

10-1-2009

In The Shadows of *Lohr*: The Disconnect Within The Supreme Court's Preemption Jurisprudence In Medical Device Liability Cases

Jen a M. Reed

Follow this and additional works at: <http://repository.law.miami.edu/umlr>

Recommended Citation

Jen a M. Reed, *In The Shadows of Lohr: The Disconnect Within The Supreme Court's Preemption Jurisprudence In Medical Device Liability Cases*, 64 U. Miami L. Rev. 305 (2009)
Available at: <http://repository.law.miami.edu/umlr/vol64/iss1/9>

This Note is brought to you for free and open access by Institutional Repository. It has been accepted for inclusion in University of Miami Law Review by an authorized administrator of Institutional Repository. For more information, please contact library@law.miami.edu.

In the Shadows of *Lohr*: The Disconnect Within the Supreme Court's Preemption Jurisprudence in Medical Device Liability Cases

JENÉA M. REED[†]

I. INTRODUCTION	305
II. THE REGULATORY AND LEGAL CONTEXT SURROUNDING MDA PREEMPTION ...	308
A. <i>History of the Medical Device Amendments of 1976</i>	308
B. <i>The FDA's Implementation of the MDA</i>	308
1. PREMARKET APPROVAL VS. SUBSTANTIAL EQUIVALENCE.....	309
2. PREEMPTION UNDER THE MDA	310
C. <i>Supreme Court Preemption Jurisprudence</i>	311
D. <i>Judicial Interpretation of Preemption Under the MDA</i>	312
1. THE SUPREME COURT'S FIRST LOOK AT MDA PREEMPTION: <i>MEDTRONIC, INC. V. LOHR</i>	313
2. <i>LOHR'S AFTERMATH</i>	315
III. IN THE SHADOWS OF <i>LOHR</i> : <i>RIEGEL V. MEDTRONIC, INC.</i>	316
A. <i>Drawing a Line in the Sand: Justice Scalia's Majority Opinion</i>	316
1. THE "RIEGEL DISTINCTION": THE PMA PROCESS IS A FEDERAL REQUIREMENT	316
2. THE <i>CIPOLLONE</i> PROPOSITION, AGAIN?: COMMON-LAW CLAIMS ARE STATE REQUIREMENTS	320
3. EXPRESS OR IMPLIED PREEMPTION?	322
B. <i>Conflicting Legal and Analytical Underpinnings: Riegel vs. Lohr</i>	324
1. STATUTORY CONSTRUCTION AND THE SCOPE OF EXPRESS PREEMPTION ANALYSIS	325
2. A FOUNDATION OF <i>LOHR</i> : CONGRESSIONAL INTENT	327
3. A FOUNDATION OF <i>LOHR</i> : THE PRESUMPTION AGAINST PREEMPTION ...	328
4. A FOUNDATION OF <i>LOHR</i> : DEFERENCE TO THE FDA	331
IV. IMPLICATIONS	333
A. <i>Litigants in Search of Framework</i>	333
B. <i>Device Manufacturers: A Spark for Innovation?</i>	334
C. <i>Physicians: Caught in the Crosshairs</i>	336
D. <i>Legislative Response</i>	337
V. CONCLUSION	338

I. INTRODUCTION

Imagine two people, each injured by different medical devices, individually sue the medical-device manufacturers under various negli-

[†] Executive Editor, *University of Miami Law Review*; J.D. Candidate 2010, University of Miami School of Law; B.S.E. 2002, University of Pennsylvania. I thank my family, particularly my mother and my husband, for always supporting me in everything that I do. I also thank Professor Mary I. Coombs for her guidance throughout the writing process.

gence theories.¹ The first litigant was injured by a Class III² pacemaker device, which had been approved under the Food and Drug Administration's (FDA) substantial equivalence³ process (also known as 510(k) review). The second litigant was injured when a recently implanted Class III medical device, a balloon catheter, ruptured and caused a heart blockage. But this device was approved under the FDA's premarket approval (PMA)⁴ process. Both litigants suffered severe injuries. Both devices were allegedly defective. Both devices went through the proper FDA channels before entering the market. However, the first litigant is able to sue the manufacturer,⁵ while the second litigant's claims are preempted by federal law. This inconsistency is exactly the result reached by the Supreme Court in *Riegel v. Medtronic, Inc.*⁶

In *Riegel*, the Supreme Court held that the Medical Device Amendments (MDA) of 1976⁷ preempted certain tort-law claims against manufacturers of medical devices that received premarket approval from the FDA.⁸ As a result, consumers no longer have a legal remedy if they are injured by certain medical devices. This result stands in stark contrast to the outcome in *Medtronic, Inc. v. Lohr*,⁹ where the court determined that tort-law claims against manufacturers of substantially equivalent devices were *not* preempted.¹⁰ The Supreme Court rarely overrules its previous decisions, and *Riegel's* treatment of *Lohr* is no exception. Rather than revisit the merits of its holding in *Lohr*, the Court distinguished the case

1. The facts in this hypothetical have been adapted from *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008), and *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

2. The FDA classifies medical devices into three categories—Class I, Class II, or Class III. 21 U.S.C. § 360c(a)(1) (2006). Class III is “the most stringent regulatory category” because these devices are typically used “to support or sustain human life.” FDA, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm> (last visited Oct. 7, 2009).

3. The FDA approves some Class III medical devices upon a showing by the manufacturer that the device is “at least as safe and effective . . . [as] a legally marketed device.” FDA, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm> (last visited Oct. 7, 2009). This process is known as the “substantial equivalence” process or § 510(k) review. *Id.*

4. Premarket approval is the FDA's rigorous regulatory process for reviewing Class III medical devices that have not been deemed substantially equivalent to currently available devices. *See* FDA, *supra* note 2. The process requires the manufacturer to show “sufficient valid scientific evidence to assure that the device is safe and effective for its intended uses(s).” *Id.*

5. In *Lohr*, the Supreme Court held that patients injured by substantially equivalent medical devices may sue the manufacturer. *See Lohr*, 518 U.S. at 494. The Court reasoned that these claims were not preempted because the FDA's substantial equivalence determination did not constitute federal requirements that would displace state requirements. *Id.* at 493.

6. 128 S. Ct. 999 (2008).

7. 21 U.S.C. §§ 360c–360m (2006).

8. *See Riegel*, 128 S. Ct. at 1008.

9. 518 U.S. 470 (1996).

10. *Id.* at 494.

and muddled the waters in MDA preemption jurisprudence by hinging its analysis on the distinction between premarket approval (reviewed in *Riegel*) and substantial equivalence (reviewed in *Lohr*).

MDA preemption jurisprudence has been cyclical, with eras of intense confusion and attempted clarification.¹¹ *Lohr* was the Court's attempt to clarify the law on MDA preemption after conflicting lower-court interpretations of *Cipollone v. Liggett Group, Inc.*¹² led to widely disparate rulings on preemption under the MDA.¹³ This article argues that after *Riegel*, MDA preemption jurisprudence will return to an era of confusion because of the inconsistencies between *Riegel* and the Court's prior preemption rulings. The legal underpinnings of *Riegel* and *Lohr* are at odds; thus, the Court's effort to harmonize the two decisions creates uncertainty in MDA preemption jurisprudence.

This article analyzes the legal, historical, and policy reasons why preemption based on such a narrow distinction is both unwise and unsupported by the text of the MDA. These reasons include the text of the regulations at issue in this preemption debate, the nature of the FDA approval process, and fundamental fairness as evidenced by the hypothetical at the beginning of this article. Although the *Riegel* ruling is directly applicable to only a limited number of devices,¹⁴ its reach is widespread because of the larger implications for preemption jurisprudence. In particular, the decision will shape how future courts view the agency's role in the preemption debate, what courts will consider when interpreting express preemption¹⁵ clauses, and whether the Supreme Court's long-articulated presumption against preemption is dead in the MDA context.

Part II focuses on the legal and regulatory climate leading up to *Riegel*. Part III reviews and critiques the rationale behind the preemption distinction set forth in *Riegel*. This section also discusses the dissimilar legal underpinnings that make *Lohr* and *Riegel* irreconcilable, including the scope of express preemption analysis and courts' deference to federal agencies. Part IV examines *Riegel*'s implications for industry stakeholders including patients, physicians, and device manufacturers. Part V offers a brief conclusion.

11. See Robert B. Leflar & Robert S. Adler, *The Preemption Pentad: Federal Preemption of Products Liability Claims after Medtronic*, 64 TENN. L. REV. 691, 696–99 (1997).

12. 505 U.S. 504 (1992).

13. Leflar & Adler, *supra* note 11, at 692–93; see discussion *infra* Part II.D.

14. Approximately 10% of medical devices reach the market through the PMA process. Catherine M. Sharkey, *What Riegel Portends for FDA Preemption of State Law Products Liability Claims*, 102 NW. U. L. REV. COLLOQUY 415, 428 (2008).

15. “[E]xpress preemption occurs where Congress . . . speak[s] directly to the preemptive effect of a particular statute.” KENNETH STARR ET AL., *THE LAW OF PREEMPTION* 15 (Paul J. Mishkin et al. eds., 1991).

II. THE REGULATORY AND LEGAL CONTEXT SURROUNDING MDA PREEMPTION

A. *History of the Medical Devices Amendments of 1976*

The federal government initially acquired oversight of medical devices through the Federal Food, Drug, and Cosmetic Act of 1938.¹⁶ However, the FDA lacked the authority to screen medical devices *before* they entered the market¹⁷ until Congress passed the Medical Device Amendments of 1976 (MDA).¹⁸ As a result, new medical devices were largely unregulated by the federal government, and that role was principally held by the states until 1976.¹⁹

The “Dalkon Shield controversy” changed Congress’s passive, hands-off approach. As technology rapidly changed, Congress recognized the need to ensure that medical devices functioned as the manufacturers claimed.²⁰ This realization was undoubtedly influenced by the circumstances surrounding the Dalkon Shield intrauterine device, a defectively designed contraceptive that injured thousands of women.²¹ The Senate acknowledged this controversy as an impetus for passing the MDA, noting that “many of the deaths and much of the illness attributed to this device could have been prevented if medical device legislation . . . had been in effect when the Dalkon shield was developed.”²²

B. *The FDA’s Implementation of the MDA*

With its new-found power, the FDA began to implement “a regime of detailed federal oversight.”²³ As directed by the statute, the FDA classified potential new devices into three categories based on the level of risk associated with the device.²⁴ Class III was reserved for the most dangerous devices.²⁵ New Class III devices can only be marketed to the general public if they pass one of two FDA-mandated review processes:

16. S. REP. NO. 94-33, at 2 (1975).

17. David C. Vladeck, *Preemption and Regulatory Failure*, 33 PEPP. L. REV. 95, 102 (2005) (noting that pre-MDA, the FDA did not have screening authority for devices, even though it had possessed that authority over drugs for decades).

18. 21 U.S.C. §§ 360c–360m (2006).

19. *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1002 (2008); *see also* Leflar & Adler, *supra* note 11, at 703 n.66 (noting at least thirteen state statutes regulating medical devices before Congress passed the MDA).

20. S. REP. NO. 94-33, at 5.

21. *See* Vladeck, *supra* note 17, at 103 (“[T]he MDA was enacted to strengthen consumer protection in light of public health tragedies like that triggered by the Dalkon Shield.”).

22. S. REP. NO. 94-33, at 2.

23. *Riegel*, 128 S. Ct. at 1003.

24. *See* 21 U.S.C. § 360c(a)(1) (2006).

