not be completely open-ended." *Id.* (footnote omitted).

Turning to the specifics of Lohr's particular claims, the Eleventh Circuit evaluated each claim to determine if the "state requirement" was "different from, or in addition to" the "specific MDA requirement." *See id.* Under this approach, the court concluded that the negligent design claims were not pre-empted because FDA regulations did not establish any specific requirements governing design. *See id.* at 1347. The court rejected Medtronic's arguments that the "substantially equivalent" process or that the FDA's continued surveillance of design changes impacted the safety of the design. *See id.* at 1347-49.

To the contrary, the court held that the negligent manufacturing claims were pre-empted. *See id.* at 1350. The court found that the negligent manufacturing claim would create a "state requirement" when a jury determined how a *reasonable manufacturer* should assemble a pacemaker and its leads. *See id.* Further, the court concluded that the reasonable manufacturer standard would be "different from, or in addition to" the Good Manufacturing Practices (GMP), 21 C.F.R. §§ 801.1-820.198 (1996), which constituted specific requirements under the MDA. *See id.* Likewise, the court held that the MDA pre-empted plaintiff's negligent failure to warn claim. *See id.* at 1351. The court observed that a jury determination of what constituted a reason-

Supreme Court granted certiorari to determine if and to what extent the MDA pre-empted the state common law claims.[155]

IV. ANALYSIS OF THE CASE

The Supreme Court reversed the judgment of the court of appeals "insofar as it held that any of the claims were pre-empted and affirmed insofar as it rejected the pre-emption defense."[156] The three separate opinions elucidate the disparate approaches of the Justices.

A. Justice Stevens's Opinion

1. Plurality Opinion

Delivering the opinion of the Court,[157] Justice Stevens examined Medtronic's contention that 21 U.S.C. § 360k pre-empts "any and all common-law claims."[158] Justice Stevens found the argument "not only unpersuasive, [but] implausible."[159] He recognized that granting pre-emption of all common-law claims via the MDA was tantamount to giving all medical device manufacturers complete immunity against civil suits for their defective products.[160]

Furthermore, Justice Stevens found that Congress's use of the word "requirement" in the MDA provided an altogether different intent.[161] Distinguishing the language under the Public Health Cigarette Smoking

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able warning could be "different from, or in addition to" the FDA's labeling requirements, 21 C.F.R. § 801.109 (1996). *See id.* Accordingly, the court upheld the district court's finding that the MDA pre-empted the negligent manufacturing and negligent warning claims. *See id.* at 1350-51.

Finally, the court addressed the strict liability claim that Medtronic introduced an unreasonably dangerous product into the market. *See id.* at 1351. The court held that the strict liability claim generally was not pre-empted; however, any contention that the manufacturing or labeling of the product created the unreasonable dangerousness, the claim would be pre-empted. *See id.* at 1352.

155. Medtronic, Inc. v. Lohr, 116 S. Ct. 806 (1996), *aff'd in part and rev'd in part*, 116 S. Ct. 2240 (1996). The Court noted that the courts of appeals were divided over the extent of pre-emption afforded common-law claims under the MDA. *See Medtronic*, 116 S. Ct. at 2250 n.6; *see also supra* notes 127-46 and accompanying text (discussing the three different approaches used by courts of appeals).

156. *Medtronic*, 116 S. Ct. at 2259.

157. *See id.* at 2245. Justice Stevens delivered the opinion of the Court as to Parts I, II, III, V, and VII, and the plurality opinion in Parts IV and VI joined only by Justices Kennedy, Souter, and Ginsburg. *See id.*

158. *See id.* at 2251.

159. *Id.*

160. *See id.*

161. *See id.* at 2252.

Act of 1969 at issue in *Cipollone*,[162] Justice Stevens clarified that the cigarette labeling statute narrowly restricted only requirements "involving the 'advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of' the [Public Health Cigarette Smoking Act]."[163] Conversely, 21 U.S.C. § 360k's broadly worded prohibitions would "require far greater interference with state legal remedies, producing a serious intrusion into state sovereignty while simultaneously wiping out the possibility of remedy for the Lohrs' alleged injuries."[164]

Finally, turning to the legislative intent underlying the MDA, Justice Stevens found that the overriding intent of Congress was "'to provide for the safety and effectiveness of medical devices intended for human use.'"[165] Although Congress may have intended to "protect innovations in device technology from being 'stifled by unnecessary restrictions,'"[166] the plurality found that such an intent was directed at over-regulation rather than pre-existing common law duties.[167]

2. Application to the Lohrs' Claims

Justice Stevens turned to the issue of whether the MDA pre-empted the Lohrs' particular state law claims.[168]

a. Design defect claim—Unanimous opinion

The Court unanimously held that the Lohr's design defect claim was

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162. 505 U.S. 504 (1992) (plurality opinion); *see supra* notes 106-23 and accompanying text (discussing the historical significance of *Cipollone*).

