

10-15-2009

## The Supreme Court's Bright Line Ruling in *Riegel v. Medtronic, Inc.* Gives Manufacturers of Defective Medical Devices Broad Immunity

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### Recommended Citation

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# The Supreme Court’s Bright Line Ruling in *Riegel v. Medtronic, Inc.* Gives Manufacturers of Defective Medical Devices Broad Immunity

By Sadaf Bathaee\*

## Table of Contents

I. INTRODUCTION .....	646
II. HISTORICAL BACKGROUND .....	647
III. FACTS .....	658
IV. ANALYSIS AND CRITIQUE OF OPINION .....	660
A. <i>Justice Scalia’s Majority Opinion</i> .....	660
1. The Background .....	661
2. Justice Scalia Determines that Premarket Approval Under the MDA Imposes Federal Requirements Under 21 U.S.C. § 360k(a) .....	663
3. Justice Scalia Determines that the Riegels’ Common Law Claims Constitute Requirements Under § 360k(a) .....	665
4. Justice Scalia Declines to Consider Whether the Riegels’ Claims Are Parallel to the Federal Requirements .....	668
B. <i>Justice Stevens’ Concurring Opinion</i> .....	669
C. <i>Justice Ginsburg’s Dissenting Opinion</i> .....	670
1. Justice Ginsburg Argues that there is a Presumption Against Pre-emption .....	671
2. Justice Ginsburg’s Contextual Analysis of §360k(a) Indicates that Congress did not Intend to Pre-empt Common Law Claims .....	672
3. Justice Ginsburg Explains that her Reading of § 360k(a) Would Not Render the FDA’s Premarket Approval Irrelevant to the Riegels’ Common Law Claims .....	674
V. IMPACT .....	675
VI. CONCLUSION .....	680

## I. INTRODUCTION

Congress enacted the Medical Device Amendments in 1976 (MDA) in order to protect consumers from defective medical devices before these medical devices are marketed by manufacturers.<sup>1</sup> Prior to the MDA's enactment, manufacturers sold products that malfunctioned inside patients, which led to serious injuries and death. Because of the thousands of tort lawsuits that resulted from such malfunctions, Congress stepped in and supplemented the current tort law system with the Medical Device Amendments.

Under the Medical Device Amendments, manufacturers of complex devices must submit applications for premarket approval by the Food and Drug Administration (FDA) before they can sell these devices to consumers.<sup>2</sup> However, ten years after the MDA was enacted, manufacturers began to use the pre-emption provision in the MDA, 21 U.S.C. § 360k, to escape liability for defective products it had marketed. Manufacturers of defective devices began arguing that because its device has been granted premarket approval by the FDA, they were no longer responsible for any damages the device has caused. However, this contradicts the purpose of the pre-emption provision. Congress designed the pre-emption statute to prevent manufacturers from being held liable in situations where state law imposes requirements that are "different from, or in addition to" those set forth by the MDA.<sup>3</sup>

On February 20, 2008, the Supreme Court interpreted the pre-emption statute broadly and overlooked Congress' purpose behind enacting the MDA. In *Riegel v. Medtronic*, the Court held that the MDA pre-empted state tort claims brought by a plaintiff who was injured by a defective catheter.<sup>4</sup> The *Riegel* decision leaves consumers who are injured by defective medical devices with no remedy. According to *Riegel*, so long as the FDA has granted a

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1. See H.R. REP. NO. 94-853, at 6-12 (1976).
2. Medical Device Amendments, 21 U.S.C. § 360e(c) (1976).
3. See H.R. REP. NO. 94-853, at 6-12 (1976).
4. See *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008).

Class III device premarket approval, then the manufacturer is no longer liable for subsequent malfunctions. Though this holding gives courts' certainty regarding the application of § 360k, it does not take into account possible mistakes by the FDA. Specifically, it does not take into account situations where the FDA wrongfully grants premarket approval to a device. If the FDA does make a mistake, *Riegel* holds that the consumer must bear the risk of injuries or even death.

This case note presents a thorough examination of the Supreme Court's recent opinion in *Riegel* and its effect on medical device manufacturers and users of these devices. Part II details the historical background of the regulation of medical devices beginning from pre-1976 to the Court's *Riegel* decision in 2008. Part III summarizes the facts of the *Riegel* decision. Part IV analyzes the Supreme Court's majority, concurring, and dissenting opinions. Part V of this case note will discuss the impact of the *Riegel* decision on plaintiffs injured by defective medical devices. Part VI concludes this article.

## II. HISTORICAL BACKGROUND

Before 1976, the marketing of medical devices was primarily unregulated.<sup>5</sup> While drugs had to receive premarket approval by the Food and Drug Administration, there were no such safeguards for medical devices.<sup>6</sup> It was not until the mid-1970s that it became clear to Congress that there needed to be a regulatory regime for medical devices.<sup>7</sup> During this time period, manufacturers had introduced numerous complex medical devices into the market.<sup>8</sup> While these technological advancements helped many patients, defects in the medical devices led to serious injuries and death, resulting in thousands of tort claims.<sup>9</sup> Such defective devices included heart valves, pacemakers, and intraocular lenses, but particularly, it was

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5. See H.R. REP. NO. 94-853 at 8-10.

6. *Id.* at 11 (a "serious drawback of the existing authority is that the FDA cannot act against a hazardous medical device until after it is on the market.")

7. See *id.* at 8.

8. *Id.* at 9.

9. *Id.*

the Dalkon Shield intrauterine device that provoked Congress to impose premarket regulations on medical devices.<sup>10</sup>

In 1976, Congress responded to this public health nightmare by enacting the Medical Device Amendments of 1976 to the Food, Drug, and Cosmetic Act (FDCA).<sup>11</sup> The sole purpose for the MDA was “to protect public health,” and to protect consumers that rely on these complex medical devices for their livelihood.<sup>12</sup>

Under the MDA, medical devices are categorized into one of three different classes depending on the level of risk they present.<sup>13</sup> First, Class I devices present the least amount of risk, and are subject to “general controls.”<sup>14</sup> These are devices that “present minimal potential for harm to the user,” and can be marketed without prior approval.<sup>15</sup> Examples of Class I devices include elastic bandages and examination gloves.<sup>16</sup> Second, Class II devices are devices that have the potential to cause injury if they are misused or are defective.<sup>17</sup> In

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10. *Id.*

11. Medical Device Amendments, 21 U.S.C. § 360k (1976).

12. See H.R. REP. NO. 94-853, at 6-12.

13. See 21 U.S.C. § 360c (2006).

14. 21 U.S.C. § 360c(a)(1)(A). Class I devices are subject to “general controls” because they “[are] not purported or represented to be for a use in supporting or sustaining human life or for use which is of substantial importance in preventing impairment of human health, and does not present a potential unreasonable risk of illness or injury . . .” 21 U.S.C. § 360c(a)(1)(A)(ii).

15. *Id.*

16. *Id.*

17. 21 U.S.C. § 360c(a)(1)(B).