25. *See id.* § 360c(a)(1)(C) (noting that Class III includes devices with the “potential [for] unreasonable risk of illness or injury”).

substantial equivalence (510(k) review) or premarket approval (PMA).²⁶

1. PREMARKET APPROVAL VS. SUBSTANTIAL EQUIVALENCE

A Class III device cannot receive PMA approval until the FDA determines that the manufacturer's application contains "sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s)."²⁷ The burden is on the manufacturer to provide the necessary information for the FDA's review.²⁸ The application is highly involved, often containing multiple volumes of information ranging from technical data to proposed labeling.²⁹ As a result of the significant amount of information contained in a PMA application, the FDA typically spends about 1,200 hours reviewing each application.³⁰

Not all Class III devices are required to obtain PMA approval.³¹ If the FDA deems a device substantially equivalent to a legally marketed device, PMA approval is not required.³² Instead, the manufacturer need only submit a 510(k) notification, which requires it to identify the comparable device, describe the applicant device's function and physical characteristics, and state the intended use of the applicant device.³³ The purpose of this provision is to allow manufacturers to introduce "me too" devices and to discourage monopolies within the medical-device market.³⁴ In contrast to the PMA, a 510(k) review typically requires twenty hours.³⁵ These distinctions would later form the basis for the Court's different approaches to preemption in *Lohr* and *Riegel*.³⁶

26. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477–78 (1996) (noting two exceptions to the PMA requirement for Class III devices—a "grandfathering provision" for existing, pre-MDA devices and substantial equivalence for devices seeking to enter the market).

27. FDA, *supra* note 2; see also 21 U.S.C. § 360e(d)(1)(A) (noting that the FDA Secretary's disposition of the application is based on "whether or not there is a reasonable assurance of safety and effectiveness").

28. See § 360e(d)(2)(A)–(B) (indicating that the FDA will deny a PMA application if the information provided by the applicant fails to demonstrate reasonable assurance of safety and effectiveness).

29. 21 C.F.R. § 814.20 (2009).

30. *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1004 (2008).

31. FDA, *supra* note 2.

32. *Id.*

33. 21 C.F.R. § 807.92(a) (2009).

34. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 494 n.14 (1996) ("[T]he 510(k) provision . . . is a procompetition mechanism that permits firms to make and quickly market me-too versions of pre-1976 devices." (quoting *FDA Oversight: Medical Devices, Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 97th Cong., 2d Sess., 9 (1982) (statement of FDA Comm'r))).

35. *Id.* at 479.

36. See discussion *infra* Part III.

2. PREEMPTION UNDER THE MDA

The MDA contains a specific preemption provision, codified at 21 U.S.C. § 360k(a):

[N]o 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.

The FDA interpreted the scope of this preemption provision as follows:

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 [FDA] requirements.³⁷

This regulation did little to help clarify the MDA's preemptive scope, and the legislative history of the MDA was silent on the issue.³⁸ This silence led to increasing debate regarding whether its preemptive scope was limited to the state regulatory schemes that proliferated before the MDA or extended to common-law tort suits like *Riegel* and *Lohr*.³⁹

A closer look at the legislative history indicates that the MDA's aim was dual in nature, with "two strong, but sometimes conflicting, interests"—the device industry's interest in scientific progress and consumers' interest in safe devices.⁴⁰ Congress acknowledged these competing aims, noting that the MDA "recognizes the benefits that medical . . . devices offer[] to mankind. It recognizes, too, the need for regulation to assure that the public is protected"⁴¹ These competing aims inevitably clash in the preemption context where courts must choose between protecting consumers' interest in ensuring medical-device safety and protecting manufacturers' interest in regulatory uniformity.⁴² This analysis becomes even more complex because it is unclear whether

37. 21 C.F.R. § 808.1(d) (2009) (emphasis added).

38. See Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 924 (1994) ("[T]here is no absolutely dispositive language in the MDA regarding preemption and the common law.").

39. See generally *id.*

40. Theresa J. Pulley Radwan, *Meeting the Objectives of the MDA: Implied Preemption of State Tort Claims by the Medical Device Amendments*, 10 J.L. & HEALTH 343, 349 (1995–96).

41. S. Rep. No. 94-33, at 6 (1975).

42. See Radwan, *supra* note 40, at 350 (permitting tort actions supports Congress's aim to shield consumers from risk, while preempting tort actions supports Congress's aim to prevent overregulation through varied state tort schemes).

Congress intended the tort scheme to protect the public from unsafe devices.

C. Supreme Court Preemption Jurisprudence

Any preemption analysis is rooted in the Supremacy Clause of the United States Constitution,⁴³ and the doctrine has been judicially recognized for nearly two centuries.⁴⁴ The scope of the federal government's power to preempt is broadly stated in the Constitution, but the Supreme Court has limited its reach by creating a presumption against preemption in areas of law typically governed by the states. In *Rice v. Santa Fe Elevator Corp.*,⁴⁵ the Court noted that its preemption analysis should "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."⁴⁶ Congress can articulate its manifest purpose through an express statutory provision,⁴⁷ as it did with the MDA,⁴⁸ or courts can find implied preemption⁴⁹ based on the pervasiveness of the federal regulation, the scope of the federal government's interest, or a specific conflict between state and federal law.⁵⁰

One case in particular, *Cipollone v. Liggett Group, Inc.*,⁵¹ marked a shift in the Court's view on whether express statutory preemption applied to state tort claims.⁵² The Court had rarely preempted these claims before it construed the Public Health Cigarette Smoking Act of 1969⁵³ in *Cipollone*.⁵⁴ The Act's preemption provision states, "No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of

43. See U.S. CONST. art. VI, cl. 2 ("This Constitution, and the Laws of the United States . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby.").

44. See *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) ("[S]ince our decision in *M'Culloch v. Maryland*, it has been settled that state law that conflicts with federal law is 'without effect.'" (citation omitted) (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981))).

45. 331 U.S. 218 (1947).

46. *Id.* at 230.

47. This form of preemption is typically referred to as express preemption. STARR ET AL., *supra* note 15.

48. The MDA's preemption provision is codified at 21 U.S.C. § 360k(a).

49. See discussion *infra* Part III.A.3.

50. *Rice*, 331 U.S. at 230.

51. 505 U.S. 504 (1992).

52. See THOMAS O. MCGARITY, *THE PREEMPTION WAR* 49–51 (2008).

53. 15 U.S.C. §§ 1331–1341 (2006).

54. MCGARITY, *supra* note 52, at 51; see Gail H. Javitt, Esq., *I've Got You Under My Skin And I Can't Get Redress: An Analysis of Recent Case Law Addressing Preemption of Manufacturer Liability for Class III Medical Devices*, 40 FOOD & DRUG L.J. 553, 566 (describing *Cipollone* as "[t]he key authority stating the rule for preemption of state law claims" (quoting *Ministry of Health v. Shiley, Inc.*, 858 F. Supp. 1426, 1436 (C.D. Cal. 1994))).

any cigarettes”⁵⁵ In concluding that this preemption statement applied to tort claims, a plurality of the Court placed particular emphasis on Congress’s use of the phrase “requirements or prohibitions.”⁵⁶ “[C]ommon-law damages actions . . . are premised on the existence of a legal duty, and it is difficult to say that such actions do not impose ‘requirements or prohibitions.’”⁵⁷ This contention would later play an important role in *Riegel* and *Lohr*.⁵⁸

D. Judicial Interpretation of Preemption Under the MDA

Few courts had considered the MDA’s preemptive scope until the early 1990s,⁵⁹ and the Supreme Court had yet to reach the issue.⁶⁰ Not surprisingly, preemption jurisprudence was in disarray, with courts reaching widely varied results.⁶¹ Courts turned to *Cipollone* for guidance⁶² but could not agree on its meaning.

Although a majority of the *Cipollone* Court did not agree that state tort law constituted requirements, this aspect of *Cipollone*’s analysis (“the *Cipollone* proposition”) nonetheless trickled down to some lower courts.⁶³ Just one year after *Cipollone* was decided, *King v. Collagen Corp.*⁶⁴ became the first case to accept the preemption defense in the MDA context.⁶⁵ *King* relied heavily on *Cipollone* in determining that the express language of the MDA required preemption of state tort claims.⁶⁶

55. 15 U.S.C. § 1334(b).

56. See *Cipollone*, 505 U.S. at 520 (plurality opinion) (noting “substantial differences in language” between the statutory phrases “statements” and “requirements and prohibitions”).

57. *Id.* at 522.

58. In *Lohr*, five Justices agreed with the *Cipollone* proposition that state tort claims were requirements within preemption analysis. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 504 (1996) (Breyer, J., concurring in part); *id.* at 512 (O’Connor, J., dissenting in part, joined by Rehnquist, C.J., Scalia and Thomas, JJ.). The *Riegel* Court noted the *Lohr* Court’s approach and summarily affirmed the *Cipollone* proposition. *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1007–08 (2008) (citing *Cipollone*, 505 U.S. at 522); see discussion *infra* Part III.

59. Vladeck, *supra* note 17, at 105.

60. See Radwan, *supra* note 40, at 355 (noting that the United States Supreme Court had not interpreted the MDA’s preemptive effect on state tort law until *Lohr*).

61. Leflar & Adler, *supra* note 11, at 692; see *Lohr*, 518 U.S. at 484 (noting the circuit split); see also cases cited *infra* notes 68–70 (providing specific examples of the circuit split).

62. There is some authority indicating that lower courts should not have applied *Cipollone* in the MDA context. See *Lohr*, 518 U.S. at 489 (plurality opinion) (distinguishing the MDA from the statute at issue in *Cipollone*).

63. See McGarity, *supra* note 52, at 49 (“[*Cipollone*] opened the door to expansive common law preemption claims . . . that precipitated the preemption war.”); Leflar & Adler, *supra* note 11, at 698 (“The *Cipollone* Court’s interpretation of the word ‘requirement’ . . . provided a springboard for subsequent courts to hold injured consumers’ claims preempted under other statutes.”).

64. 983 F.2d 1130 (1st Cir. 1993).

65. Javitt, *supra* note 54, at 554.

66. See *King*, 983 F.2d at 1137.

But the circuit courts were not uniform in their application of *Cipollone* to the MDA. Three different approaches emerged:⁶⁷ (1) all tort claims were preempted by the MDA;⁶⁸ (2) only some tort claims were preempted, often depending on FDA regulations;⁶⁹ or (3) the MDA was not intended to preempt tort claims at all.⁷⁰

1. THE SUPREME COURT'S FIRST LOOK AT MDA PREEMPTION:
MEDTRONIC, INC. V. LOHR

In 1996, the Supreme Court attempted to resolve the dispute among the circuits.⁷¹ The Court's analysis centered on the meaning of the MDA's statutory phrase "requirement."⁷² The *Lohr* Court addressed two main issues: (1) whether the substantial equivalence § 510(k) approval process constitutes a "federal requirement" within the meaning of the MDA,⁷³ and (2) whether the MDA preempts all common-law causes of action against medical-device manufacturers.⁷⁴

On the first issue, the Court held that the § 510(k) process was "not sufficiently concrete to constitute a pre-empting federal requirement."⁷⁵ It viewed the § 510(k) process as merely focusing on the device's equivalence to pre-MDA devices, rather than on safety.⁷⁶ The Court also said that federal requirements must be "device-specific" in order to have pre-emptive effect.⁷⁷ This analysis set the stage for the *Riegel* Court's

67. Mark E. Gelsinger, Note, *Medtronic, Inc. v. Lohr: Is Federal Pre-emption a Heartbeat Away from Death Under the Medical Device Amendments?*, 25 PEPP. L. REV. 647, 664-67 (1998).

68. The First Circuit was the primary proponent of this broad view of preemption, which was based on the conclusion that state tort claims were requirements within the meaning of the MDA. See *Talbot v. C.R. Band, Inc.*, 63 F.3d 25, 27 (1st Cir. 1995) (noting that in multiple cases, the First Circuit had found that state tort laws were "requirements" and therefore subject to preemption under the MDA (citing *King*, 983 F.2d at 1135-37; *Mendes v. Medtronic, Inc.*, 18 F.3d 13, 16 (1st Cir. 1994))).

69. The Fifth Circuit is an example of this intermediate approach. See *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1421 (5th Cir. 1993) (noting that preemption applies if, "in the context of the particular case," the tort claim constitutes a requirement relating to safety or effectiveness (emphasis added)).