163. *Medtronic*, 116 S. Ct. at 2252 (quoting *Cipollone*, 505 U.S. at 515).

164. *Id.* The Court also gave credence to the fact that the pre-emptive effect in *Cipollone* was derived from Congressional action whereas the action in *Medtronic* was derived from agency action. *See id.* at 2252 n.9.

165. *Id.* at 2253 (quoting Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified as amended in scattered sections of 15 U.S.C., 21 U.S.C., 42 U.S.C.)); *see supra* note 71 (criticizing the misguided notion that the "overriding" or "primary" intent of Congress in passing the MDA was the protection of the individual).

166. *Medtronic*, 116 S. Ct. at 2253 (quoting Brief for Petitioner, *supra* note 1, at 3 (quoting H.R. REP. NO. 94-853, at 12 (1976))).

167. *See id.*

168. *See id.* at 2253-58.

not pre-empted.[169] The Court noted that Medtronic's defective pacemaker lead entered the market under the § 510(k)[170] process which "'focus[es] on *equivalence*, not safety.'"[171] The Court reasoned that a device "substantially equivalent" to a pre-existing device is not necessarily safe or effective.[172] Thus, a plaintiff is not pre-empted from bringing a design defect cause of action for a product gaining market access via the § 510(k) process.[173]

b. Breach of a duty claim—Unanimous opinion

The full Court also agreed that the MDA did not pre-empt a breach of a duty claim against a manufacturer that also violates a federal statute or regulation.[174] The Court concluded that "[n]othing in § 360k denies [a state] the right to provide a traditional damages remedy for violations of common law duties when those duties parallel federal requirements."[175] The Court reasoned that such state-law causes of action granting damages do not constitute a requirement different from, or in addition to, any requirement applicable under the MDA.[176]

c. Manufacturing and labeling claims—Plurality opinion

A plurality of the Court held that the Lohrs' manufacturing and warning defect claims were not pre-empted.[177] The plurality deferred to the FDA's regulations and judgment that "state requirements are pre-empted 'only' when the FDA has established 'specific counterpart regulations

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169. *See id.* at 2255.

170. 21 U.S.C. § 360c(f)(2)(C)(ii) (1994). Under the premarket notification process (also referred to as the "510(k) mechanism" and "substantial equivalence" method), a company may market and distribute a new device without first obtaining FDA approval if the manufacturer establishes that the device is "substantially equivalent" to a device that has already been approved. *See id.*; H.R. CONF. REP. NO. 94-1090, at 56-57 (1976), *reprinted in* 1976 U.S.C.C.A.N. 1070, 1103-18; *see also* BRADLEY M. THOMPSON, FDA REGULATION OF MEDICAL DEVICES 41-58 (1995) (providing a detailed description of the premarket notification procedure, the substantial equivalence method, the § 510(k) process, and other special rules). The FDA requires significantly less information for premarket notification than for a PMA application. *See supra* notes 61-70 and accompanying text (discussing the PMA process).

171. *Medtronic*, 116 S. Ct. at 2254 (quoting Lohr v. Medtronic, Inc., 56 F.3d 1335, 1348 (11th Cir. 1995), *aff'd in part, rev'd in part, Medtronic*, 116 S. Ct. 2240).

172. *See id.*

173. *See id.* at 2255.

174. *Id.* at 2255-56.

175. *Id.* at 2255.

176. *See id.*; *see also supra* notes 72-146 and accompanying text (discussing federal pre-emption).