**Class II Special Controls.—**

A device which cannot be classified as a class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, post-market surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 360(k) of this title), recommendations, and other appropriate actions as the Secretary deems necessary to provide such assurance. For a device that is purported or represented to be for use in supporting or sustaining human life, the Secretary shall examine and identify the special controls, if any, that are

addition to being subject to “general controls,” these devices may also be subject to “special controls” such as post-market surveillance, performance standards, and/or any other measures the FDA deems necessary.<sup>18</sup> Class II devices include powered wheelchairs, surgical drapes, and infusion pumps.<sup>19</sup> Finally, Class III devices are the riskiest and most regulated category of medical devices.<sup>20</sup> Class III devices impose the greatest risks, but also provide the greatest benefits because they are life supporting or life-sustaining devices.<sup>21</sup> Examples of Class III devices include catheters, pacemakers, replacement heart valves, and implanted cerebella stimulators.<sup>22</sup>

In order to be marketed to consumers, Class III devices are required to undergo a premarket approval process, or the PMA.<sup>23</sup> Though all Class III devices eventually have to go through this process, Class III devices that were on the market prior to 1976 are

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necessary to provide adequate assurance of safety and effectiveness and describe how such controls provide such assurance.

*Id.*

18. *Id.*

19. *Id.*

20. 21 U.S.C. § 360c(a)(1)(C).

Class III, Premarket Approval.—

A device which because—

(i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and (II) cannot be classified as a class II device because insufficient information exists to determine that the special controls described in subparagraph (B) would provide reasonable assurance of its safety and effectiveness, and (ii)(I) is purported or represented to be for a use in supporting and sustaining human life or for a use which is of substantial importance in preventing impairment of human health or (II) presents a potential unreasonable risk of injury, is to be subject in accordance with section 360e of this title, to premarket approval to provide reasonable assurance of its safety and effectiveness.

*Id.*

21. *Id.*

22. *Id.*

23. 21 U.S.C. § 360e(b)(1) (2006).

not required to go through this process right away.<sup>24</sup> Instead, these devices can continue to be marketed until the FDA issues a regulation requiring that particular device to go through premarket approval.<sup>25</sup> Additionally, if the FDA finds that a new Class III device is “substantially equivalent” to a device marketed before the MDA was enacted, then this device can be “grandfathered” in.<sup>26</sup> If a device is “grandfathered” in, then it does not need to be granted premarket approval until the time the FDA promulgates a regulation.<sup>27</sup> According to 21 U.S.C. § 510(k), the process by which a Class III device is determined to be a substantial equivalent of a device already on the market is referred to as the “510(k)” process.<sup>28</sup>

The premarket approval process requires the manufacturer of a medical device to submit an application for review by the FDA.<sup>29</sup> The application includes extensive reports, proposed labeling, and proposed manufacturing and processing.<sup>30</sup> Additionally, the FDA requires a sample of the device.<sup>31</sup> On average, the FDA spends about 1,200 hours reviewing each application.<sup>32</sup> Premarket approval is granted only when the FDA has found that there is a “reasonable assurance” of the device’s “safety and effectiveness.”<sup>33</sup> Pursuant to 21 U.S.C. § 350c(a)(2)(C) of the MDA, the agency must “weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.”<sup>34</sup> The FDA also requires a specimen of the proposed labeling for the device, and reviews it to determine whether it is false or misleading.<sup>35</sup> When the FDA completes its review of the Class III device, it then decides whether to grant or deny premarket approval of the device.<sup>36</sup>

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24. 21 U.S.C. §§ 360e(b)(1)(B), 360c(f)(1)(A).

25. 21 U.S.C. § 360e(b)(1).

26. *Id.*

27. *Id.*

28. 21 U.S.C. § 360e(c).

29. *See* 21 C.F.R. §§ 814.20, 814.4.

30. *Id.*

31. *Id.*

32. *See Riegel*, 128 S. Ct. at 1004.

33. 21 U.S.C. § 360e(d).

34. 21 U.S.C. § 360c(a)(2)(C).

35. 21 U.S.C. §§ 360c(a)(2)(B), 360e(d)(1)(A).

36. 21 U.S.C. § 360e(d).

After reviewing the PMA application, the FDA can do one of four things.<sup>37</sup> It can choose to grant the device premarket approval.<sup>38</sup> It can choose to grant premarket approval, but only if the manufacturer fulfills certain conditions.<sup>39</sup> The FDA can choose to deny premarket approval and instead send an “approvable letter,” which indicates to the manufacturer what it needs to do in order for its device to be granted premarket approval.<sup>40</sup> Or, the FDA can send a “not approvable” letter to the manufacturer stating why the FDA has chosen not to grant premarket approval for the proposed device.<sup>41</sup>

Moreover, even after a device has been granted premarket approval, the PMA process still has not been fully completed.<sup>42</sup> Under the process, the manufacturer is prohibited from making any changes to the proposed specifications in the premarket approval application.<sup>43</sup> The manufacturer cannot make any changes to the design specifications, the manufacturing processes, labeling, or any other aspect of the device that relates to safety and effectiveness.<sup>44</sup> In order to make changes, the applicant must submit a new application for supplemental premarket approval.<sup>45</sup> The application for a supplemental premarket approval is identical to the initial application.<sup>46</sup>

Additionally, the manufacturer of the approved device must comply with specific requirements set forth in 21 U.S.C. § 360i.<sup>47</sup> The FDA requires manufacturers to report any incidents in which a device may have caused or contributed to serious injury or death.<sup>48</sup> Also, it must report any malfunctions that may recur, and any new clinical investigations or scientific studies relating to the device, which the manufacturer either knows about or should reasonably

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37. *Id.*

38. *Id.*

39. 21 C.F.R. § 861.1(b)(3) (2009).

40. 21 C.F.R. § 814.44(e) (2009).

41. 21 C.F.R. § 814.44(f) (2009).

42. 21 U.S.C. § 360e(d)(6)(A)(i).

43. *Id.*

44. *Id.*

45. 21 U.S.C. § 360e(d)(6); 21 C.F.R. § 814.39(c).

46. *Id.*

47. *See* 21 U.S.C. § 360i (2006).

48. 21 U.S.C. § 360i; 21 C.F.R. §§ 814.84(b)(2), 803.50(a) (2009).



know about.<sup>49</sup> If the reports indicate that the device is not safe or is ineffective under the terms of its labeling, then the FDA has the power to withdraw the device's premarket approval.<sup>50</sup>

Congress also included a pre-emption provision in the MDA.<sup>51</sup> Congress included this pre-emption provision because, before the MDA's enactment, some states had already created medical device regulatory programs.<sup>52</sup> Perhaps most notable is California's statute that requires medical devices to undergo a premarket approval process before being commercially distributed in that state.<sup>53</sup> California also requires medical device manufacturers to comply with good manufacturing practices regulations.<sup>54</sup> Because of these state statutes, Congress included a pre-emption provision in the MDA in order to ensure that these state provisions do not conflict with those set forth in the MDA.<sup>55</sup> The MDA's pre-emption provision, 21 U.S.C. § 360k, states:

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49. *Id.*

50. 21 U.S.C. § 360e(e)(1) (2006); *see also* § 360h(e) (the FDA's recall authority).