70. The Ninth Circuit appears to be the only circuit that narrowly construed the MDA preemption provision. See *Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1459 n.2 (9th Cir. 1995) ("[T]he MDA does not preempt claims based upon state common law of general applicability" therefore limiting the preemption provision to state regulatory regimes).

71. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 474 (1996) ("Because the Courts of Appeals are divided over the extent to which state common-law claims are pre-empted by the MDA, we granted [certiorari].").

72. See *Vladeck*, *supra* note 17, at 98 ("[T]he crucial interpretive question [in medical device preemption cases] is what does the word 'requirement' mean?").

73. *Lohr*, 518 U.S. at 492-93.

74. *Id.* at 486-91 (plurality opinion).

75. *Id.* at 492 (majority opinion).

76. *Id.* at 493.

77. *Id.* at 497-500 (holding that manufacturing and labeling requirements that were generally applied to all devices were not device-specific and therefore not preempted).

analysis.

Regarding the second issue, a four-Justice plurality⁷⁸ rejected Medtronic's argument that the MDA preempted all common-law claims.⁷⁹ Relying heavily on Congress's intent, the plurality characterized this assertion as "unpersuasive [and] implausible" because it would "have the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation."⁸⁰

Given its holding that § 510(k) approval did not impose federal requirements, the Court was not required to reach an important third issue—whether state common-law actions constituted "state requirements" under the MDA.⁸¹ Nonetheless, the Justices provided glimpses into their respective stances. In determining that the MDA did not preclude all common-law suits, the Stevens plurality noted that "when Congress enacted §360k, it was primarily concerned with the problem of specific, conflicting state statutes and regulations rather than the general duties enforced by common-law actions."⁸² Four Justices, led by Justice O'Connor, reached the opposite conclusion: that state common-law actions *do* constitute "requirements,"⁸³ relying on *Cipollone* as the basis for this interpretation. Justice Breyer, in a separate concurring opinion, agreed with the O'Connor cohort on this point.⁸⁴ O'Connor's interpretation would later shape the *Riegel* Court's view of the *Cipollone* proposition.

Lohr's holding rested not on its interpretation of "state requirements," but rather on the "federal requirements" prong of the MDA. This reliance on "federal requirements" allowed the *Lohr* Court to resolve the specific question regarding the preemptive effect of the substantial equivalence process but avoid the *Cipollone* proposition that had been a source of division among the circuits.⁸⁵ So in effect, *Lohr* had little impact on clarifying the applicability of the *Cipollone* proposition to MDA preemption cases.

78. The plurality was led by Justice Stevens and joined by Justices Kennedy, Ginsburg, and Souter.

79. *Lohr*, 518 U.S. at 487 (plurality opinion).

80. *Id.*

81. *See id.* at 502 (noting the plaintiff's argument that "common-law duties are never 'requirements' within the meaning of § 360k, and that the statute therefore never pre-empts common-law actions," but refusing to directly address the issue).

82. *Id.* at 489. The plurality also distinguished the statute at issue in *Cipollone*, noting "significant textual and historical differences." *Id.* at 502.

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

84. *Id.* at 504 (Breyer, J., concurring in part).

85. *See* discussion *supra* Part II.D.

2. LOHR'S AFTERMATH

Although the *Lohr* holding seemed simple enough—the MDA did not preempt tort claims against manufacturers that obtained substantial equivalence approval—lower courts struggled with its application to PMA-approved devices.⁸⁶ The example most illustrative of this struggle is the litigation surrounding a Medtronic cardiac pacemaker with an allegedly defective component part (a Model 4004/M lead). The Eleventh Circuit determined that claims against this manufacturer were not preempted,⁸⁷ but the Sixth Circuit reached the opposite conclusion regarding the exact same device.⁸⁸ Thus, one injured plaintiff was able to bring a claim, while another plaintiff—injured by the same device, in a different jurisdiction—was unable to sue the manufacturer.

The time had come for the Supreme Court to address the unanswered questions that remained after *Lohr*:⁸⁹ (1) whether the PMA process constituted a federal requirement within the meaning of the MDA⁹⁰ and (2) whether common-law duties were state requirements within the meaning of the MDA.⁹¹ In *Riegel*, the Court answered each question in the affirmative, first holding that the PMA process (unlike 510(k) review) did constitute federal requirements within the meaning of the

86. See *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 224 (6th Cir. 2000) (“The various courts of appeals that have confronted issues of preemption arising under the MDA have struggled mightily with *Lohr*’s language in the effort to discern its holding.”); Vladeck, *supra* note 17, at 109 (noting a division among courts regarding the MDA’s preemptive effect in the PMA context).

87. *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1382 (11th Cir. 1999). In determining that the claims were not preempted, the court reasoned that “while a PMA review is considerably more rigorous and detailed than the premarket notification [510(k)] process at issue in [*Lohr v.*] *Medtronic*, it is, in fact, no more ‘specific’ a requirement.” *Id.* at 1376 (alterations in original) (quoting *Sowell v. Bausch & Lomb, Inc.*, 656 N.Y.S. 2d 16, 20 (App. Div. 1997)) (internal quotation marks omitted).

88. *Kemp*, 231 F.3d at 226 (noting the court’s disagreement with *Goodlin* and holding that the PMA process is a federal requirement that preempts state tort law.)

89. The Court had rejected multiple opportunities to clarify these looming questions in the years after *Lohr*. See *McMullen v. Medtronic, Inc.*, 421 F.3d 482 (7th Cir. 2005) (preempting a post-sale failure to warn claim against the manufacturer of a device that passed PMA scrutiny), *cert. denied*, 547 U.S. 1003 (2006); *Martin v. Medtronic, Inc.*, 254 F.3d 573, 575 (5th Cir. 2001) (“Medtronic’s compliance with the Food and Drug Administration’s . . . rigorous premarket approval procedure . . . [preempts] the plaintiffs’ Texas common law products liability tort claims.”), *cert. denied*, 534 U.S. 1078 (2002); *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000) (finding that the PMA process constituted a federal requirement under the MDA), *cert. denied*, 534 U.S. 818 (2001); *Smiths Indus. Med. Sys., Inc. v. Kernats*, 669 N.E.2d 1300 (Ill. App. Ct. 1996) (refusing to preempt tort claims against a manufacturer of a Class III device approved through the PMA process), *cert. denied*, 522 U.S. 1044 (1998), *overruled by* *Weiland v. Teletronics Pacing Sys., Inc.*, 721 N.E.2d 1149 (Ill. 1999).

90. The Court took up this question in *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1006 (2008).

91. In *Lohr*, the Court left open the question of whether the MDA preemption clause applies to state common law, but a plurality noted that such situations “will be rare indeed.” *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 502–03 (1996) (plurality opinion).

MDA. The Court then concluded that common-law tort duties were state requirements subject to preemption by the MDA.

III. IN THE SHADOWS OF *LOHR*: *RIEDEL V. MEDTRONIC, INC.*

As noted previously, the *Lohr* Court decided not to preempt tort claims based on its determination that the § 510(k) process had not established “device-specific” requirements.⁹² The *Riegel* Court used this framework to reach a different result by distinguishing the PMA process from § 510(k) review.⁹³ These differences, which formed the basis for the different outcomes in *Lohr* and *Riegel*, can be described as the “*Riegel* distinction.”

Ultimately, there can be no doubt that the PMA process differs from the § 510(k) process—the key distinction being the nature and extent of the review. The PMA process evaluates the device on its own merits, whereas substantial equivalence looks at the device in comparison to other devices.⁹⁴ The question is whether this distinction forms a sufficient basis for a different preemption rule.

A. *Drawing a Line in the Sand: Justice Scalia’s Majority Opinion*

1. THE “*RIEGEL* DISTINCTION”: THE PMA PROCESS IS A FEDERAL REQUIREMENT

First, the Court addressed whether the PMA process is a “federal requirement” under the MDA. *Riegel* relied extensively on the analysis set forth in *Lohr*,⁹⁵ which established the device-specific requirement of MDA preemption analysis.⁹⁶ In *Lohr*, the Court characterized the § 510(k) process as a simple equivalence review that merely compares the new device to a pre-MDA device.⁹⁷ The *Riegel* Court agreed with this assessment and further characterized the § 510(k) process as merely “a qualification for an exemption [from the PMA requirement].”⁹⁸

In distinguishing the PMA process, the *Riegel* Court characterized it as “a rigorous process” that required multiple volumes of detailed data.⁹⁹ The Court discussed the FDA’s time-intensive review process,¹⁰⁰

92. See discussion *supra* Part II.D.1.

93. See *Riegel*, 128 S. Ct. at 1006–07.

94. See *Lohr*, 518 U.S. at 493.

95. *Lohr* is the only case cited in the *Riegel* Court’s analysis of the contours of “federal requirement” within the meaning of the MDA. See *Riegel*, 128 S. Ct. at 1006–07.

96. See *Lohr*, 518 U.S. at 500 (determining that only federal requirements that are “applicable to the device” have preemptive effect).

97. *Id.* at 493.

98. *Riegel*, 128 S. Ct. at 1007.

99. *Id.* at 1004 (internal quotation marks omitted).

100. See *id.* (“The FDA spends an average of 1,200 hours reviewing each application . . .”).

which requires the agency to “weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.”¹⁰¹ Finally, the *Riegel* Court placed particular emphasis on the PMA’s focus on safety.¹⁰²

But any device approved by the FDA, regardless of which approval process it undergoes, has the potential to harm consumers. As noted by a former Chief Counsel to the FDA, “[e]ven the most thorough regulation of a product such as a critical medical device may fail to identify potential problems presented by the product.”¹⁰³ Although the FDA devotes more resources to reviewing PMA applications than it does to § 510(k) notifications,¹⁰⁴ it does not necessarily follow that PMA-approved devices are categorically safer than substantially equivalent devices. “Devices subject to the premarket approval process . . . tend to be more technologically advanced, expensive, and in some instances, risky.”¹⁰⁵ This suggests that the potential for dangerous and unsafe devices may in fact be higher among PMA-approved devices, despite the FDA’s more expansive review. Additionally, the FDA has its fair share of resource challenges¹⁰⁶ and questionable decisions,¹⁰⁷ which undermine the public’s trust in the depth and quality of the agency’s product reviews.¹⁰⁸

Further, it is debatable whether the PMA process, standing alone, establishes “device-specific requirements” as required for preemption under the MDA. Even the federal government has taken contradictory positions in this debate. In 1997, soon after the Court decided *Lohr*, the

101. *Id.* (alteration in original) (quoting 21 U.S.C. § 360c(a)(2)(C) (2006)) (internal quotation marks omitted).

102. *See id.* at 1007 (“[P]remarket approval is focused on safety, not equivalence. . . . [T]he FDA may grant premarket approval only after it determines that a device offers a reasonable assurance of safety and effectiveness.” (citing 21 U.S.C. § 360e(d) (2006))).

103. Margaret Jane Porter, *The Lohr Decision: FDA Perspective and Position*, 52 *FOOD & DRUG L.J.* 7, 11 (1997).

104. *See Lohr*, 518 U.S. at 479 (noting that the FDA spends 1,200 hours reviewing a PMA application but only twenty hours conducting a § 510(k) review).

105. Linda Greenhouse, *Justices Shield Medical Devices from Lawsuits*, *N.Y. TIMES*, Feb. 21, 2008, at A1.

106. *See* Terry Carter, *The Pre-emption Prescription*, *A.B.A. J.*, Nov. 2008, at 42, 47 (characterizing the FDA as “understaffed, underfunded and outgunned by the industries it regulates”).

107. *See* SUSAN BARTLETT FOOTE, *MANAGING THE MEDICAL ARMS RACE: PUBLIC POLICY AND MEDICAL DEVICE INNOVATION* 136 (1992) (noting that Congress “has sharply and regularly criticized the FDA for underregulation and failure to enforce regulatory standards”); Suzanne Cook, et al., *Supreme Court Preview: Riegel v. Medtronic (06-179)*, *FED. LAW.*, Feb. 2008, at 61, 62 (referencing a survey that determined that sixty percent of “FDA scientists knew of cases in which commercial interests had influenced FDA approval”).