177. *See Medtronic*, 116 S. Ct. at 2256-58.

or . . . other specific requirements applicable to a particular device.'"[178] Finding that tort actions reflect only "generic concerns about device regulation generally," and that "general state common-law requirements . . . were not specifically developed 'with respect to' medical devices," Justice Stevens concluded that the Lohrs' claims did not constitute "requirements" pre-empted by federal law.[179]

3. An Issue Left Open

The Court left open the issue of whether the MDA pre-empts claims regarding a device that obtained premarket approval.[180] The Court stated that it need not resolve hypothetical cases and believed "[i]t will be rare indeed for a court hearing a common-law cause of action to issue a decree that has 'the effect of establishing a substantive requirement for a specific device.'"[181]

B. Justice Breyer's Opinion

Justice Breyer, concurring in part and concurring in the judgment, raised two questions: "First, do the Medical Device Amendments (MDA) . . . ever pre-empt a state law tort action? Second, if so, does the MDA pre-empt the particular state-law tort claims at issue here?"[182] To the first question, Justice Breyer adopted Justice O'Connor's rationale and found that the MDA will sometimes pre-empt a state-law tort claim.[183] To the second question, Justice Breyer turned to the intent of Congress, finding that Lohr's claims were not pre-empted by the MDA.[184]

178. *Id.* at 2257 (quoting 21 C.F.R. § 808.1(d) (1995) (current version at 21 C.F.R. § 801.1(d) (1997))) (omission in original).

179. *See id.* at 2258.

180. *See id.* at 2259.

181. *Id.* (quoting 21 C.F.R. § 808.1(d)(6)(ii) (1995) (current version at 21 C.F.R. § 801.1(d)(6)(ii) (1997))).

182. *Id.* (Breyer, J., concurring in part and concurring in the judgment).

183. *See id.* at 2259-60 (Breyer, J., concurring in part and concurring in the judgment).

184. *See id.* at 2260-61 (Breyer, J., concurring in part and concurring in the judgment).

C. *Justice O'Connor's Opinion*

Justice O'Connor, joined by Chief Justice Rehnquist and Justices Scalia and Thomas, concurred in part and dissented in part.[185] The dissent reasoned that *Cipollone* was controlling and commanded that the phrase "no requirement or prohibition" included certain state law claims.[186] Justice O'Connor concluded, contrary to the plurality, that the term "requirement" in the MDA includes state common law tort actions.[187] Accordingly, the MDA pre-empts such state-law tort claims "to the extent that their recognition would impose 'any requirement' different from, or in addition to, FDCA requirements applicable to the device."[188] Justice O'Connor concluded that the design defect claim is not pre-empted because under the § 510(k) "substantial equivalency" process, no federal requirements have been placed on Medtronic's pacemaker device.[189]

Furthermore, the dissenters agreed that a state tort action based on a violation of a federal requirement (i.e., the FDCA or a FDA regulation) would not be pre-empted.[190] Justice O'Connor reasoned that a state action requiring a standard of care equal to the federal requirements does not create a requirement "different from, or in addition to" any federal requirement.[191]

Justice O'Connor disagreed, however, with the Court's conclusion that state common law claims not based on a violation of a federal requirement survive pre-emption.[192] Justice O'Connor took issue with the plurality's use of the FDA's regulations in order to determine the meaning of "requirement" as used in the MDA pre-emption provision.[193] Accordingly, the dissent more broadly defined "requirement" to

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185. *See id.* at 2262-64 (O'Connor, J., concurring in part and dissenting in part).

186. *See id.* at 2262-63 (O'Connor, J., concurring in part and dissenting in part).

187. *See id.* at 2263 (O'Connor, J., concurring in part and dissenting in part) (noting that Justice Breyer's separate opinion is consistent with the notion that the term requirement encompasses state common law tort actions).

188. *Id.* (O'Connor, J., concurring in part and dissenting in part).

189. *See id.* at 2263-64 (O'Connor, J., concurring in part and dissenting in part). Justice O'Connor specifically noted that the § 510(k) review process for substantially equivalent devices places no requirements on the manufacturer and the FDA merely determines if the new device is equivalent to a pre-1976 device. *See id.* at 2264 (O'Connor, J., concurring in part and dissenting in part).

190. *See id.* at 2264 (O'Connor, J., concurring in part and dissenting in part).

191. *See id.* (O'Connor, J., concurring in part and dissenting in part).

192. *See id.* (O'Connor, J., concurring in part & dissenting in part).