51. 21 U.S.C. § 360k (2006).

52. *See* Robert B. Leflar & Robert S. Adler, *The Preemption Pentad: Federal Preemption of Products Liability Claims After Medtronic*, 64 TENN. L. REV. 691, 703, n. 66 (1997) (discussing how thirteen states enacted statutes governing medical devices after the Dalkon Shield failure).

53. 1970 Cal. Stats. Ch. 1573, §§ 26670-26693. When enacting the MDA, the House Report observed the following with regards to the California premarket approval process:

In the absence of effective Federal regulation of medical devices, some States have established their own programs. The most comprehensive State regulation of which the Committee is aware is that of California, which in 1970 adopted the Sherman Food, Drug, and Cosmetic Law. This law requires premarket approval of all new medical Devices, requires compliance of device manufacturers with good manufacturing practices and authorizes inspection of establishments which manufacture devices. Implementation of the Sherman Law has resulted in the *requirement* that intrauterine devices are subject to clearance in California.

H.R. REP. NO. 94-853, at 45 (emphasis added).

54. *Id.*

55. *Id.*

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

(1) which is different from, or in addition to, any requirement applicable under this Chapter [21 USCS §§ 301 et seq.] to the device, and

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

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

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

(2) the requirement-

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of applicable requirement under this Chapter.<sup>56</sup>

Further, Congress also included a savings clause in the MDA.<sup>57</sup> The savings clause, 21 U.S.C. § 360h(d), states: “[c]ompliance with an order issued under this section shall not relieve any persons from liability under Federal or State law.”<sup>58</sup>

Approximately ten years after the MDA was enacted, device manufacturers started arguing that 21 U.S.C. § 360k expressly pre-

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56. 21 U.S.C. § 360k.

57. 21 U.S.C. § 360h(d).

58. *Id.*

empties common law claims under state law.<sup>59</sup> In 1996, the Supreme Court considered the scope of the pre-emption provision of the MDA in the seminal case *Medtronic, Inc. v. Lohr*, and determined that the statute does not pre-empt a state common law negligence claim against the manufacturer of an allegedly defective pacemaker that had been marketed under the 510(k) process.<sup>60</sup>

In *Lohr*, the plaintiff's pacemaker failed three years after it was implanted.<sup>61</sup> This failure resulted in a "complete heart block," which required plaintiff to undergo immediate surgery.<sup>62</sup> The plaintiff's doctor attributed the Medtronic pacemaker's failure to a defect in the pacemaker's leads.<sup>63</sup> The pacemaker was a Class III device that was grandfathered in under the 510k process, and had not yet been required to undergo the premarket approval process.<sup>64</sup> Plaintiff and her husband brought suit against Medtronic, the manufacturer of the pacemaker, for negligence and strict liability under Florida state law.<sup>65</sup> In its defense, Medtronic argued that the Lohrs' claims under Florida State law were expressly pre-empted by the statutory text of 21 U.S.C. § 360k(a).<sup>66</sup>

Justice Stevens, the author of the Court's opinion in *Lohr*, states that Congress "does not cavalierly pre-empt state law causes of action," and that the Court must consider the congressional purpose behind the MDA's pre-emption statute.<sup>67</sup> He first tackles Medtronic's argument that the term "requirement" in 21 U.S.C. § 360k is intended to include state common law claims.<sup>68</sup> In Justice

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

60. *Id.*

61. *Id.* at 480-81.

62. *Id.* at 481.

63. *Id.*

64. *Id.*

65. *Lohr*, 518 U.S. at 481. The negligence count alleged a breach of Medtronic's "duty to use reasonable care in the design, manufacture, assembly, and sale of the subject pacemaker." *Id.* Further, the Lohr's alleged strict liability on the basis that "the device was in a defective condition and unreasonably dangerous to foreseeable users at the time of its sale." *Id.*

66. *Id.* at 486.

67. *Id.* at 485. The majority opinion mentions that the Court should assume that the Federal Act would not supersede the historic police powers of the States. *Id.*

68. *Id.* at 487.

Stevens' opinion, the term "requirement" should refer to a "specific duty upon the manufacturer."<sup>69</sup> He finds that Medtronic's interpretation of requirement would foreclose injured plaintiffs from being able to bring a private cause of action against manufacturers for its defective product.<sup>70</sup> He interprets the term requirement narrowly and considers the MDA's legislative history:

There is, to the best of our knowledge, nothing in the hearings, the Committee Reports, or the debates suggesting that any proponent of the legislation intended a sweeping pre-emption of traditional common-law remedies against manufacturers and distributors of defective devices. If Congress intended such a result, its failure to even hint at it is spectacularly odd, particularly since Members of both Houses were acutely aware of ongoing product liability litigation. Along with the less-than precise language of § 360k(a), that silence surely indicates that at least some common law claims against medical device manufacturers may be maintained after the enactment of the MDA.<sup>71</sup>

Next, Justice Stevens finds that the 510(k) process does not impose any federal requirement under the MDA that would pre-empt the Lohr's common law claims.<sup>72</sup> Because the Class III device was grandfathered in, it has only been determined that the device is a substantial equivalent of another device already on the market.<sup>73</sup> He reasons that the process has not imposed any requirements on the device.<sup>74</sup> Additionally, the Court held that 21 U.S.C. § 360k does not pre-empt state requirements that are parallel to federal requirements.<sup>75</sup> The statute can only pre-empt state requirements that are "different to, or in addition to," federal requirements.<sup>76</sup> Thus, he

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69. *Id.* at 487-88.

70. *Id.* at 487.

71. *Lohr*, 518 U.S. at 490.

72. *Id.* at 493.

73. *Id.*

74. *Id.*

75. *Id.* at 498.

76. *Id.*

concludes that none of the Lohrs' claims based on alleged defective manufacturing or labeling are pre-empted by § 360k of the MDA.<sup>77</sup>

Lastly, Justice Stevens responds to the Lohrs' argument that common law duties are never state requirements under § 360k.<sup>78</sup> However, the Court refuses to determine this issue, and Justice Stevens writes:

Nevertheless, we do not respond directly to this argument for two reasons. First, since none of the Lohr's claims is pre-empted in this suit, we need not resolve hypothetical cases that may arise in the future. Second, given the critical importance of design specificity in our (and the FDA's) construction of § 360k, it is apparent that few, if any, common law duties have been pre-empted by this statute. It will be rare indeed for a court hearing a common-law of action to issue a decree that has "the effect of establishing a substantive requirement for a specific device." 21 CFR § 808.1(d)(6)(ii) (1995). Until such a case arises, we see no need to determine whether the statute explicitly preempts such a claim.<sup>79</sup>

Both Justice Breyer, in his concurring opinion, and Justice O'Connor, in her dissenting in part opinion, consider the Lohrs' argument that common law duties are never state "requirements" under § 360k.<sup>80</sup> In Justice Breyer's concurring opinion, he states that § 360k will "sometimes preempt a state-law tort suit."<sup>81</sup> In determining this issue, he considers the rationale of the Court in *Cipollone v. Liggett Group, Inc.*, where the Court found that similar language included tort actions.<sup>82</sup> According to *Cipollone*: "[state] regulations can be as effectively exerted through an award of damages as through some other form of preventive relief."<sup>83</sup> He

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77. *Lohr*, 518 U.S. at 502.