108. *See* Carter, *supra* note 106, at 47 (noting that the FDA process “depends on a widespread trust in the system that has been wavering in recent years”).

government filed an amicus brief in a case similar to *Riegel*.¹⁰⁹ There, the government expressed its belief that “the agency’s decision to grant . . . [a] PMA . . . did not establish specific federal requirements within the meaning of Section 360k.”¹¹⁰ Just ten years later in *Riegel*, the government completely reversed course.¹¹¹ This inconsistency within the government’s own interpretation of “federal requirements” supports the conclusion that the meaning of this phrase is far from clear.

In holding that § 510(k) was not a “federal requirement,” the *Lohr* Court determined that the process “did not ‘require’ [the manufacturer’s device] to take any particular form.”¹¹² However, the same could be said of the PMA process.¹¹³ For example, the FDA can take one of four separate actions with any PMA: (1) issue an approval order, (2) issue an approvable letter, (3) issue a not approvable letter, or (4) issue an order denying the application.¹¹⁴ In the first situation, the FDA approves the application as submitted and makes only “minor” or “editorial” changes to the device label.¹¹⁵ Since the manufacturer bears the burden of providing the substantive device specifications,¹¹⁶ the FDA does not provide any substantive input into the device’s design when it merely issues an approval order;¹¹⁷ thus, it is unlikely that the FDA has imposed any “requirement.”

In contrast, a not approvable letter “identif[ies] measures required to place the PMA in approvable form.”¹¹⁸ Similarly, an approvable letter specifically describes the information that the applicant must provide to gain approval.¹¹⁹ These conditional approvals appear more in line with

109. Brief for the United States as Amicus Curiae, *Smith Indus. Med. Sys., Inc. v. Kernats*, 522 U.S. 1044 (1997) (No. 96-1405), 1997 WL 33561767.

110. *Id.* at 14 (characterizing the PMA as the FDA’s indication “that the manufacturer had complied with the applicable federal minimum standards for use and marketing”).

111. See Brief for the United States as Amicus Curiae Supporting Respondent at 8, *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008) (No. 06-179), 2007 WL 3231418 (“[P]remarket approval of a Class III device imposes specific federal requirements . . . and thus has preemptive effect.”).

112. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996).

113. *But see Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1007 (2008) (noting that substantially equivalent devices are not required to “take any particular form for any particular reason,” but distinguishing the PMA process because the manufacturer cannot deviate from the FDA-approved formulation (quoting *Lohr*, 518 U.S. at 493)).

114. 21 C.F.R. § 814.44(c) (2009).

115. *Id.* § 814.44(d)(1).

116. See 21 U.S.C. § 360e(d)(2)(A)-(B) (2006) (indicating that the FDA will deny a PMA application if the information provided by the applicant fails to demonstrate reasonable assurance of safety and effectiveness).

117. See 21 C.F.R. § 814.44(d)(1) (noting that the device will be approved if the sole deficiency in the application relates to “editorial or similar minor deficiencies in the draft final labeling”).

118. *Id.* § 814.44(f).

119. *Id.* § 814.44(e).

the preemptive “device-specific requirements” contemplated by *Lohr*.¹²⁰ Further, the FDA’s interpretive regulation demands that only “specific requirements applicable to a particular device” have preemptive effect.¹²¹ This regulation has been interpreted as requiring “the imposition of some identifiable precondition that applies to the device in question.”¹²²

Justice Ginsburg provided two specific examples of such a situation at oral argument in *Riegel*.¹²³ Where the FDA denies a manufacturer’s request to make a specific safety improvement, a tort suit premised on the manufacturer’s failure to make that improvement would likely be preempted.¹²⁴ Another likely example of a federally imposed requirement is where the FDA conditions premarket approval on the inclusion of X, but a future lawsuit claims that X caused the device to become unreasonably dangerous.¹²⁵

These examples demonstrate that situations do indeed exist where the FDA has promulgated preemptive federal requirements within the meaning of the MDA; otherwise the regulation’s reference to “federal requirements” would be superfluous. But these examples also lead to the question: is a bright-line rule, such as the “*Riegel* distinction,” appropriate in MDA preemption jurisprudence? In an express preemption analysis, “appropriateness” depends on whether Congress intended such a distinction.¹²⁶ On the one hand, by conditioning preemption on the depth of the FDA’s review, the Court arguably meets the congressional objective of balancing the risks of the device against the benefits.¹²⁷ Congress certainly recognized and accounted for the varying degrees of risk associated with medical devices.¹²⁸ But on the other hand, it did not recognize any categorical distinction between the risks associated with substantially equivalent devices and the risks associated with PMA-

120. These examples would likely cause to the courts to become bogged down in a cumbersome analysis of each and every FDA review of the various medical devices. They are not proffered as a solution to the MDA preemption quagmire but merely illustrate the inherent problems with the “*Riegel* distinction.”

121. 21 C.F.R. § 808.1(d).

122. *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1374 (11th Cir. 1999).

123. See Transcript of Oral Argument at 13–17, *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008) (No. 06-179).

124. See *id.* at 13.

125. See *id.* at 16.

126. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485–86 (1996) (“[A]ny understanding of the scope of a pre-emption statute must rest primarily on ‘a fair understanding of congressional purpose.’” (quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 530 n.27 (1992))).

127. See S. REP. NO. 94-33, at 6 (1975) (discussing the need for regulation to protect consumers, while also encouraging medical research).

128. See *id.* at 10 (recommending that “all medical devices be classified into one of three categories based upon the degree of risk to the public health and safety represented by each individual device or class of devices”).

approved devices.¹²⁹ And the MDA's preemption provision is silent on the matter.¹³⁰ Thus the justification for the bright-line rule established by the "*Riegel* distinction" seems to lie beyond the text of the MDA and congressional intent.

2. THE *CIPOLLONE* PROPOSITION, AGAIN?: COMMON-LAW CLAIMS ARE STATE REQUIREMENTS

After resolving the "federal requirements" issue, the *Riegel* Court addressed whether state tort law is a "state requirement" under the MDA. In contrast to the *Lohr* Court, which was not required to reach this issue,¹³¹ the *Riegel* Court needed to tackle the issue head on. "[C]ommon-law causes of action for negligence and strict liability do impose 'requirement[s]' and would be preempted by federal requirements specific to a medical device."¹³² *Riegel* relied on *Lohr*'s concurring and dissenting opinions, which represented the views of five Justices, to support this proposition.¹³³ *Riegel* also cited *Cipollone*, as well as another express preemption case (*Bates v. Dow Agrosciences, LLC*),¹³⁴ where the Court had interpreted the statutory phrase "requirement" to include common-law actions.¹³⁵ Justice Scalia noted that Congress "regularly used" the term "requirement" in its enactments.¹³⁶

Indeed, the two preemption statutes in *Cipollone* and *Bates* each contain the phrase "requirement,"¹³⁷ as does the MDA.¹³⁸ However,

129. For example, the devices at issue in *Riegel* and *Lohr* were both Class III devices—the class associated with the most risk—even though one device reached the market through the § 510(k) process and the other through the PMA process.

130. The preemption statute, 21 U.S.C. § 360k, merely makes a general reference to "requirement." The statute only preempts state requirements that are: (1) "different from, or in addition to" federal requirements and (2) "related to the safety or effectiveness of the device." 21 U.S.C. § 360k(a)(1)–(2) (2006).

131. See discussion *supra* Part II.D.1.

132. *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1007 (2008) (second alteration in original).

133. See *id.* (citing *Lohr*, 518 U.S. at 512 (O'Connor, J., concurring in part and dissenting in part); *id.* at 503–505 (Breyer, J., concurring)).

134. 544 U.S. 431 (2005).

135. See *Riegel*, 128 S. Ct. at 1007–08.

136. *Id.* at 1008.

137. The statute at issue in *Cipollone* states, "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 chapter." 15 U.S.C. § 1334(b) (2006) (emphasis added). The statute at issue in *Bates* provides, "[A] State shall not impose or continue in effect any requirements for labeling or packaging [of a federally registered pesticide or device] in addition to or different from those required under this subchapter." 7 U.S.C. § 136v(b) (2006) (emphasis added).

138. The MDA's preemption provision states "[N]o State . . . may establish or continue in effect with respect to a device intended for human use any requirement" that is different from the federal requirement regarding safety and effectiveness. 21 U.S.C. § 360k(a) (2006) (emphasis added).

neither *Cipollone* nor *Bates* involved the MDA.¹³⁹ Therefore, it should not be assumed that “requirement” has the same meaning in all three statutes.

Although the Court has often held that “identical words and phrases within the same statute should normally be given the same meaning,”¹⁴⁰ there does not appear to be any comparable presumption in regards to words used in *different* statutes. Rather, in a recent case involving statutory construction, the Supreme Court noted that “[m]ost words have different shades of meaning and consequently may be variously construed . . . when they occur in different statutes.”¹⁴¹ Certainly, this statement cannot be deemed a prohibition against Justice Scalia’s rationale in *Riegel*, given the Court’s use of the phrase “*may* be variously construed.”¹⁴² However, the Court’s instruction on statutory interpretation, at the very least, calls into question *Riegel*’s strong reliance on *Cipollone* and *Bates*.

Further, the legislative history of the MDA belies the *Riegel* Court’s expansive interpretation of state requirements. *Riegel* seemed to imply that the MDA’s legislative history lacked any evidence of Congress’s intent to exclude common-law claims from the meaning of “state requirements.”¹⁴³ But the *Lohr* plurality had previously noted that “the legislative history [of the MDA] indicates that any fears regarding regulatory burdens were related more to the risk of *additional* federal and state regulation rather than the danger of pre-existing duties under common law.”¹⁴⁴ In passing the MDA, Congress specifically took note of state-established, medical-device regulatory regimes that existed before

139. *Cipollone* required the Court to interpret the Public Health Cigarette Smoking Act of 1969, codified at 15 U.S.C. §§ 1331–1341. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 510 (1992). *Bates* required the Court to interpret the Insecticide, Fungicide, and Rodenticide Act, codified at 7 U.S.C. § 136. *Bates*, 544 U.S. at 434.

140. *Powerex Corp. v. Reliant Energy Servs., Inc.*, 551 U.S. 224, 232 (2007) (noting that this interpretation is a “standard principle of statutory construction”). Courts *may* infer different interpretations of the same word within a statute when warranted by the context of the statute. *See* *Env’tl. Def. v. Duke Energy Corp.*, 549 U.S. 561, 575–76 (2007) (“There is . . . no ‘effectively irrebuttable’ presumption that the same defined term in different provisions of the same statute must ‘be interpreted identically.’ Context counts.” (quoting *United States v. Duke Energy Corp.*, 411 F.3d 539, 550 (4th Cir. 2005), *vacated sub nom.*, *Env’tl. Def. v. Duke Energy Corp.*, 549 U.S. 561 (2007))).

141. *Env’tl. Def.*, 549 U.S. at 574 (2007) (8-1 decision) (first alteration in original) (quoting *Atl. Cleaners & Dyers, Inc. v. United States*, 286 U.S. 427, 433 (1932)) (internal quotation marks omitted). Ironically, Justice Scalia was among the eight Justices who joined this opinion, despite reasoning in *Riegel* that “requirement” had the same meaning in three unrelated statutes.

142. *Id.* (emphasis added).

143. *See Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1008 (2008) (“*Absent other indication*, reference to a State’s ‘requirements’ includes its common-law duties.” (emphasis added)). *Riegel* could be read broadly as supporting the proposition that *any* statute referencing “state requirements” includes state common law.

144. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 490 (1996) (plurality opinion).

the implementation of the MDA and determined that such regimes would burden interstate commerce.¹⁴⁵ Thus, the legislative history indicates Congress's intent to preempt these regimes rather than common law.¹⁴⁶

3. EXPRESS OR IMPLIED PREEMPTION?

Riegel claims to derive preemption authority from the statute itself,¹⁴⁷ but the "*Riegel* distinction" appears to be devoid of any support in the text of the statute or in congressional intent. In the absence of clear direction from Congress, the proper basis for the "*Riegel* distinction" may lie more appropriately in implied preemption. Courts typically conduct this analysis when congressional intent is unclear.¹⁴⁸ However, the Court is divided over whether the existence of an express preemption provision precludes the Court from conducting implied preemption analysis.¹⁴⁹

At least three forms of implied preemption are generally recognized: (1) actual conflict preemption is limited to circumstances where the state law directly conflicts with the federal law; (2) obstacle preemption occurs when "imposition of the state liability will *frustrate* the ends of the federal statute"; and (3) field preemption occurs where the federal scheme is so pervasive that preemption can be reasonably inferred.¹⁵⁰

The analysis in *Riegel* seems to draw from some of these implied preemption principles. For example, in a field preemption analysis,

145. See Adler & Mann, *supra* note 38, at 924 n.131 (noting Congress's recognition that "a substantial number of differing requirements . . . imposed by jurisdictions other than the Federal government" would unduly burden interstate commerce (quoting H.R. REP. NO. 94-853, at 45 (1976) (internal quotation marks omitted))).

146. See *Riegel*, 128 S. Ct. at 1018 (Ginsburg, J., dissenting) ("[S]tate premarket regulation of medical devices, not any design to suppress tort suits, accounts for Congress' inclusion of a preemption clause in the MDA."); Vladeck, *supra* note 17, at 104-105 (suggesting that the MDA's preemption provision was aimed at state regulatory regimes, which Congress allowed the states to maintain until the FDA promulgated regulations).

147. See *Riegel*, 128 S. Ct. at 1009.

148. Radwan, *supra* note 40, at 352. The clarity of the statute, of course, is debatable. See discussion *infra* Part III.B.1.

149. The *Cipollone* majority noted, "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." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992) (citation omitted) (internal quotation marks omitted). The only current Justices who joined this part of the opinion are Justices Stevens and Kennedy. Justices Scalia and Thomas rejected this new rule noting that "we have never expressed such a rule before, and our prior cases are inconsistent with it." *Id.* at 547-48 (Scalia, J., concurring in the judgment in part and dissenting in part). Apparently, the Supreme Court has not directly addressed this issue since *Cipollone*.

150. Richard A. Epstein, *The Case for Field Preemption of State Laws in Drug Cases*, 103 NW. U. L. REV. COLLOQUY 54, 55 (2008); see also STARR ET AL., *supra* note 15, at 18-30.

courts evaluate whether the “scheme of federal regulation is sufficiently comprehensive” to reasonably infer no room for state regulation.¹⁵¹ By relying principally on the depth of the FDA approval process,¹⁵² *Riegel* and *Lohr* appear to be evaluating the pervasiveness of the federal scheme.¹⁵³ Even the examples of likely preemption that Justice Ginsburg raised during the *Riegel* oral argument¹⁵⁴ involved issues of implied preemption, because the device manufacturer would be unable to comply with the federal and state requirements simultaneously, which raises an actual conflict.

The *Riegel* majority’s analysis of the state law’s impact on the federal regulatory scheme also points to an implied preemption analysis. When the Court determined that “[s]tate tort law . . . disrupts the federal scheme,”¹⁵⁵ its language mirrored that of several implied preemption cases.¹⁵⁶ But Justice Scalia refused to embrace any hint of implied preemption in *Riegel*, asserting that the statute was clear and unambiguous.¹⁵⁷ The *Riegel* Court evaluated the jury’s ability to determine the safety and effectiveness of medical devices and concluded that the FDA was superior in that regard.¹⁵⁸ At oral arguments, Justice Scalia expressed his concern that “the jury is doing the same thing that the FDA did.”¹⁵⁹ At oral arguments, Justice Kennedy expressed his concern that “the jury is doing the same thing that the FDA did” and questioned whether “the finder of fact weigh[ed] the potential risks of injury and illness against the probable benefits to the health of the patient” when deciding a negligence claim.¹⁶⁰ Ultimately, the *Riegel* Court concluded

151. *Cal. Fed. Sav. & Loan Ass’n v. Guerra*, 479 U.S. 272, 281 (1986).

152. *See Riegel*, 128 S. Ct. at 1006–07; *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996).

153. Field preemption likely would not sweep as broadly as the Court did in *Riegel*, because it rarely applies to state common-law claims. *McGarity*, *supra* note 52, at 52. The MDA likely precludes field preemption analysis because “[t]he existence of an express pre-emption provision tends to contradict any inference that Congress intended to occupy a field broader than the statute’s express language defines.” *Cipollone*, 505 U.S. at 547 (Scalia, J., concurring in the judgment in part and dissenting in part).

154. *See* discussion *supra* Part III.A.1.

155. *Riegel*, 128 S. Ct. at 1008.

156. The Court impliedly preempted a state statute that was in tension with the National Labor Relations Act after determining that the statute was “disruptive” to the “complex and interrelated federal scheme.” *Wis. Dep’t of Indus., Labor & Human Relations v. Gould, Inc.*, 475 U.S. 282, 286 (1986) (emphasis added) (citation omitted). The Court impliedly preempted a state regulation that “disturb[ed] the uniformity of the federal scheme.” *Transcon. Gas Pipe Line Corp. v. State Gas and Oil Bd.*, 474 U.S. 409, 423 (1986) (emphasis added).

157. *See Riegel*, 128 S. Ct. at 1009 (noting that the Court relied only on the statute’s text, which “speaks clearly”).

158. *See id.* at 1008 (noting the jury’s limited ability to conduct a proper cost-benefit analysis of the medical device).

159. Transcript of Oral Argument at 7, *Riegel*, 128 S. Ct. 999 (No. 06-179), 2007 WL 4241897.

160. *Id.* at 6.

that the jury's disposition of the case "disrupts the federal scheme no less than state regulatory law to the same effect."¹⁶¹

As a policy matter, these observations may be true; but they are more properly directed to an implied preemption analysis than an express preemption analysis.¹⁶² When evaluating an ambiguous preemption statute, "the Court has generally required *clear evidence* of legislative intent to preempt state law."¹⁶³ In *Riegel*, that evaluation would require clear evidence that Congress intended to preempt state tort law.

However, there appears to be nothing in the MDA or in the legislative history that would support this level of preemption.¹⁶⁴ The *Lohr* plurality concluded as much when it failed to find "[any]thing in the hearings, the Committee Reports, or the debates suggesting that any proponent of the [MDA] intended a sweeping pre-emption of traditional common-law remedies against manufacturers and distributors of defective devices."¹⁶⁵ Since *Lohr* and *Riegel* interpret the same statute, the *Lohr* Court's analysis leads to the inference that the MDA is not sufficiently clear as to Congress's intent regarding the preemption of state tort claims. Therefore, if the "*Riegel* distinction" is appropriate, its basis appears to derive from implied preemption.¹⁶⁶

B. *Conflicting Legal and Analytical Underpinnings: Riegel vs. Lohr*

Riegel and *Lohr* cannot be reconciled because of the paramount differences in the foundational concepts underlying each Court's rationale. First, the *Riegel* and *Lohr* Courts appear to fundamentally disagree over the ambiguity, or lack thereof, of the MDA.¹⁶⁷ Second, the *Riegel* Court largely rejected two key provisions that anchored *Lohr*'s holding: "the 'ultimate touchstone' in every preemption case"¹⁶⁸ (congressional intent) and the fundamental presumption against preemption.¹⁶⁹ The two

161. *Riegel*, 128 S. Ct. at 1008.

162. See Sharkey, *supra* note 14, at 423 (noting that analysis of the conflict between the roles of the FDA and the jury "could prove influential, if not dispositive, in resolving implied conflict preemption disputes"). In an *implied* preemption case, the defendant manufacturer raised similar arguments to those set forth by the *Riegel* majority. See *Wyeth v. Levine*, 129 S. Ct. 1187, 1194 (2009) (noting Wyeth's argument that state tort law "substitutes a lay jury's decision . . . for the expert judgment of the FDA").

163. STARR ET AL., *supra* note 15, at 16.

164. Adler & Mann, *supra* note 38, at 924.

165. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 491 (1996) (plurality opinion).

166. This article principally critiques the rationale set forth by the Court in *Riegel* and takes no specific position on whether the MDA is so pervasive as to preempt state tort claims against manufacturers or whether state liability stands as an obstacle to the MDA.

167. See discussion *infra* Section III.B.1.

168. *Lohr*, 518 U.S. at 485 (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963) and citing *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992)).

169. See discussion *infra* Section III.B.2-3.

opinions also differ in the amount of deference each is willing to accord the FDA.¹⁷⁰

1. STATUTORY CONSTRUCTION AND THE SCOPE OF EXPRESS PREEMPTION ANALYSIS

The fundamental rift over the meaning of state requirements is rooted in the debate over statutory construction, particularly whether the Court should resort to congressional intent.¹⁷¹ When interpreting a statute, the Court must first determine “whether the language at issue has a plain and unambiguous meaning with regard to the particular dispute in the case.”¹⁷² *Riegel* and *Lohr* reached opposite conclusions on this important issue.¹⁷³ The *Riegel* majority saw no need to go beyond the four corners of the statute,¹⁷⁴ while the *Lohr* Court viewed the statute as ambiguous.¹⁷⁵ A finding of statutory ambiguity is often a precursor to the Court’s use of interpretive tools such as legislative history and agency interpretations.¹⁷⁶

These rules of statutory construction appear to inform the *Riegel* Court’s interpretation of the MDA’s preemption provision. It is well settled that any express preemption analysis must begin with the text of the preemption provision contained within the statute.¹⁷⁷ *Cipollone* further instructed that express preemption provisions should be construed narrowly.¹⁷⁸ In his dissent in *Cipollone*, Justice Scalia rejected the majority’s narrow construction rule and proclaimed, “The proper rule of construction for express preemption provisions is . . . the one that is

170. See discussion *infra* Section III.B.4.

171. See *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1009 (2008) (rejecting speculation about congressional intent); *id.* at 1016–18 (Ginsburg, J., dissenting) (relying heavily on congressional intent).

172. *Robinson v. Shell Oil Co.*, 519 U.S. 337, 340 (1997).

173. See Sharkey, *supra* note 14, at 415 n.4 (contrasting Justice Scalia’s assertion in *Riegel* that “‘the statute itself speaks clearly to the point at issue’” with the *Lohr* Court’s assertion that the statute had substantial ambiguity (quoting *Riegel*, 128 S. Ct. at 1009 and citing *Lohr*, 518 U.S. at 496)).

174. See *id.*

175. *Lohr*, 518 U.S. at 489 (plurality opinion) (citing the “ambiguities in the statute” as a reason to reject preemption of all common-law causes of action); *id.* at 505 (Breyer, J., concurring in part and in the judgment) (characterizing the MDA’s preemption provision as “highly ambiguous”).

176. CHRISTIAN E. MAMMEN, USING LEGISLATIVE HISTORY IN AMERICAN STATUTORY INTERPRETATION 31–32 (2002). However, preemption analysis appears to be an exception to this rule. See *id.* at 32 (noting that preemption analysis is a “special circumstance[] in which the Court will consult legislative history”).

177. *Lohr*, 518 U.S. at 484; *CSX Transp. Inc. v. Easterwood*, 507 U.S. 658, 664 (1993) (“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.”).