193. *See id.* (O'Connor, J., concurring in part and dissenting in part). "'If the statute contains an express pre-emption clause, the task of statutory construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent.'" *Id.* at 2263 (O'Connor, J., concur-

include a state tort action and did not require that the state claim be "device-specific."[194] Therefore, the dissenters found, in contrast to the plurality, that the manufacturing defect and failure-to-warn claims should be pre-empted.[195] Justice O'Connor reasoned that the manufacturing and failure-to-warn claims, if successful, would create state-created requirements differing from the FDA's Good Manufacturing Practice (GMP)[196] and labeling requirements.[197]

V. IMPACT OF THE DECISION

The *Medtronic* holding will have immediate and far reaching effects. First, the immediate impact will be felt by the parties to six medical devices cases remanded for further consideration in light of the *Medtronic* decision.[198] The holdings of the courts of appeals could have lasting ramifications for the medical devices industry and customers who rely on their products.[199] In addition to federal regulation of the medical devices industry, many other federal regulatory schemes contain pre-emption clauses.[200] Analyzing the methodology of statutory

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ring in part and dissenting in part) (quoting CSX Transp., Inc. v. Easterwood, 507 U.S. 658, 664 (1993)).

194. *See id.* at 2263-64 (O'Connor, J., concurring in part and dissenting in part).

195. *See id.* at 2264 (O'Connor, J., concurring in part and dissenting in part).

196. *See* 21 C.F.R. §§ 820.20-.198 (1996) (requiring specific organizational, personnel, reporting, storage, manufacturing, and safety standards).

197. *See Medtronic*, 116 S. Ct. at 2264 (O'Connor, J., concurring in part and dissenting in part); 21 C.F.R. § 801.109 (1996) (requiring label to include such information as indications, effects, routes, methods, frequency and duration of administration, relevant hazards, contraindications, side effects, and precautions).

198. *See* Mentor Corp. v. Bingham, 116 S. Ct. 2577, *granting cert. to, vacating judgment of, and remanding* 77 F.3d 478 (5th Cir. 1996); Martin v. Telectronics Pacing Sys., Inc., 116 S. Ct. 2576 (1996), *granting cert. to, vacating judgment of, and remanding* 70 F.3d 39 (6th Cir. 1995), *on remand to* 105 F.3d 1090 (6th Cir. 1997), *cert. denied*, 118 S. Ct. 850 (1998); Duvall v. Bristol-Myers Squibb Co., 116 S. Ct. 2575 (1996), *granting cert. to, vacating judgment of, and remanding* 65 F.3d 392 (4th Cir. 1995), *on remand to* 103 F.3d 324 (4th Cir. 1996); English v. Mentor Corp., 116 S. Ct. 2575 (1996), *granting cert. to, vacating judgment of, and remanding* 67 F.3d 477 (3d Cir. 1995); Mentor Corp. v. Feldt, 116 S. Ct. 2575 (1996), *granting cert. to, vacating judgment of, and remanding* 61 F.3d 431 (5th Cir. 1995), *on remand to* 95 F.3d 4 (5th Cir. 1996); Mitchell v. Collagen Corp., 116 S. Ct. 2575 (1996), *granting cert. to, vacating judgment of, and remanding* 67 F.3d 1268 (7th Cir. 1995), *on remand to* 126 F.3d 902 (7th Cir. 1997), *cert. denied*, 118 S. Ct. 1300 (1998).

199. *See infra* notes 203-17 and accompanying text (discussing the possible impact of the *Medtronic* decision on the medical devices industry).

200. *See, e.g.*, Federal Cigarette Labeling and Advertising Act, 15 U.S.C. §§ 1331-1341

interpretation may elucidate the underlying and elusive rationale of the Court's pre-emption decision, thus providing a means to predict future pre-emption controversies.[201] Finally, although limiting its discussion to the issue of pre-emption and focusing its analysis on statutory interpretation, the Court obfuscated its holdings on other important public policy and constitutional considerations.[202]

A. Impact on the Medical Devices Industry

Prior to the Supreme Court rendering its decision, commentators hailed the *Medtronic* case as pitting consumer protection against medical device development.[203] On the one side, consumers, concerned by inadequate federal regulation, feared that pre-emption would eliminate the only viable economic check on manufacturers—a state common-law tort claim.[204] On the other hand, medical devices manufacturers feared that "out-of-control" products liability litigation would significantly hamper the industry's ability to cost-effectively research, develop, and manufacture new lifesaving devices.[205]

Consumers, and their attorneys, argue that in appropriate situations, tort litigation can "insure that the costs of injuries resulting from defective products are borne by the manufacturers that put such products on the market rather than by the injured persons who are powerless to protect themselves."[206] Even the threat of tort action creates an eco-

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(1994); Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-136y (1994). The impact on the above referenced regulatory schemes is beyond the scope of this Note. For a summary of developments in pre-emption case law related to state product liability actions, see Richard C. Ausness, *Federal Preemption of State Products Liability Doctrines*, 44 S.C. L. REV. 187 (1993).