78. *Id.* at 502-03.

79. *Id.*

80. *Id.* at 503-14.

81. *Id.* at 503 (Breyer, J., concurring).

82. *Id.* at 504-05. In *Cipollone*, the Court considered pre-emption of state regulations with regards to cigarette labeling. See *id.*; *infra* note 151 and accompanying text; see also *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992).

83. *Cipollone*, 505 U.S. at 521.

finds this rationale applicable to the case at hand, and finds that where a state regulation and a state tort suit would have the same effect, and the state regulation would be pre-empted by the MDA, then the MDA would also pre-empt the common law claims under state law.<sup>84</sup>

Justice Breyer concludes that the MDA does not pre-empt the tort claims brought by the Lohrs.<sup>85</sup> He finds the MDA's preemption statute "highly ambiguous," and says that the words "any [state] requirement" and "any [federal] requirement," do not indicate what Congress intended.<sup>86</sup> However, he states that "in the absence of clear congressional command as to pre-emption, courts may infer that the relevant administrative agency possesses a degree of leeway to determine which rules, regulations, or other administrative actions will have pre-emptive effect."<sup>87</sup> Here, he concludes that the Lohrs' claims are not pre-empted because the FDA requirements are not "specific."<sup>88</sup> Thus, he concurs with the judgment of the majority, but concludes that the MDA can in fact pre-empt state tort actions.<sup>89</sup>

Justice O'Connor filed a separate opinion where she concurred in part and dissented in part.<sup>90</sup> She finds that where state common law actions do impose requirements, they are pre-empted if they are different than those under the MDA.<sup>91</sup> However, Justice O'Connor disagrees with Justice Stevens' statement that a common law action that would impose a "requirement" would be rare.<sup>92</sup> She refers to the majority's decision as "bewildering and seemingly without guiding principle."<sup>93</sup> Instead, Justice O'Connor reads the pre-emption statute broadly and does not require the same level of "specificity" as the majority did.<sup>94</sup> She considers the Court's decision in *Cipollone*, where the Court had determined that state common law damage

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84. *Lohr*, 518 U.S. at 521 (Breyer, J., concurring).

85. *Id.* at 505-08.

86. *Id.* at 505.

87. *Id.* at 505-08.

88. *Id.*

89. *Id.*

90. *Lohr*, 518 U.S. at 509-14 (O'Connor, J., dissenting in part).

91. *Id.* at 509.

92. *Id.*

93. *Id.*

94. *Id.* at 513.

actions do constitute “requirements.”<sup>95</sup> The Court in *Cipollone* found no distinction between “positive enactments and common law.”<sup>96</sup> She agrees with this rationale and construes § 360k broadly.<sup>97</sup> She finds that “[s]ome, if not all, of the Lohr’s common-law claims regarding the manufacturing and labeling of Medtronic’s device would compel Medtronic to comply with requirements different from, or in addition to, those required by the FDA.”<sup>98</sup>

In 2006, the Court of Appeals for the Second Circuit held in *Riegel v. Medtronic* that Class III Devices that have undergone premarket approval are subjected to federal requirements that preempt state common law actions.<sup>99</sup> In order to resolve the inconsistencies that resulted in the aftermath of *Lohr*, the Supreme Court granted certiorari to *Riegel v. Medtronic*.<sup>100</sup>

### III. FACTS

Plaintiff Charles Riegel had a diseased and calcified right coronary.<sup>101</sup> In 1996, he suffered a myocardial infraction and shortly thereafter underwent coronary angioplasty.<sup>102</sup> During the coronary angioplasty, Riegel’s doctor attempted to dilate the artery by inserting the Evergreen Balloon Catheter.<sup>103</sup> However, the catheter’s labeling had advised against using the catheter for patients with diffuse or calcified stenoses.<sup>104</sup> Also, the label warned that the catheter should not be inflated beyond its rated burst pressure of eight atmospheres.<sup>105</sup> Yet despite these warnings, Riegel’s doctor inflated the catheter five times at a pressure of ten atmospheres.<sup>106</sup> On his

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95. *Id.* at 510-11.

96. *Lohr*, 518 U.S. at 510-11.

97. *Id.* at 514.

98. *Id.* at 513.

99. *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 107 (2nd Cir. 2006).

100. *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1002 (2008).

101. *Riegel*, 451 F.3d at 107.

102. *Id.*

103. *Id.*

104. *Id.*

105. *Id.*

106. *Id.*

fifth inflation, the catheter ruptured.<sup>107</sup> Consequently, Riegel developed a heart block and was placed on life support.<sup>108</sup> Shortly after, he underwent emergency coronary bypass surgery.<sup>109</sup>

Plaintiff Charles Riegel and his wife Donna Riegel brought this lawsuit against defendant Medtronic, Inc., the manufacturer of the catheter, in the United States District Court for the Northern District of New York.<sup>110</sup> In their complaint, Plaintiffs allege that the design, labels, and manufacturing of the catheter violated New York common law, and that as a result of these violations, Riegel suffered severe and permanent injuries.<sup>111</sup> The complaint raised a number of common law claims.<sup>112</sup> On March 14, 2002, the district court held that the Medical Device Amendments of 1976 pre-empted Plaintiff's New York common law claims of strict liability, breach of implied warranty, and negligence in design, testing, inspection, distribution, labeling, marketing, and sale of the catheter.<sup>113</sup> Additionally, the district court also held that the MDA pre-empted *any* negligent manufacturing claim that was not premised on a theory that Medtronic violated federal law.<sup>114</sup> Finally, the district court concluded that the MDA also pre-empted plaintiff Donna Riegel's claims for loss of consortium, to the extent that it was a derivative of the pre-empted claims.<sup>115</sup>

Plaintiffs then appealed the district court's decision to the United States Court of Appeals for the Second Circuit.<sup>116</sup> The court of appeals affirmed the district court's dismissals and concluded that Medtronic was "clearly subject to the federal, device-specific requirement of adhering to the standards contained in its individual, federally approved" pre-market approval application.<sup>117</sup> Plaintiff's claims were pre-empted because they "would, if successful, impose

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107. *Riegel*, 451 F.3d at 107.

108. *Id.*

109. *Id.*

110. *Id.*

111. *Id.*

112. *Id.*

113. *Riegel*, 451 F.3d at 107.

114. *Id.*

115. *Id.*

116. *Riegel*, 128 S. Ct. at 1006.