178. See *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 518 (1992).

customary for statutory provisions in general: Their language should be given its ordinary meaning.”¹⁷⁹

In keeping with this view of statutory construction, Justice Scalia relied primarily on a text-based interpretation of the MDA in *Riegel*.¹⁸⁰ He specifically rejected any intimation that anything other than the text was necessary to interpret the statute.¹⁸¹ *Lohr*’s approach to statutory interpretation was sharply different. *Lohr* was heavily guided by congressional intent¹⁸² and the FDA’s interpretation of the MDA.¹⁸³ The *Lohr* Court specifically rejected a solely text-based interpretation, noting that “[a]lthough our analysis of the scope of the preemption statute must begin with its text, our interpretation of that language does not occur in a contextual vacuum.”¹⁸⁴

These differences illustrate a larger problem in the doctrine of preemption analysis. In *Riegel*, Justice Scalia noted that “Congress is entitled to know what meaning this Court will assign to terms regularly used in its enactments.”¹⁸⁵ But lawyers and litigants are entitled to know what approach the Court will take in reviewing ambiguity and preemption provisions, because their claims depend on it. Nonetheless, ambiguity is a fluid concept that has not been fully defined by the Court.¹⁸⁶

In a case decided shortly after *Riegel*, the Court stated that “[w]hen the text of a pre-emption clause is susceptible of more than one plausible reading, courts ordinarily ‘accept the reading that disfavors pre-emption.’”¹⁸⁷ The existence of more than one plausible reading also gives rise to an inference of statutory ambiguity,¹⁸⁸ which suggests that the Court should consult legislative history or other interpretive tools. Despite the uncertainty surrounding the text of the MDA’s preemption provision,¹⁸⁹ the *Riegel* Court apparently rejected these principles of statutory construction and preemption analysis. Its textual statutory construction is also at odds with the Supreme Court’s command—a pre-

179. *Id.* at 548 (Scalia, J., concurring in the judgment in part and dissenting in part).

180. Sharkey, *supra* note 14, at 415.

181. *See Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1009 (2008) (rejecting any notion that the Court should rely on congressional intent or the FDA’s interpretation of the MDA’s meaning because the statute was clear on its face).

182. *Lohr*, 518 U.S. at 485–86.

183. *Id.* at 495 (“The FDA regulations interpreting the scope of § 360k’s pre-emptive effect . . . substantially informed [this opinion].”).

184. *Id.* at 484–85 (citation omitted).

185. *Riegel*, 128 S. Ct. at 1008.

186. MAMMEN, *supra* note 176, at 33.

187. *Altria Group, Inc. v. Good*, 129 S. Ct. 538, 543 (2008) (quoting *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005)).

188. *See MAMMEN*, *supra* note 176, at 32 (defining ambiguity as a situation where “the statutory text could plausibly be interpreted in two or more ways”).

189. *Lohr*, 518 U.S. at 495 (“[T]he language of . . . section [360k] is not entirely clear.”).

sumption against preemption. Further, the Court should have relied on Congress's intent, as has traditionally been the case in preemption jurisprudence.¹⁹⁰ *Riegel*'s departure from these principles injects uncertainty into preemption analysis.

2. A FOUNDATION OF *LOHR*: CONGRESSIONAL INTENT

Although ordinary rules of statutory interpretation typically require courts to find textual ambiguity before exploring legislative history, this rule appears to yield in the preemption context.¹⁹¹ The Court frequently relies on congressional intent in preemption cases because it is the core of *every* preemption analysis.¹⁹² However the *Riegel* Court rejected the use of congressional intent, with Justice Scalia boldly stating, "It is not our job to speculate upon congressional motives."¹⁹³ In contrast, *Lohr*—a case upon which *Riegel* heavily relied—noted that preemption must be "the clear and manifest purpose of Congress."¹⁹⁴ By finding that state law was not preempted, the *Lohr* Court implicitly determined that Congress's purpose was neither clear nor manifest as it related to preemption and substantially equivalent devices. If that proposition is true, then the question becomes whether Congress's purpose regarding preemption and PMA-approved devices was "clear and manifest."

The evidence suggests that Congress's purpose was no clearer regarding PMA devices than it was for substantially equivalent devices. In fact, the preemption provision articulated by Congress reflects no difference between the categories of devices.¹⁹⁵ Rather, § 360k refers generally to "any requirement applicable under this chapter."¹⁹⁶ It does not evince any effort to distinguish between devices approved under the PMA process or the § 510(k) process.

The legislative history of the MDA gives no indication that preemption should turn on the depth of the FDA's analysis or the length of time spent reviewing the device. "[A]ny understanding of the scope of a pre-emption statute must rest primarily on 'a fair understanding of *con-*

190. See *id.* at 485 (noting that Congress's intent is the cornerstone of preemption analysis).

191. See *MAMMEN*, *supra* note 176, at 40 (noting that "the presumption of controlling text is weakened" in preemption cases). The debate remains whether courts' consideration of congressional intent should be limited to *implied* preemption analysis rather than express preemption analysis.

192. *Lohr*, 518 U.S. at 485 (noting that "[t]he purpose of Congress is the ultimate touchstone" in *every* preemption case" (emphasis added) (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963))).

193. *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1009 (2008).

194. *Lohr*, 518 U.S. at 485 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

195. 21 U.S.C. §360k (2006).

196. *Id.*

gressional purpose.’”¹⁹⁷ Congress’s stated purpose in passing the MDA was to encourage medical-device research and development, while also balancing the device’s medical benefits against potential risks.¹⁹⁸ Arguably, the first objective may be achieved by preempting torts suits because manufacturers may be inclined to invest more money in research and development due to the decreased risk of postmarket litigation costs.¹⁹⁹ But it does not logically follow that subjecting a limited subset of Class III devices to preemption will further this objective.

3. A FOUNDATION OF *LOHR*: THE PRESUMPTION AGAINST PREEMPTION

The “*Riegel* distinction” also does not square with the consistent staple²⁰⁰ of preemption jurisprudence—the presumption against preemption. Indeed, the Court likely could not reach its conclusion in *Riegel* without rejecting the presumption against preemption. Recently, the Court has moved away from the presumption by construing express preemption statements broadly.²⁰¹ But in *Lohr*, the Court proclaimed that “we have long presumed that Congress does not cavalierly pre-empt state-law causes of action.”²⁰² This principle is grounded in the Court’s “respect for the States as ‘independent sovereigns.’”²⁰³ Yet the *Riegel* majority never mentioned this long-held presumption against preemption.²⁰⁴

The absence of the presumption against preemption in *Riegel* cannot be explained by *Riegel*’s purported grounding in express preemption.²⁰⁵ The *Lohr* Court, which interpreted the same express preemption provision, mandated that its interpretation be “informed” by the pre-

197. *Lohr*, 518 U.S. at 485–86 (quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 530 (1992)).

198. S. REP. NO. 94-33, at 2 (1975).

199. Cf. FOOTE, *supra* note 107, at 20 (characterizing FDA regulation and products liability as inhibiting discovery). But cf. *Lohr*, 518 U.S. at 490 (plurality opinion) (noting that the MDA lacks any indication that Congress feared that tort suits would hinder the development of medical devices).

200. See *Lohr*, 518 U.S. at 485 (citing cases as early as 1947 that proclaim the presumption against preemption).

201. See Sharkey, *supra* note 14, at 416 (noting that the presumption “has receded of late in the imagination of the Supreme Court Justices”).

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

203. *Wyeth v. Levine*, 129 S. Ct. 1187, 1195 n.3 (2009).

204. Sharkey, *supra* note 14, at 416–17.

205. *Id.* at 417 n.11 (“[T]he Court has—paradoxically—applied the presumption in the express preemption products liability cases, but not in the implied ones.” (citing Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 458 (2008))). Less than one year after Professor Sharkey’s observation, the Court applied the presumption against preemption in *Wyeth v. Levine*, a case involving implied preemption and pharmaceuticals. See *Wyeth*, 129 S. Ct. at 1194–95.

sumption.²⁰⁶ *Cipollone*—another express preemption case upon which *Lohr* and *Riegel* relied—also gave credence to the presumption,²⁰⁷ despite finding that some state-law claims were preempted.

Now the question arises: is the presumption against preemption dead in the express preemption context? Justice Scalia's comments in his *Cipollone* concurrence provide some inkling as to why the presumption may have died in the twelve years between *Lohr* and *Riegel*. He stated, "[I]t seems to me that assumption [against preemption] dissolves once there is conclusive evidence of intent to pre-empt in the express words of the statute itself."²⁰⁸ These comments indicate that Justice Scalia disfavors any presumption against preemption in the express preemption context.

Apparently, Justice Scalia is not alone in his effort to erode the presumption.²⁰⁹ Judicial sentiment has shifted from the "Consumer Decade"²¹⁰ of the 1960s and 70s, which gave rise to consumer-protection laws such as the MDA, to a probusiness stance that favors commerce at the expense of state autonomy.²¹¹ This sentiment has seeped into current Supreme Court jurisprudence with the addition of Chief Justice John Roberts, who is "strongly pro-business."²¹² Commentators have also noted Justice Alito's affinity for businesses.²¹³ The change in the Supreme Court's composition post-*Lohr* allowed the *Riegel* Court to hold that state common law constitutes a "requirement" that may be pre-

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

207. See *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) ("Consideration of issues arising under the Supremacy Clause 'start[s] with the assumption that the historic police powers of the States [are] not to be superseded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress.'" (alterations in original) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947))).

208. *Id.* at 545 (Scalia, J., concurring in the judgment in part and dissenting in part).

209. Justice Thomas joined Justice Scalia's *Cipollone* dissent, which rejected the presumption against preemption in the express preemption context. *Id.* Justice Alito has discouraged the use of the presumption in *implied* preemption cases. See *Wyeth*, 129 S. Ct. at 1228–29 (Alito, J., dissenting, joined by Roberts, C.J. and Scalia, J.).

210. Adler & Mann, *supra* note 38, at 895 n.1 (noting that more than half of the consumer protection laws enacted by the federal government between 1891 and 1972 were enacted in the "Consumer Decade" between 1966 and 1972 (citing Teresa M. Schwartz, *The Consumer Product Safety Commission: A Flawed Product of the Consumer Decade*, 51 GEO. WASH. L. REV. 32, 34 n.2 (1982))); see also Foote, *supra* note 107, at 114 ("The late 1960s and the 1970s were a time of growing consumer activism and power.").

211. Adler & Mann, *supra* note 38, at 895–96; see Erwin Chemerinsky, *A Troubling Trend in Preemption Rulings*, TRIAL, May 2008, at 62, 62 ("A tendency to find in favor of businesses pushing the preemption argument began with the Rehnquist Court.").

212. Chemerinsky, *supra* note 211, at 64.

213. See, e.g., Greg Stohr, *Alito Champions Business Causes in First Full High-Court Term*, BLOOMBERG.COM, June 26, 2007, <http://www.bloomberg.com/apps/news?pid=20601103&sid=A8MaW0PF9zK4&refer=US>.

empted by federal requirements.²¹⁴

Political influences have also played a role in the judicial shift from consumerism to probusiness. The “preemption push” exploded in 2000 when then-presidential candidate, George W. Bush, ran on a platform that emphasized tort reform.²¹⁵ After his election, President Bush appointed legal counsels to key agencies, including the FDA, who shared his views on tort reform.²¹⁶ In 2002, the FDA began to insert itself into drug and medical device preemption cases by filing amicus briefs in support of the manufacturers.²¹⁷ Justice Breyer’s inclination for strong deference to agencies²¹⁸ combined with the probusiness stance of the Roberts Court²¹⁹ set the stage for the Court to preempt state tort suits in *Riegel*.

But is the erosion of the presumption against preemption a good thing? Preemption provisions are rarely clear-cut.²²⁰ Thus, courts need an anchor in which to begin their preemption analysis. The presumption has provided that anchor for over sixty years.²²¹ The principle is so embedded in the Court’s jurisprudence that the Court recognized the rule even after its decision in *Riegel* largely ignored it.²²² But precedent is not the only reason favoring the presumption. More importantly, the principle is constitutionally grounded in state sovereignty.²²³ The presumption also provides an additional layer of protection for those areas

214. In *Lohr*, five Justices agreed with the proposition regarding common law as “state requirements”: Justices Breyer, O’Connor, Rehnquist, Scalia, and Thomas. When *Riegel* reached the Supreme Court, Justices O’Connor and Rehnquist were no longer part of the Court, but Chief Justice Roberts and Justice Alito filled the void by voting for the proposition.

215. Thomas O. McGarity, *Curbing the Abuse of Corporate Power: The Perils of Preemption*, TRIAL, Sept. 2008, at 20, 21 (noting that as a presidential candidate, George W. Bush vowed to make tort reform a high priority to combat “vexatious litigation”).