201. *See generally* Ausness, *supra* note 200, at 200-52 (reviewing product liability pre-emption cases and theories of statutory interpretation).

202. *See infra* notes 218-59 and accompanying text (discussing the unstated constitutional forces favoring the use of pre-emption as the basis for rendering a decision).

203. *See* Henry, *supra* note 13, at 1 (noting that the issue of pre-emption depends on balancing two competing interests—compensating an injured plaintiff and promoting medical device development—and may lean in favor of the medical devices industry).

204. *See* Walsh & Pyrich, *supra* note 29, at 931-48 (discussing the various problems and shortcomings of the FDA approval process for drugs and medical devices).

205. *See* Henry, *supra* note 13, at 8; *Product Liability: Senator to Seek Changes in Product Liability Law*, 1994 DER (BNA) No. 97, at D6 (May 23, 1994) [hereinafter *Senator to Seek Changes in Product Liability Law*]. In fact, even Lohr admitted in her complaint that it was likely she would not be alive but for her heart pacemaker. *See id.* (quoting Brief for Petitioner, *supra* note 1, at 1).

206. Greenman v. Yuba Power Products, 377 P.2d 897, 901 (1962) (establishing strict liability against manufacturer of power tool); *Cf.* Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 248-56 (1983) (holding that a tort action against a nuclear power plant was

nomic incentive for the manufacturer to take the necessary precautions to ensure that a product is safe for public use.[207]

Tort actions, however, may have a negative impact on another important public policy concern, namely promoting the development and manufacture of innovative medical devices.[208] Tort claims can have a chilling effect on manufacturers' willingness to fund research and development of medical devices.[209] The industry's fear stems not only from the direct cost of tort litigation, but collateral cost as well.[210] For example, Paul Citron, Vice President of Medtronic, Inc., and Eleanor Gackstatter, President of Meadox Medicals, Inc., have testified that suppliers of raw materials discontinued deliveries to manufacturers of permanently implantable devices due to product liability concerns.[211] Without the protection of federal pre-emption, industry leaders argue, medical advances are impeded and society loses.[212]

Despite the industry's concerns, the Court's decision in *Medtronic* does not terminate the federal pre-emption debate.[213] First, the pacemaker at issue in *Medtronic* reached the market without the FDA fully determining its safety or effectiveness.[214] Additionally, manufacturers of medical devices can focus their efforts on persuading Congress to re-evaluate and amend the MDA.[215] Furthermore, the Court's opinion was

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not pre-empted by federal regulations governing nuclear power because tort civil claims provide an additional safeguard against mismanagement).

207. *See Greenman*, 377 P.2d at 901 (1944) (citing Escola v. Coca Cola Bottling Co., 150 P.2d 436, 440 (1944) (Traynor, J., concurring)); William L. Prosser, *The Assault Upon the Citadel (Strict Liability to the Consumer)*, 69 YALE L.J. 1099, 1122-23 (1960)).

208. *See Senator to Seek Changes in Product Liability Law*, *supra* note 205, at D6; *see also supra* notes 51-56 and accompanying text (discussing the legislative intent underlying the MDA).

209. *See Senator to Seek Changes in Product Liability Law*, *supra* note 205, at D6. Katherine F. Knox of Dupont Co. noted that suppliers of raw materials, like Dupont, feared liability, even in design defect suits to which a supplier most likely would not be liable. *See id.* Knox stated, "Our company cannot justify the millions of dollars in litigation costs, the court appearances, and the press coverage which may accompany these controversies over medical implants." *Id.*

210. *See id.*

211. *See id.*

212. *See id.*

213. *See supra* notes 180-81 and accompanying text (discussing an issue left unaddressed by the *Medtronic* opinion).

214. *See supra* notes 62-70 and accompanying text (discussing the substantially equivalent exception to FDA review via the premarket approval process).