117. *Id.*



state requirements that differed from, or added to” the device-specific federal requirements.<sup>118</sup> The Supreme Court of the United States granted certiorari.<sup>119</sup>

#### IV. ANALYSIS AND CRITIQUE OF OPINION

The majority opinion, written by Justice Scalia, was joined by Justice Roberts, Justice Kennedy, Justice Souter, Justice Thomas, Justice Breyer, and Justice Alito.<sup>120</sup> Justice Stevens filed an opinion concurring in part and concurring in the majority’s judgment.<sup>121</sup> Justice Ginsburg filed a dissenting opinion.<sup>122</sup>

##### A. Justice Scalia’s Majority Opinion

Justice Scalia begins his opinion by identifying the main issue before the Court: “[w]hether the pre-emption clause enacted in the Medical Device Amendments of 1976, 21 U.S.C. § 360k, bars common-law claims challenging the safety and effectiveness of a medical device given premarket approval by the FDA.”<sup>123</sup> Justice Scalia resolves this issue in his four-part opinion.<sup>124</sup> Part I discusses the passage of the MDA of 1976, the FDA’s regulation of complex medical devices, and sets forth the main facts of the case.<sup>125</sup> His analysis begins in Parts II and III, where Justice Scalia interprets the statutory text of 21 U.S.C. § 360k(a), and concludes that the Riegels’ claims are pre-empted by the statute.<sup>126</sup> Finally, in Part IV Justice Scalia notes that state duties “parallel” to the federal requirements are not pre-empted by the statute, but that the Court declines to address

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118. *Id.*

119. *Id.*

120. *Id.* at 1002.

121. *Id.* at 1011. Specifically, Justice Stevens joins all of the majority’s opinion except Parts III-A and III-B. *Id.* at 1013.

122. *Riegel*, 128 S. Ct. at 1013.

123. *Id.* at 1002.

124. *Id.* at 1002-11.

125. *Id.* at 1002-06.

126. *Id.* at 1006-11.

whether the Riegels' claims are "parallel" because they failed to make this contention in their prior briefs.<sup>127</sup>

## 1. The Background

First, Justice Scalia describes the change in FDA's regulation of complex medical devices after Congress passed the Medical Device Amendments of 1976.<sup>128</sup> Justice Scalia explains that Congress passed the MDA in order to impose a regime of federal oversight after the thousands of tort claims that resulted in the 1970s, when medical devices were primarily regulated by the States.<sup>129</sup> After reciting the statutory text of MDA's pre-emption provision, 21 U.S.C. § 360k(a), Justice Scalia explains that under the MDA, medical devices were assigned to one of three classes based upon the level of risks the device presents.<sup>130</sup> Particularly, he focuses on Class III devices, which are granted the most federal oversight under the MDA.<sup>131</sup> While he could have discussed the risks imposed by Class III devices, Justice Scalia instead focuses on the advantages that Class III devices provide to human health.<sup>132</sup> Further, he refers to the

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127. *Id.* at 1011.

128. *Riegel*, 128 S. Ct. at 1002-03. 21 U.S.C § 360c et seq.

129. *Riegel*, 128 S. Ct. at 1003. He explains that in the 1960s and 1970s, the introduction of many complex devices led to some device failures, resulting in tort claims against manufacturers. *Id.* In particular, he discusses the controversy associated with the Dalkon Shield intrauterine device, which led to several deaths, serious infections, and a large number of pregnancies. *Id.* (citing R. BACIGAL, *THE LIMITS OF LITIGATION: THE DALKON SHIELD CONTROVERSY* 3 (1990)). Justice Scalia further notes that the resulting law suits led many to believe that the common law tort system was unable to manage the risks that accompany dangerous devices. *Id.* (citing S. FOOTE, *MANAGING THE MEDICAL ARMS RACE* 151-152 (1992)). Thus, to supplement the common law tort system, states adopted statutes to impose premarket regulations on devices. *Id.*

130. *Id.* See *supra* notes 9-18 and accompanying text.

131. *Id.* at 1003-05. According to Justice Scalia, a device is assigned to Class III if "it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness." *Id.* at 1003. He gives examples of Class III devices: replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators. *Id.*

132. *Id.* at 1004. In his discussion of how the FDA grants premarket approval, he states that the agency must "weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." *Id.*

premarket approval process as a “rigorous regime of premarket approval for new Class III devices,” and describes the premarket approval process in detail, concentrating specifically on the steps manufacturers must comply with in order to market a device.<sup>133</sup> He states that manufacturers have to complete a “multivolume” application, which the FDA spends an average of 1,200 hours reviewing.<sup>134</sup> Additionally, he emphasizes that even after the FDA approves an application, the FDA has recall authority under the MDA.<sup>135</sup>

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(citing 21 U.S.C. § 360c(a)(2)(C)). Thus, if the benefits in light of the available alternatives outweigh the great risks of a device, then the FDA may grant approval. *Id.* To further illustrate this point he explains that the FDA granted approval, under the Humanitarian Device Exemption procedures, to a ventricular assist device for children with failing hearts, despite a less than fifty percent survival rate with children using the device. *Id.* He reasons that because of the advantages that Class III devices bring to human health, they are granted the most federal oversight. *Id.* at 1003.

133. *Id.* He notes that most Class III devices do not have to undergo the premarket approval process because they are “grandfathered” into the market under the § 510(k) process. *Id.* at 1004. *See supra* notes 20-24 and accompanying text. He sets forth the statistics from 2005, where the FDA “grandfathered” in 3,148 devices under the § 510k process, and granted premarket approval of only thirty-two devices. *Id.* at 1004.

134. *Id.* To emphasize the amount of information the manufacturer must submit, Justice Scalia states that the manufacturer must submit, “among other things,” full reports of all studies and investigations of the device’s safety and effectiveness that have been published or should reasonably be known to the applicant, a full statement of the device’s components, the methods used in manufacturing, a specimen of the proposed labeling, and samples or device components required by the FDA. *Id.* *See supra* notes 25-32 and accompanying text. By focusing on the information that needs to be submitted to the FDA, Justice Scalia is trying to show that the FDA has obtained all the important information about the device in question when determining whether or not to grant premarket approval to the device. *Id.* Additionally, the FDA may consult with a panel of outside experts who may request additional data from the manufacturer. *Id.* at 1004. (citing 21 U.S.C. § 360e(c)(1)(G)).

135. *Riegel*, 128 S. Ct. at 1005. Even after premarket approval, the manufacturer still must comply with reporting requirements, and the FDA may withdraw premarket approval if it determines “that a device is unsafe or ineffective under the conditions in its labeling.” *See id. supra* note 45 and accompanying text; *see infra* notes 189-90 and accompanying text; 21 U.S.C. § 360e(e)(1); *see also* § 360h(e) (recall authority).

Next, Justice Scalia states the facts of the case and the Riegels' claims against Medtronic.<sup>136</sup> In concluding Part I, he notes that the United States Court of Appeals for the Second Circuit held that the Riegels' claims were pre-empted by 21 U.S.C. § 360k(a) because their claims would impose state requirements on Medtronic that "differed from, or added to" the device specific federal requirements.<sup>137</sup>

## 2. Justice Scalia Determines that Premarket Approval Under the MDA Imposes Federal Requirements Under 21 U.S.C. § 360k(a).