216. *Id.* at 21. Bush-appointee Daniel Troy served as Chief Counsel to the FDA from August 2001 to November 2004 and was instrumental in promulgating the agency’s push for preemption. Carter, *supra* note 106, at 44.

217. Carter, *supra* note 106, at 43.

218. See Sharkey, *supra* note 14, at 421 (“Justice Breyer’s strong-form deference to agencies is guided by his conviction that agencies have a ‘special understanding of the likely impact of both state and federal requirements.’” (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 506 (1996) (Breyer, J., concurring))).

219. See Chemerinsky, *supra* note 211, at 64 n.22 (characterizing the Roberts Court as potentially “the most probusiness Court since the mid-1930s” (citing Jeffrey Rosen, *Supreme Court Inc.*, N.Y. TIMES MAG., Mar. 16, 2008, at 38, 40)).

220. Sharkey, *supra* note 14, at 415; Epstein, *supra* note 150, at 55.

221. See *supra* note 200 (noting that the presumption has been recognized since at least 1947).

222. See *Wyeth v. Levine*, 129 S. Ct. 1187, 1194–95 (2009) (characterizing the presumption as a cornerstone of preemption jurisprudence); *Altria Group, Inc. v. Good*, 129 S. Ct. 538, 543 (2008) (noting the applicability of the presumption in express and implied preemption cases).

223. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (“[B]ecause the States are independent sovereigns in our federal system, we have long presumed [against preemption].” (emphasis added)).

left untouched by the preemption provision, by acting as a check on unwarranted judicial intrusion to ensure that courts do not exceed the bounds prescribed by Congress.²²⁴

4. A FOUNDATION OF *LOHR*: DEFERENCE TO THE FDA

Agency interpretations are another interpretive tool used by the Court to construe ambiguous statutes.²²⁵ Agencies interpret statutes in many different media including, but not limited to, duly promulgated regulations and amici briefs.²²⁶ The level of deference that should be afforded to each is unclear,²²⁷ and *Riegel* did nothing to clarify the issue. This section will briefly address deference to agency regulations, followed by agency positions in amici briefs.

The *Lohr* opinion was “substantially informed” by FDA regulations interpreting the scope of the MDA’s preemption provision.²²⁸ Specifically, *Lohr* interpreted the MDA in light of 21 C.F.R. § 808.1(d), which provides: “State or local requirements are preempted only when the [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the [MDA].” *Lohr* has been described as one of the “peaks of modern judicial deference to the FDA.”²²⁹

Riegel acknowledged *Lohr*’s reliance on the FDA’s regulation and used *Lohr*’s regulation-based framework to determine that the PMA process is device specific and therefore a federal requirement.²³⁰ Indeed, the *Riegel* Court could not rely on *Lohr* without accepting (to a certain degree) the FDA’s interpretation of the statute, because *Lohr*’s “device-specific” analysis was predicated on the FDA’s interpretation of the

224. See *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992) (noting that when Congress expressly defines the bounds of preemption, it is implied that matters beyond those bounds are not preempted).

225. MAMMEN, *supra* note 176, at 18.

226. Richard C. Ausness, “*After You, My Dear Alphonse!*”: *Should the Courts Defer to the FDA’s New Interpretation of § 360k(a) of the Medical Device Amendments?*, 80 TUL. L. REV. 727, 772 (2006). Many scholars and judges have debated the amount of deference that courts should generally give the FDA, and no clear answer has emerged. Compare Sharkey, *supra* note 14, at 418 (proposing a model that “facilitate[s] input from federal agencies”), and *Lohr*, 518 U.S. at 496 (noting that the FDA is “uniquely qualified” to determine the preemptive effect on state law), with Epstein, *supra* note 150, at 62–63 (criticizing agency deference in favor of field preemption), and *Lohr*, 518 U.S. at 512 (O’Connor, J., concurring in part and dissenting in part) (questioning the majority’s deference to the agency’s interpretation where a “clear statute [is] at issue”).

227. Ausness, *supra* note 226, at 772.

228. *Lohr*, 518 U.S. at 495.

229. James T. O’Reilly, *Losing Deference in the FDA’s Second Century: Judicial Review, Politics, and a Diminished Legacy of Expertise*, 93 CORNELL L. REV. 939, 943 (2008).

230. See *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1006–07 (2008).

MDA's preemption provision.²³¹

But in another part of its analysis, *Riegel* adopted a neutral stance on deference to regulations, "[n]either accepting nor rejecting the proposition that [§ 808.1(d)(1)] can properly be consulted to determine the statute's meaning."²³² The Court's reluctance to defer to FDA regulations is puzzling in light of its heavy reliance on § 808.1(d) in determining that the PMA process was device specific. Thus the level of deference that the Court will give to FDA regulations remains unclear after *Riegel*.

FDA interpretations expressed in amici briefs may be entitled to even less deference than agency regulations,²³³ because the former are not subject to formal adjudication procedures such as notice and comment periods.²³⁴ Further, Professor Richard A. Epstein points out "the dangers of agency flip-flop" that generally accompany agency deference.²³⁵ A forerunner to *Riegel* is illustrative of this danger. In *Smith Industries Medical Systems, Inc. v. Kernats*,²³⁶ the government submitted an amicus brief, expressing its view that the PMA process did not preempt state tort law claims.²³⁷ This position was, of course, in direct opposition to the government's stance in *Riegel*, where it deemed the PMA process a federal requirement that should preempt state law.²³⁸ The *Riegel* majority noted this "flip-flop" and hypothesized that the level of deference to the FDA's new position "*might be reduced* by the fact that the agency's earlier position was different."²³⁹

Presidents have differing philosophies regarding preemption, tort reform, and federalism that leave agencies' positions on these matters

231. *Lohr* acknowledged "the critical importance of device specificity in our (and the FDA's) construction of § 360k." *Lohr*, 518 U.S. at 502 (plurality opinion).

232. *Riegel*, 128 S. Ct. at 1011. The Court's ambivalence regarding agency deference signals a larger divide among the Court than the 8-1 *Riegel* majority would suggest. See Sharkey, *supra* note 14, at 421 (noting that "equivocation was [likely] necessary to carry an eight-Justice majority").

233. See generally Ausness, *supra* note 226 (discussing the reasons why the FDA's new position on preemption, articulated in multiple amici curiae briefs, is not entitled to deference).

234. *Id.* at 773.

235. Epstein, *supra* note 150, at 63 (citing Richard A. Epstein, *Why the FDA Must Preempt Tort Litigation: A Critique of Chevron Deference and a Response to Richard Nagarenda*, 1 J. TORT L. art.5, at 15 (2006), available at <http://www.bepress.com/jtl/vol1/iss1/art5/>).

236. 669 N.E. 2d 1300 (1996), cert. denied, 522 U.S. 1044 (1998).

237. Brief for the United States as Amicus Curiae at 19, *Smith Indus. Med. Sys., Inc. v. Kernats*, 522 U.S. 1044 (1998) (No. 96-1405), 1997 WL 33561767 ("[T]he FDA's grant of . . . a PMA does not, by itself, have preemptive effect.").

238. Brief for the United States as Amicus Curiae Supporting Respondents, *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008) (No. 06-179), 2007 WL 3231418.

239. *Riegel*, 128 S. Ct. at 1009 (emphasis added). The Court noted that deference was *not* warranted in this case because the text of the statute was clear. *Id.*

open to modifications.²⁴⁰ “A change in presidential administrations could bring a change in philosophy, yet again.”²⁴¹ Thus, *Riegel*’s possible shift away from deference to agency amici briefs may help to bring more consistency to the Court’s MDA preemption jurisprudence.

IV. IMPLICATIONS

A. *Litigants in Search of a Framework*

Ultimately, *Riegel* prevents injured consumers from bringing some common-law tort suits against manufacturers of PMA-approved devices.²⁴² Given that *Lohr* is left undisturbed,²⁴³ injured consumers still have a defective-design cause of action against manufacturers of substantially equivalent devices.²⁴⁴ Although it seems fundamentally unfair that consumers’ ability to recover for their injuries is bifurcated depending on how the device came to market,²⁴⁵ *Riegel* does not preclude all claims against manufacturers of PMA-approved devices. State-law claims alleging that a manufacturer has acted in violation of FDA regulations are not preempted.²⁴⁶ For example, negligent manufacturing claims still survive because they rest upon a showing that the manufacturer did not follow FDA requirements; therefore, there is no conflict between state and federal requirements.²⁴⁷ A claim may also exist for “situations where new product risks come to light *after* the FDA’s initial approval.”²⁴⁸

Though *Riegel*’s holding is somewhat narrow in the medical-device context, it has the potential to reach beyond the device industry. The central issue is the uncertainty that *Riegel* has injected into the express preemption debate. After *Riegel*, it is unclear whether the presumption against preemption will resurface.²⁴⁹ Some of the Justices, particularly

240. See discussion *supra* Part III.B.3 (discussing President Bush’s sweeping change in the FDA’s approach to preemption and tort reform).

241. Carter, *supra* note 106, at 47.

242. See *Riegel*, 128 S. Ct. at 1009.

243. By relying heavily on *Lohr*, the *Riegel* Court implicitly found that *Lohr*’s holding is still good law. See *id.* at 1006.

244. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 492 (1996).

245. This fundamental unfairness is magnified by the fact that the legislative history does not appear to indicate any intent to create such a barrier. See discussion *supra* Part III.B.2.

246. See *Greenhouse*, *supra* note 105 (“The [*Riegel*] decision . . . does not foreclose lawsuits claiming that a device was made improperly, in violation of FDA specifications.”).

247. See *Riegel*, 128 S. Ct. at 1011 (noting that state tort laws that “‘parallel,’ rather than add to, federal requirements” are not preempted).

248. Sharkey, *supra* note 14, at 428 (emphasis added) (citing *Riegel*, 128 S. Ct. at 1013 n.1 (Ginsburg, J., dissenting)).

249. See discussion *supra* Part III.B.3 (discussing the notable absence of the presumption against preemption in *Riegel*). But see *Altria Group, Inc. v. Good*, 129 S. Ct. 538, 543 (2008) (indicating that the presumption is still alive in the cigarette labeling context).

Justices Scalia and Thomas, seem unwilling to recognize the presumption against preemption when the statute contains an express preemption provision.²⁵⁰ Although the majority of the Supreme Court has yet to accept this position,²⁵¹ the judicial shift in this direction is instructive for express preemption analysis. The level of deference that the Court will give to congressional intent and agency interpretations is also unpredictable.²⁵²

In *Wyeth v. Levine*,²⁵³ the Supreme Court provided some answers regarding *Riegel*'s implications for implied preemption cases. In the implied preemption realm, the Court has yet to reject or ignore congressional intent, as it did in *Riegel*. The Court's treatment of congressional intent in *Levine* sheds light on this issue. Before determining that the Food, Drug, and Cosmetic Act (FDCA) did not impliedly preempt state tort-law claims,²⁵⁴ the *Levine* Court noted the importance of congressional purpose as one of the "cornerstones of . . . pre-emption jurisprudence"²⁵⁵ and analyzed the Act's history to determine congressional purpose.²⁵⁶ The presumption against preemption also resurfaced, and the Court explicitly rejected the notion that the presumption should not be applied in implied preemption cases.²⁵⁷ Although *Levine* seems to have provided some clarity for implied preemption analysis, the future of express preemption analysis is more unsettled.

B. *Device Manufacturers: A Spark for Innovation?*

The result in *Riegel* was the best that device manufacturers could have hoped for,²⁵⁸ short of overturning *Lohr*. *Riegel* may not have wide-sweeping effect because fewer devices undergo the premarket approval process as compared to the number of devices subject to substantial

250. See *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 545 (1992) (Scalia, J., concurring in the judgment in part and dissenting in part, joined by Thomas, J.) (noting that the presumption against preemption disappears when Congress expresses its intent to preempt in the statute).