215. *See, e.g.*, The Safe Medical Devices Act of 1990, Pub. L. No. 101-629, § 4(a),

based on a scant, pre-discovery record replete of many of the factual findings that could give rise to an actual conflict between FDA regulations and a state tort claim.[216] Far from providing definitive guidance to the lower courts, the *Medtronic* decision should be narrowly construed and may, therefore, have less of a deleterious effect than originally assumed.[217]

B. Pre-emption, Statutory Interpretation, and Public Policy

The Supreme Court's pre-emption decisions have long been condemned as "extreme examples of the unwarranted substitution of judicial wisdom for that of Congress."[218] Professor Richard Ausness proposes, however, a more probing analysis in search of the Court's guiding principles.[219] Under Professor Ausness's analysis, policy concerns including interstate commerce, federalism, agency decisionmaking, consumer safety, and compensation[220] guide the Court in determining pre-emption decisions even though conveyed as statutory interpretation.[221]

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104 Stat. 4511, 4515 (1990) (codified as amended at 21 U.S.C. § 360c(i) (1994)).

216. *See* Medtronic, Inc. v. Lohr, 116 S. Ct. 2240, 2255 (1996) (noting that "the precise contours of [Lohr's] theory of recovery have not been defined" because the litigation was only at the pleading stage).

217. *See* R. Lawrence Purdy & Michael C. McCarthy, Medtronic, Inc. v. Lohr: *A Work in Progress*, 1 MEALEY'S LITIG. REP.: DRUGS & MED. DEVICES 21 (1996).

218. *See* Everett C. McKeage, *Judicial Supergovernment and States' Rights*, 64 PUB. UTIL. FORT. 486, 489-91 (1959). *But see* Note, *Pre-emption as a Preferential Ground: A New Canon of Construction*, 12 STAN. L. REV. 208, 224-25 (1959) (concluding that the Court uses pre-emption analysis to implement constitutional principles outside of the Supremacy Clause).

219. *See* Ausness, *supra* note 200, at 238-251 (describing the Eskridge-Frickey "Practical Reasoning" Model of statutory interpretation).

220. *See id.* at 244-45 (defining five policy considerations inevitable in statutory interpretation).

221. *See* Doctor's Assocs., Inc. v. Casarotto, 116 S. Ct. 1652, 1657 (1996) (holding that the Federal Arbitration Act pre-empted a Montana state law which conditioned enforceability of arbitration clause on compliance with special notice requirements); Reynoldsville Casket Co. v. Hyde, 115 S. Ct. 1745, 1747 (1995) (holding that the Supremacy Clause barred Ohio from applying tolling statute to pre-*Bendix* torts); New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 115 S. Ct. 1671, 1683 (1995) (holding that ERISA did not pre-empt state surcharges on health maintenance organizations (HMOs) paid by an ERISA plan); Freightliner Corp. v. Myrick, 115 S. Ct. 1483, 1488 (1995) (holding National Traffic and Motor Vehicle Safety Act did not pre-empt state common-law claims); American Airlines, Inc. v. Wolens, 115 S. Ct. 817, 826-27 (1995) (holding Airline Deregulation Act pre-empted state fraud and deception causes of action but did not pre-empt breach of contract action).

1. Interstate Commerce

To ensure the vitality of an open economic market, the drafters of the United States Constitution empowered Congress "[t]o Regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes."[222] When state legislation inhibits the free flow of commerce, the Supreme Court consistently invalidates the state law under the Commerce Clause.[223] Similarly, state tort claims can impose financial barriers to an open, national market if excessive or oppressive.[224] Therefore, when state action, either legislative or judicial, interferes with interstate commerce, the Court is more likely to invoke the pre-emption doctrine.[225]

The influence of the Commerce Clause on the Court is evident in Justice Stevens's opinion in *Medtronic*.[226] Nevertheless, Justice Stevens discounted the legislative history indicating that Congress was concerned with protecting industry.[227] "[F]urthermore, any such concern [for protecting industry] was far outweighed by concerns about the primary issue motivating the MDA's enactment: the safety of those who use medical devices."[228] Therefore, Justice Stevens implicitly rejected the need for pre-emption to protect trade, but only by balancing it against the need to protect the health and safety of the individual.[229]

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222. *See* U.S. CONST. art. I, § 8; *see also* Ausness, *supra* note 200, at 245 (stating that "[p]rotection of trade and maintenance of national markets has long been a national priority").

223. *See, e.g.*, Kassel v. Consolidated Freightways Corp., 450 U.S. 662, 678-79 (1981) (holding state ban on certain commercial vehicles violative of the Commerce Clause).

224. *See* Ausness, *supra* note 200, at 246 & nn.448-49 (stating that varying state liability standards may alter the interstate flow of commercial goods).

225. *See id.* at 246.