In Part II, Justice Scalia begins analyzing whether 21 U.S.C. § 360k(a) pre-empt the Riegels' common law claims.<sup>138</sup> He starts his determination by dissecting the statutory text.<sup>139</sup> By the terms of the statute, the MDA only preempts state requirements that are "different from, or in addition to, any requirement applicable...to the device" under federal law.<sup>140</sup> In deciding whether the preemption statute applies to the Riegels' claims, Justice Scalia first examines whether the premarket approval process is a "requirement" under federal law.<sup>141</sup>

To address this inquiry, Justice Scalia first discusses the Court's opinion in *Lohr*.<sup>142</sup> Justice Scalia states that in *Lohr*, the Court decided that the federal manufacturing and labeling requirements that applied to almost all devices were not specific to the device in question, and were not the kind of requirement under federal law that pre-empt common

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136. *See id.* at 1005-06 and *supra* Part III.

137. *See id.* at 1006 and *supra* notes 72-74 and accompanying text.

138. *Id.* at 1006.

139. *Id.*

140. *Id.*

141. *Riegel*, 128 S. Ct. at 1006. Justice Scalia examines § 360k(a) and finds two components necessary in order for the statute to pre-empt the Riegels' claims. *Id.* First, there must be a requirement established by the Federal Government applicable to the catheter. *Id.* Second, if there is a federal requirement, the Court "must then determine whether the Riegels' common law claims are based upon New York requirements with respect to the device that are 'different from, or in addition to the' federal ones, and that relate to safety and effectiveness." *Id.* Part II initiates the pre-emption analysis by considering whether the Federal Government has established a requirement applicable to the catheter. *Id.*

142. *Id.*

law claims under 21 U.S.C. § 360k(a).<sup>143</sup> Instead, they were “entirely generic concerns about device regulation generally.”<sup>144</sup> Also, he notes that the Court rejected the manufacturer’s argument that the § 510(k) approval process imposed device specific requirements.<sup>145</sup> Instead, he explains that devices that may be marketed through the § 510(k) process are qualified for an exemption rather than a requirement.<sup>146</sup>

Next, Justice Scalia applies the rationale used by the Court in *Lohr* to the Riegels’ claims, and finds that the premarket approval process, unlike the § 510(k) substantial equivalence review, does impose federal requirements under the MDA.<sup>147</sup> He reasons that unlike the general labeling duties the Court considered in *Lohr*, the premarket approval process is specific to individual devices.<sup>148</sup> He states: “[T]he attributes that *Lohr* found lacking in § 510(k) review are present here.”<sup>149</sup> He distinguishes the § 510(k) review in *Lohr* from the premarket approval process by explaining that the FDA does not impose any requirements on devices that may be marketed under the § 510(k) process and does not review the devices for safety and effectiveness.<sup>150</sup> This is in

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143. *Id.* According to Justice Scalia, the Court in *Lohr* was “substantially informed” by the FDA regulation found in 21 C.F.R. § 808.1(d). *Id.* at 1006 (citing *Lohr*, 116 S. Ct. at 2240). The regulation states that state claims are pre-empted “only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device...” 21 C.F.R. § 808.1(d). Based on this regulation, Justice Scalia states that the Court in *Lohr* “concluded that federal manufacturing and labeling requirements applicable across the board to almost all medical devices did not pre-empt the common-law claims of negligence and strict liability at issue in *Lohr*.” *Id.* at 1006. He further states that the Court in *Lohr* came to this conclusion after a “careful comparison between state and federal duties at issue.” *Id.* at 1007.

144. *Id.* at 1006.

145. *Id.* at 1007. Justice Scalia explains that the Court in *Lohr* did not find the § 510(k) process to be a device specific requirement because devices that have gone through the process have only been found to be the substantial equivalent of a pre-1976 device. *Id.* Thus, he reasons that instead of meeting a federal requirement, these devices are qualifying for an exemption. *Id.*

146. *Id.*

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

148. *Id.*

149. *Id.*

150. *Id.* Instead, Justice Scalia emphasizes that devices entering the market through the § 510(k) process are being reviewed for equivalence and not safety. *Id.*

contrast to the premarket approval process, where the FDA focuses on the safety and effectiveness of the device, and does not allow manufacturers to deviate from the specifications in its approved application.<sup>151</sup>

### 3. Justice Scalia Determines that the Riegels' Common Law Claims Constitute Requirements Under § 360k(a).

In Part III of the majority opinion, Justice Scalia considers whether the Riegels' common-law claims constitute a requirement under New York law, which is "different from, or in addition to" federal requirements and "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device."<sup>152</sup> Because "[s]afety and effectiveness are the very subject of the Riegels' common law claims," Justice Scalia finds that the main consideration is "whether New York's tort duties constitute 'requirements' under the MDA."<sup>153</sup>

In accordance with Justice O'Connor's concurring opinion in *Lohr*, Justice Scalia concludes that common law causes of action can be pre-empted by federal requirements specific to a medical device.<sup>154</sup> To

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According to the Court in *Lohr*, the FDA is not requiring the device to "take any particular form for any particular reason." *Id.* (citing *Lohr*, 116 S. Ct. at 2240).

151. *Riegel*, 128 S. Ct. at 1007. Justice Scalia classifies the premarket approval process as a federal requirement because the FDA is approving an application based on a "reasonable assurance of safety and effectiveness..." *Id.* After the application has been approved, the manufacturer must comply with every specification in the approved application. *Id.* Essentially, Justice Scalia is arguing that the premarket approval stands in contrast to the §510(k) process because when the FDA approves a premarket application, it requires a device to take a particular form, which obligates the manufacturer to meet device specific requirements. *Id.*

152. *Id.* (citing 21 U.S.C. § 360k(a)). For Justice Scalia, interpreting the MDA statutes is two-fold. *Id.* The threshold question has been resolved because he concludes that the premarket approval process constitutes a Federal "requirement" under the MDA. *Id.* He now decides the second question: whether common law claims can be considered state requirements. *Id.*

153. *Id.* (citing 21 U.S. § 360k(a)).

154. *Id.* (citing *Lohr*, 518 U.S. at 512). In her concurring opinion in *Lohr*, Justice O'Connor states:

To summarize, I conclude that § 360k(a)'s term "requirement" encompasses state common-law claims. Because the statutory language does not indicate that a "requirement" must be

bolster his position, Justice Scalia cites to *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), and *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), where the Court analyzed pre-emption statutes and “held that a provision pre-empting ‘state requirements’ pre-empted common law duties.”<sup>155</sup> He believes that the Court must adhere to this “normal meaning” and interpret the MDA to pre-empt the Riegels’ common law claims, because Congress did not indicate otherwise.<sup>156</sup> He cites the plurality opinion in *Cipollone* for the proposition that common-law liability is “premised on the existence of a legal duty.”<sup>157</sup> Because the common law remedy is damages, the states are “governing conduct and controlling policy.”<sup>158</sup>

To conclude his statutory analysis, he argues that it would make little sense to pre-empt state law requirements yet not pre-empt

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“specific,” either to pre-empt or be pre-empted, I conclude that a state common-law claim is pre-empted if it would impose “any requirement” “which is different from, or in addition to,” any requirement applicable to the device under the FDCA.