251. Justice Thomas recently noted, "Since *Cipollone*, the Court's reliance on the presumption against pre-emption has waned in the express pre-emption context." *Altria Group*, 129 S. Ct. at 556 (Thomas, J., dissenting) (emphasis added). However, he never states that the presumption has been explicitly rejected. See *id.* (noting that the Supreme Court has in fact relied on the presumption in express preemption cases since *Cipollone*).

252. See discussion *supra* Parts III.B.2, III.B.4 (discussing the *Riegel* majority's rejection of the need to rely on congressional intent and its middle-of-the-road approach to agency deference).

253. 129 S. Ct. 1187 (2009).

254. See *id.* at 1204.

255. *Id.* at 1194.

256. *Id.* at 1195-96.

257. *Id.* at 1195 n.3.

258. See Brief for the Advanced Medical Technology Association (AdvaMed), et al. as Amici Curiae in Support of Respondent, *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008) (No. 06-179), 2007 WL 3095371 (advocating preemption of state tort law on behalf of various medical device organizations).

equivalence review.²⁵⁹ *Riegel* will also cause some manufacturers to be subject to inconsistent standards for their devices,²⁶⁰ but most manufacturers will likely believe that some preemption is better than none at all. Manufacturers were looking for relief because they had become increasingly subject to liability suits.²⁶¹ Now that *Riegel* has held that manufacturers of some devices are exempt from defective design liability, this trend toward increased liability suits may change.

The legal protection that *Riegel* afforded to PMA-approved devices may be tempting for some manufacturers, but whether it will cause more manufacturers to pursue PMA review remains to be seen. The PMA process is “a much more significant financial barrier to the market” (with costs ranging from \$111,000 to \$828,000 per device) than the § 510(k) process (which typically costs less than \$2,000 per device).²⁶² Smaller medical-device companies are far more burdened by these regulatory costs than large companies like Medtronic.²⁶³ Product-liability risks remain a significant challenge for “emerging companies,” which often have limited resources, limited liability expertise, and limited ability to properly estimate the risks.²⁶⁴

Although larger companies are better able to absorb the financial risks associated with the PMA process, protection from products liability—which manufacturers characterize as an inhibitor of innovation²⁶⁵—is unlikely to impact a manufacturer’s business decision to pursue new, cutting-edge technology that would be subject to PMA review.²⁶⁶ Substantial equivalence review remains the most attractive, short-term option for manufacturers because it is less expensive and less time consuming, allowing manufacturers to enter the market more

259. See Sharkey, *supra* note 14, at 428 (noting that only about 10% of devices undergo PMA review).

260. Only manufacturers that market PMA-approved devices and substantially equivalent devices will be subject to different liability standards after the outcome in *Riegel*.

261. See FOOTE, *supra* note 107, at 147 (noting that device manufacturers has become frequently named defendants in device liability litigation).

262. *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1369 n.1 (11th Cir. 1999).

263. See FOOTE, *supra* note 107, at 136.

264. *Product Liability Risks for Emerging Life Sciences Technology Companies*, RX FOR RISK (Medmarc Ins. Group, Chantilly, Va.), Mar. 2007, at 1, 1, available at <http://www.medmarc.com/Resources/Newsletters/Rx%20for%20Risk%20-%20Issue%2007.pdf>.

265. See MCGARITY, *supra*, note 52, at 222 (noting a Medtronic representative’s statement that “[e]very dollar that we need to divert to pay for lawsuits takes money away from research and development” (quoting Joan Biskupic, *Manufacturer Liability Is at Heart of Pacemaker Case*, WASH. POST, Apr. 22, 1996, at A4)).

266. MX Business Strategies for Medical Technology Executives, <http://www.devicelink.com/mx/issuesupdate/08/02/Riegel.html> (last visited Oct. 7, 2009) (“[T]he business imperative of getting to market faster via 510(k) clearance is likely to override the enhanced legal protection afforded to PMA devices.”).

quickly.²⁶⁷ The number of FDA approvals illustrates this concept. In 2005, the FDA granted over 3,000 § 510(k) submissions compared to only thirty-two PMAs.²⁶⁸ These numbers are unlikely to change overnight. Nonetheless, the long-term savings on litigation costs and liability insurance²⁶⁹ that may result from *Riegel* are undeniable. The unanswered question is where will manufacturers choose to spend this money.

C. Physicians: Caught in the Crosshairs

“Device manufacturers [had] replaced physicians as the most frequently named defendants in cases involving medical device use,”²⁷⁰ largely because of caps on medical malpractice liability in various states.²⁷¹ *Riegel* provides an illustrative example of a patient choosing to sue the manufacturer, rather than the doctor, when something goes wrong with a medical device. The evidence suggests that Mr. Riegel’s physician did not use the device in accordance with the labeling.²⁷² But it appears that the Riegels did not attempt to sue the doctor.²⁷³

Doctors are obviously concerned that the tide may change post-*Riegel*, now that some patients may be left without a claim against the manufacturer. Several editors of the *New England Journal of Medicine* implied that *Riegel* could signal bad news for doctors: “If injured patients are unable to seek legal redress from manufacturers of defective products, they may instead turn elsewhere.”²⁷⁴ This may be especially true when doctors use the device for an “off-label” use that has not been specifically approved by the FDA.²⁷⁵

But doctors are unlikely to take a passive approach to the potential

267. *Id.*

268. *Id.*

269. Cf. Sara Dyson, *Protecting PMA Devices and Their Makers*, MED. DEVICE & DIAGNOSTIC INDUSTRY MAG., Feb. 2009, available at <http://www.devicelink.com/mddi/archive/09/02/007.html> (noting that the cost of defending a products liability suit caused a pharmaceutical manufacturer’s insurance premiums to increase to an estimated ten million dollars).

270. FOOTE, *supra* note 107, at 147.

271. *Id.* at 148.

272. See *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1005 (2008) (noting that the doctor inserted the balloon catheter into a patient with “diffusely diseased and heavily calcified” arteries even though the device was contraindicated for such patients). The doctor also inflated the balloon beyond the recommended pressure. *Id.*

273. Dr. Eric Roccario, the physician who treated Mr. Riegel, served as an expert in the Plaintiff’s case. See *Riegel v. Medtronic, Inc.*, No. 99-CV-0649, 2003 WL 25556778, at *1 (N.D.N.Y. Dec. 2, 2003) (noting that Mr. Riegel’s treating physician was Dr. Eric S. Roccario); Affidavit of Eric Roccario, M.D., *Riegel*, 2003 WL 25556778 (No. 99-CV-0649), 1996 WL 34432790.

274. Dr. Gregory Curfman et al., *Why Doctors Should Worry About Preemption*, 359 NEW ENG. J. MED. 1, 3 (2008).

275. See James B. Riley, Jr. & P. Aaron Basillus, *Physicians’ Liability for Off-Label*

change in the liability landscape. Doctors have already testified before Congress in support of reversing *Riegel*²⁷⁶ and written strong rebukes of *Riegel* in leading medical journals.²⁷⁷ Although doctors have traditionally enjoyed good relationships with medical-device manufacturers, this tradition may change if manufacturers enjoy reduced liability exposure at doctors' expense.²⁷⁸ "[P]hysicians are becoming more willing to blame drug and device manufacturers for perceived problems with . . . allegedly defective drug[s] or device[s]."²⁷⁹ Thus the future of doctor-manufacturer relationships bears watching.

D. Legislative Response

Some Congressmen have reacted strongly to the *Riegel* ruling. Senator Edward Kennedy, who filed an amicus brief in support of the Riegels,²⁸⁰ commented: "Congress never intended that FDA approval would give blanket immunity to manufacturers from liability for injuries caused by faulty devices. . . . Congress obviously needs to correct the court's decision."²⁸¹ U.S. Representative Henry Waxman, who joined Senator Kennedy's amicus brief²⁸² and sat on the House Committee that approved the MDA in 1976, reportedly characterized *Riegel*'s effect as "nonsensical."²⁸³

Congress has proposed legislation to counter *Riegel*'s effect. The Medical Device Safety Act of 2009, introduced by Senator Kennedy and United States Representative Frank Pallone, Jr. would effectively overturn *Riegel* by exempting state tort-law claims from preemption under the MDA.²⁸⁴ Specifically, the Act would amend the preemption provi-

Prescriptions, HEMATOLOGY & ONCOLOGY NEWS & ISSUES, May-June 2007, at 24, 37 (noting that off-label use of medical devices may increase physicians' exposure to liability).

276. *Should FDA Drug and Medical Device Regulation Bar State Liability Claims?* Hearing Before the H. Comm. on Oversight and Government Reform, 110th Cong. 106-09 (2008) (statement of Dr. Gregory Curfman, Executive Editor of the *New England Journal of Medicine*).

277. *See, e.g.*, Lawrence O. Gostin, *The Deregulatory Effects of Preempting Tort Litigation: FDA Regulation of Medical Devices*, 299 J. AM. MED. ASS'N 2313 (2008) (criticizing the effects of the *Riegel* decision).

278. *See* Edward J. Sebold & John Q. Lewis, *Physician Suits Against Pharmaceutical and Medical Device Manufacturers: Friend Turned Foe?*, MEALEY'S LITIG. REP.: DIABETES DRUGS, July 2002, available in LEXIS Mealey's Publication File ("[I]ncreased exposure associated with . . . physician [malpractice] lawsuits may affect the way business is done between drug and device manufacturers and the physicians who purchase or use their products.").

279. *Id.*

280. Brief of Senator Edward M. Kennedy and Representative Henry A. Waxman, as Amici Curiae in Support of Petitioners, *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008) (No. 06-179), 2007 WL 2456945.

281. Greenhouse, *supra* note 105.

282. *See supra* note 280.

283. Greenhouse, *supra* note 105.

284. S. 540, 111th Cong. (2009); H.R. 1346, 111th Cong. (2009).

sion to state, "Nothing in this section shall be construed to modify or otherwise affect any action for damages or the liability of any person under the law of any State."²⁸⁵ Dr. Gregory Curfman, executive editor of the *New England Journal of Medicine*, testified in support of this legislation before a House of Representatives Committee, noting that preemption "is ill advised and will result in less safe medical products for the American people."²⁸⁶

V. CONCLUSION

What a difference twelve years can make. Had the Court decided *Riegel* twelve years ago, the outcome might have been drastically different. But with new Justices and new philosophies, the Supreme Court went out of its way to reject any deference to the FDA, congressional intent, or the deeply rooted presumption against preemption. With its new brand of express preemption analysis, the Supreme Court pushed aside nearly sixty years of preemption jurisprudence.

Though *Riegel* might provide an interesting lesson in judicial philosophy, it stands alone in a long line of preemption jurisprudence, largely because it cannot be reconciled with its predecessor, *Lohr*. *Lohr* likely reached the right outcome (denying preemption), but its underlying basis was shaky due to the Court's inability to settle the *Cipollone* proposition. This series of missteps by the Court—first in *Cipollone*, then in *Lohr*—culminated in the "*Riegel* distinction." This bright-line rule does not achieve Congress's desire to establish a uniform standard because it subjects device manufacturers to different levels of liability based on the nature of the FDA approval process. The PMA and § 510(k) processes may differ substantially in the amount of resources that the FDA expends in reviewing each application, but the conclusion that they differ substantially in their specificity to the device does not follow.

Certainly, the MDA's preemption provision must displace some state law, or it would be deprived of all meaning. But the indicators suggest that Congress did not intend to displace state common law. Congress is, and should remain, the ultimate voice in the preemption debate. Legislators seem poised to take back their role as that ultimate voice by passing legislation that would abrogate *Riegel*. In the end, Justice Scalia might argue that this is the proper result because of his resistance to "legislating from the bench." But it will be too late for the Riegels.

285. S. 540 § 2(a).

286. *Should FDA Drug and Medical Device Regulation Bar State Liability Claims?* Hearing Before the H. Comm. on Oversight and Government Reform, 110th Cong. 106-09 (2008) (statement of Dr. Gregory Curfman, Executive Editor of the *New England Journal of Medicine*).