226. *See* Medtronic, Inc. v. Lohr, 116 S. Ct. 2240, 2251 (1996). "Also relevant, however, is the 'structure and purpose of the statute as a whole,' . . . as revealed not only in the text, but through the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law." *Id.* (quoting Gade v. National Solid Wastes Management Ass'n, 505 U.S. 88, 98 (1992)) (citations omitted).

227. *See id.* at 2253.

228. *Id.*

229. *See id.*

2. Federalism

The Founding Fathers believed that a strong centralized government designed to advance the common welfare of the nation must be balanced by responsive local government.[230] Federalism encourages citizens to participate actively in government and to have a voice in the political process.[231] Federalism embraces diversity by supporting local government in touch with community needs, thereby allowing states to craft solutions particularly tailored to their constituencies.[232] The domain of protecting the health and safety of its citizens clearly lies with the states.[233] Therefore, the Court has held that, in general, federal law cannot pre-empt the police powers of the states unless Congress indicates a "clear and manifest" intent to do so.[234]

In *Medtronic*, Justice Stevens devoted several pages addressing whether a state tort action constitutes a requirement under the meaning of the MDA.[235] Contrasting the "limited set of state requirements" pre-empted in *Cipollone v. Liggett Group, Inc.*,[236] the Court found that "Medtronic's sweeping interpretation of the statute would require far greater interference with state legal remedies, *producing a serious intrusion into state sovereignty* while simultaneously wiping out the possibility of remedy for the Lohrs' alleged injuries."[237] Once again, while on the surface the Court appears to be interpreting the statutory language to determine Congress's intent to pre-empt state law, a policy concern to protect the power of the states (i.e., federalism) crept into the analysis.[238] The Court found repugnant the idea that Congress could intrude into the state's domain of protecting the health and safety

230. *See* Ausness, *supra* note 200, at 246-47 (citing Herbert Wechsler, *The Political Safeguards of Federalism: The Role of the States in the Composition and Selection of the National Government*, 54 COLUM. L. REV. 543, 543 (1954)).

231. *See id.* at 247.

232. *See id.*

233. *See id.*

234. *See id.* (citing Maryland v. Louisiana, 451 U.S. 725, 746 (1981); City of Milwaukee v. Illinois, 451 U.S. 304, 316 (1981); Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)).

235. *See* Medtronic, Inc. v. Lohr, 116 S. Ct. 2240, 2251-52 (1996).

236. 505 U.S. 504 (1992).

237. *Medtronic*, 116 S. Ct. at 2252 (emphasis added). Additionally, the *Medtronic* Court found that Congress did not "clearly signal[ ] its intent to deprive States of any role in protecting consumers from the dangers inherent in many medical devices." *Id.*

238. *See id.*

of its citizens without clearly stating such an intent.[239] Accordingly, the Court, guided by the principles of federalism, found that Congress did not intend to pre-empt state tort claims.[240]

3. Agency Decisionmaking

As regulatory agencies become more pervasive and specialized, courts are more inclined to defer to agency rules and regulations which are properly promulgated.[241] Courts generally trust administrative standards due to an agency's superior resources, technical expertise, and familiarity with the relevant issues.[242] Therefore, public policy favors federal pre-emption to protect agency decisionmaking when appropriate.[243]

The *Medtronic* Court continued the trend of giving deference to agency regulations.[244] Justice Stevens acknowledged that the FDA is "uniquely qualified to determine whether a particular form of state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'"[245] The Court found that the authoritative regulations set forth by the FDA supported the conclusion that the MDA does not pre-empt state tort claims.[246] Even though the state tort action was not pre-empted, the Court adopted the policy considerations that support agency decisionmaking.

4. Public Health and Safety

Protecting the health and safety of the public can be achieved by state tort doctrines or federal regulatory schemes.[247] Due to the consistent aims of state products liability doctrines and federal product

239. *See id.*; *see also* Ausness, *supra* note 200, at 248.
240. *See Medtronic*, 116 S. Ct. at 2252. *Cf. Cipollone*, 505 U.S. 504, 514 (1992) (holding federal law limiting any state requirement on cigarette labeling was pre-empted).
241. *See* Ausness, *supra* note 200, at 248-50 (citing Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842-43 (1984)).
242. *See id.* at 249.
243. *See id.*
244. *See Medtronic*, 116 S. Ct. at 2255-56.
245. *Id.* at 2255 (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)).
246. *See id.* at 2256.
247. *See* Ausness, *supra* note 200, at 251; *see supra* notes 203-17 and accompanying text (comparing tort remedies and regulatory remedies).