*Lohr*, 518 U.S. at 514.

155. *Riegel*, 128 S. Ct. at 1007-08 (citing *Bates v. Agrosciences LLC*, 544 U.S. 431 (2004); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992) (plurality opinion)). In *Bates*, the Court held that common law actions could be pre-empted by the provision of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) that pre-empted different or additional State requirements. *Bates*, 544 U.S. at 443. Pursuant to 7 U.S.C. § 136v(b) of FIFRA: “Such *State* shall not impose or continue in effect *any requirements* for labeling or packaging in addition to or different from those required under this subchapter.” *Id.* (emphasis added). Likewise, the plurality opinion in *Cipollone* held that common law actions constitute state law requirements that can be pre-empted by the Public Health Cigarette Smoking Act of 1969. *Cipollone*, 505 U.S. at 523. The pre-emption provision of the Public Health Cigarette Smoking Act of 1969 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 Act.” 15 U.S.C. § 1334(b) (emphasis added).

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

157. *Id.* at 1008 (citing *Cipollone*, 505 U.S. at 522). The Court in *Cipollone* reasoned that because common law liability results in a tort judgment, then the defendant who is liable for this tort judgment has violated an obligation under State law. *Id.* Thus, the plaintiff’s common law claims in *Cipollone* constituted state law requirements pursuant to 15 U.S.C. § 1334(b). *Id.*

158. *Id.* at 1008 (citing *Cipollone*, 505 U.S. at 521).

common law duties.<sup>159</sup> To do so would mean that the MDA is granting more power to “a single state jury than to state officials acting through state administrative or legislative lawmaking processes.”<sup>160</sup> He concludes that there is no distinction between state common law and state regulatory law in the MDA, and that the Court “will not turn somersaults to create it.”<sup>161</sup>

Following his interpretation of § 360k(a), Justice Scalia dismisses two arguments advanced by Justice Ginsburg in her dissenting opinion.<sup>162</sup> First, the dissent contends that it is “difficult to believe that Congress would without comment, remove all means of judicial recourse.”<sup>163</sup> Justice Scalia rejects this contention by stating: “[T]his is exactly what a pre-emption clause for medical devices does by its terms.”<sup>164</sup> Second, he responds to the dissent’s argument that because tort suits are permitted for drugs and additives, then the MDA should be read to allow tort suits for medical devices.<sup>165</sup> Justice Scalia counters this argument by asserting that if Congress wanted to treat both systems

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159. *Id.* at 1008. “State tort law that requires a manufacturer’s catheter to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect.” *Id.*

160. *Id.* Justice Scalia finds it hard to believe that the MDA would consider tort liability imposed by juries outside of the scope of pre-emption, yet would preempt state statutes that are adopted by state agencies. *Id.* The state agency is applying a “cost-benefit analysis similar to that applied by the experts at the FDA: How many more lives will be saved by a device which, along with its greater effectiveness, brings a greater risk of harm?” *Id.* On the other hand, the jury’s paramount consideration is the cost of the device, and is not concerned with the benefits because “the patients who reaped benefits are not represented in the court.” *Id.*

161. *Id.* “That perverse distinction is not required or even suggested by the broad language Congress chose in the MDA, and we will not turn somersaults to create it.” *Id.*

162. *Riegel*, 128 S. Ct. at 1009.

163. *See id.*

164. *Id.* Justice Scalia finds “[i]t is not our job to speculate upon congressional motives.” *Id.* Even if he were to look at Congress’ motive in enacting the MDA, he would consider the text of the statute, which he finds is “the only indication available.” *Id.* In his opinion, the text reveals: “the solicitude for those injured by FDA-approved devices, which the dissent finds controlling, was overcome in Congress’s estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations.” *Id.*

165. *See id.*



the same, it would not have wrote the pre-emption clause specifically for medical devices.<sup>166</sup>

Lastly, Justice Scalia addresses the Riegels' argument against pre-emption.<sup>167</sup> The Riegels' contend that even if common law claims do impose requirements, they are not pre-empted by the MDA because "general common law duties are not requirements maintained 'with respect to devices.'"<sup>168</sup> However, Justice Scalia finds this contrary to the text of § 360k(a), and states that the statute does not require any state requirement to apply only to the device in question, or just to a medical device.<sup>169</sup>

#### 4. Justice Scalia Declines to Consider Whether the Riegels' Claims Are Parallel to the Federal Requirements.

Justice Scalia concludes his opinion by recognizing that 21 U.S.C. § 360k(a)(1) does not pre-empt state claims that are "parallel" to federal requirements.<sup>170</sup> However, he finds that although the Riegels' now raise the argument that their common-law claims are parallel to the premarket approval process, the Court will not address this argument because the Riegels did not make this contention in their briefs before the Second Circuit, nor did they raise this argument in their petition for certiorari.<sup>171</sup>

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166. *Id.*

167. *Riegel*, 128 S. Ct. at 1009-10.

168. *Id.* (quoting Brief for Petitioner 34-36).

169. *Id.* at 1010.

The language of the statute does not bear the Riegel's reading. The MDA provides that no State "may establish or continue in effect *with respect to a device...any requirement*" relating to safety and effectiveness that is different from, or in addition to, federal requirements." § 360k(a) (emphasis added). The Riegels' suit depends upon New York's "continu[ing] in effect" general tort duties "with respect to" Medtronic's catheter. Nothing in the statutory text suggests that the pre-empted state requirement must apply *only* to the relevant device, or only to medical devices and not all products and all actions in general.

*Id.*

170. *Id.* at 1011.

171. *Id.*

### B. Justice Stevens' Concurring Opinion

Justice Stevens joins the Court's judgment and all of its opinion, except for Parts III-A and III-B.<sup>172</sup> While he agrees with the Court's conclusion that the Riegels' common law claims are pre-empted by § 360k(a), he does not agree with the Court's discussion of the MDA's principal purpose, and the history behind the pre-emption provision.<sup>173</sup> Thus, he "write[s] separately to add these few words about the MDA's history and the meaning of 'requirements.'"<sup>174</sup>

Specifically, Justice Stevens opposes statements made by Justice Scalia, where Stevens attempts to explain the history and congressional purpose behind the MDA's enactment.<sup>175</sup> First, he states that there is nothing in the pre-enactment history that would suggest that Congress enacted the MDA because state tort remedies were "imped[ing] the development of medical devices."<sup>176</sup> Also, he notes that there is no evidence that would show that the FDA thought the cost of injury by approved medical devices was outweighed by "solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 State to all innovations."<sup>177</sup> Justice Stevens refers to the Court's statements as policy arguments that lack supporting evidence.<sup>178</sup>

Instead, Justice Stevens finds Justice Ginsburg's dissent persuasive.<sup>179</sup> Specifically, he advocates Justice Ginsburg's description of the MDA's purpose and states that: "the overriding purpose of the legislation was to provide additional protection to consumers, not to withdraw existing protections."<sup>180</sup> Further, he reasons that Congress enacted the pre-emption provision of the MDA

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172. *Id.* 1013 (Stevens, J., concurring).