safety regulations, pre-emption does not further policy goals because of their complimentary nature.[248]

Throughout the *Medtronic* opinion, the Court wove in its concern for the health and safety of the individual.[249] Particularly telling, the Court dismissed Medtronic's contention that Congress intended to protect the entire public by removing obstacles, such as state tort liability, hindering the research, development, and production of lifesaving medical devices.[250] While protecting individuals rather than groups conforms with general notions of American jurisprudence, the Court appears to have overlooked the tremendous public benefit gleaned from advances in the medical devices field.[251] Under the particular circumstances of the *Medtronic* case, the Court's individualistic view of public health and safety could have a devastating effect on the medical devices industry and, in turn, on the public at large.[252]

5. Compensation

Contemporary principles on compensation contend that manufacturers will be deterred from producing unsafe products if the possible financial harm outweighs the possible gain.[253] Furthermore, compensation should be targeted at the individual or entity in the best position to spread the risk.[254] While state tort remedies and regulatory schemes both aim at deterring injurious conduct, only tort law shifts the risks to the manufacturers who are able to spread the losses among a large consumer population.[255] Thus, under the loss-spreading rationale supporting state tort claims, the public policy of compensation disfavors pre-emption which would otherwise "immunize[] manufacturers from liability."[256]

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248. *See* Ausness, *supra* note 200, at 251.

249. *See Medtronic*, 116 S. Ct. at 2252-59.

250. *See id.* at 2253.

251. *See supra* notes 51-71 and accompanying text (discussing the history of medical devices and their regulation).

252. *See supra* notes 203-17 and accompanying text (comparing the impact of tort liability and FDA regulation on the development of medical devices).

253. *See* Ausness, *supra* note 200, at 251-52 (defining the principle as "corrective justice").

254. *See id.* (defining the principle as "utilitarian-based theories of risk distribution").

255. *See id.* (noting that although individuals can spread the risk through insurance, manufacturers can spread the loss more efficiently).

256. *See id.* at 252 (postulating that "pre-emption forces the victim, rather than the manufacturer, to bear the personal injury loss, even though the manufacturer could include the loss as a cost of production").

In *Medtronic*, the Court found that "[t]he presence of a damages remedy does not amount to the additional or different 'requirement' that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing 'requirements' under federal law."[257] Additionally, the Court concluded that some tort claims do not interfere with the FDA requirements.[258] Accordingly, the Court's holding implicitly supports the compensation principle disfavoring pre-emption of state tort claims.

In sum, the Supreme Court implicitly found that the policy concerns of interstate commerce, federalism, agency decisionmaking, consumer safety, and compensation support a finding rejecting federal pre-emption under the MDA.[259]

VI. CONCLUSION

Little did Lora Lohr know that when her Medtronic pacemaker failed sending her into cardiac arrest her story would some day be told before the United States Supreme Court.[260] Yet her story would settle the long-disputed issue of whether the Medical Device Amendments pre-empt state tort actions. In the end, a plurality of the Supreme Court Justices found that Congress did not intend for the MDA to pre-empt state tort claims.[261]

The *Medtronic* decision may have immediate and far reaching effects on the medical devices industry. The six cases that were remanded to the courts of appeals will undoubtedly send shockwaves through the medical devices industry.[262] *Medtronic*, however, also clarifies the often elusive and confusing rationale of the Court's pre-emption decisions. A probing examination of the Court's opinion reveals that the apparent focus on statutory interpretation belies the deeper constitutional and policy considerations at work. This Note concludes that, in fact, the Court implicitly considered the broader policy concerns of interstate commerce, federalism, agency decisionmaking, consumer

257. Medtronic, Inc. v. Lohr, 116 S. Ct. 2240, 2255 (1996).
258. *See id.* at 2258.
259. *See id.* at 2259; Ausness, *supra* note 200, at 244-45 (defining five policy considerations inevitable in statutory interpretation).
260. *See Medtronic*, 116 S. Ct. at 2245.
261. *See id.* at 2259.
262. *See supra* notes 198, 203-17 and accompanying text (discussing the possible impact of the *Medtronic* decision on the medical device industry).

safety, and compensation in its pre-emption analysis.[263] Therefore, what appeared to be a result-oriented pre-emption decision may rather signal a new era of constitutional analysis.

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263. *See supra* notes 218-63 and accompanying text (discussing the unstated constitutional forces favoring pre-emption as the basis of rendering a decision).