173. *Riegel*, 128 S. Ct. at 1011.

174. *Id.*

175. *Id.*

176. *Id.*

177. *See id.* at 1009; *supra* note 45.

178. *Riegel*, 128 S. Ct. at 1012 (Stevens, J., concurring).

179. *Id.* Specifically, he agrees with the dissent's description of the history and purpose behind the MDA. *Id.*

180. *Id.*

to avoid conflicts between specific state statutes and the FDA's premarket regulation.<sup>181</sup>

Despite his opposition to the Court's view on the history and purpose of the MDA, Justice Stevens agrees that the language of § 360k(a) does pre-empt common law claims.<sup>182</sup> Justice Stevens believes that "[b]ecause common law rules administered by judges, like statutes and regulations, create and define legal obligations, some of them unquestionably qualify as 'requirements.'"<sup>183</sup> Thus, he agrees with the Court's explanation as to why the New York common-law duties constitute "requirements" with respect to the device at issue.<sup>184</sup>

### C. Justice Ginsburg's Dissenting Opinion

In her dissenting opinion, Justice Ginsburg argues that the Court's interpretation of the MDA, "cut[s] deeply into a domain historically occupied by state law."<sup>185</sup> She writes: "I dissent from today's constriction of state authority. Congress, in my view, did not intend § 360k(a) to effect a radical curtailment of state common-law suits seeking compensation for injuries caused by defectively designed or labeled medical devices."<sup>186</sup> In order to explain her reasoning, Justice Ginsburg organizes her opinion into three parts.<sup>187</sup> Part I argues that absent a "clear and manifest purpose" by Congress, the presumption is against pre-emption.<sup>188</sup> In Part II, she counters the Court's argument that absent any indication by Congress, common law claims constitute state requirements under the MDA.<sup>189</sup> She argues that contrary to the Court's opinion, it has been indicated that

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181. *Id.*

182. *Id.*

183. *Id.* To strengthen his argument, Justice Stevens quotes *Cipollone*: "[I]t is the essence of common law to enforce duties that are either affirmative requirements or negative prohibitions." *Id.* at 1012 (Stevens, J., concurring) (quoting *Cipollone*, 505 U.S. at 522 (1002) (emphasis added)).

184. *Id.* at 1012-13 (Stevens, J., concurring).

185. *Riegel*, 128 S. Ct. at 1013 (Ginsburg, J., dissenting).

186. *Id.*

187. *Id.* at 1013-20.

188. *Id.* at 1013-14.

189. *Id.* at 1014-19.

common law claims do not constitute state requirements under the MDA.<sup>190</sup> Lastly, Justice Ginsburg concludes her opinion in Part III by noting that even if the Court had adopted her opinion, the premarket approval process would still be a relevant factor to be considered by the jury.<sup>191</sup>

### 1. Justice Ginsburg Argues that There is a Presumption Against Pre-emption.

In order to interpret the meaning of § 360k(a), Justice Ginsburg considers Congress' purpose.<sup>192</sup> She cites to *Lohr* and states that "Courts have 'long presumed that Congress does not cavalierly preempt state law causes of action.'" <sup>193</sup> Thus, she emphasizes that if Congress intended for § 360k(a) to pre-empt an area traditionally regulated by state law, then Congress would have clearly indicated this as its purpose.<sup>194</sup> Because Congress did not make such an indication, the federal-state balance should not be disrupted.<sup>195</sup> According to Justice Ginsburg, where there are two plausible readings of § 360k(a), the Court must find against pre-emption.<sup>196</sup>

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190. *Id.*

191. *Riegel*, 128 S. Ct. at 1019-20.

192. *Id.* at 1013. She emphasizes the importance of Congress' purpose by quoting the Court in *Cipollone*: "The 'purpose of Congress is the ultimate touchstone of pre-emption analysis.'" *Id.* (quoting *Cipollone*, 505 U.S. at 504).

193. *Id.* (quoting *Lohr*, 518 U.S. at 470).

194. *Id.* Justice Ginsburg states: "Preemption analysis starts with the assumption that 'the historic police powers of the States [a]re not to be superseded . . . unless that as the clear and manifest purpose of Congress.'" *Id.* (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218 (1947)).

195. *Id.* at 1013 (Ginsburg, J., dissenting). Justice Ginsburg states that "[t]he presumption against preemption is heightened 'where federal law is said to bar state action in fields of traditional state regulation.'" *Id.* (quoting *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645 (1995)).

196. *Id.* (citing *Bates*, 544 U.S. at 449).

## 2. Justice Ginsburg's Contextual Analysis of § 360k(a) Indicates that Congress did not Intend to Pre-empt Common Law Claims.

In the Court's opinion, Justice Scalia states: "Absent other indication, reference to a State's 'requirements' includes its common law duties."<sup>197</sup> Justice Ginsburg argues that a contextual analysis of § 360k(a) reveals that there has been indication that a state's requirement does not include common law duties.<sup>198</sup>

First, Justice Ginsburg discusses the history behind the MDA's enactment.<sup>199</sup> She elaborates on the failures of the Dalkon Shield intrauterine device, and the immense amount of litigation that resulted from these failures.<sup>200</sup> After taking these events into consideration, she states: "Given the publicity attending the Dalkon Shield litigation and Congress' awareness of the suits at the time the MDA was under consideration, I find informative the absence of any sign of a legislative design to preempt state common-law tort actions."<sup>201</sup> Because the MDA was enacted during a time where numerous plaintiffs brought suit under state tort law, Congress would have unambiguously stated that the MDA was intended to pre-empt common law claims.<sup>202</sup>

Justice Ginsburg then addresses the Court's argument that consumers have a remedy under § 360k(a), because the plaintiff can seek a damages remedy for a claim based on a violation of FDA regulations.<sup>203</sup> While she finds this remedy important, Justice Ginsburg finds that it does not provide a remedy for consumers who are injured by a device approved by the FDA.<sup>204</sup> Because Congress has not provided a federal compensatory remedy for consumers, Justice Ginsburg believes that Congress did not intend to broadly pre-empt common law claims.<sup>205</sup> She compellingly argues "[i]t is 'difficult to believe that Congress would, without comment, remove all means of

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

198. *Id.* at 1014 (Ginsburg, J., dissenting).

199. *Id.* at 1014-15.

200. *Id.*

201. *Id.* at 1015.

202. *Id.*

203. *Riegel*, 128 S. Ct. at 1011.

204. *Id.* at 1015 (Ginsburg, J., dissenting).

205. *Id.*

judicial recourse' for large numbers of consumers injured by defective medical devices."<sup>206</sup> The Court's interpretation takes away a significant layer of consumer protection, yet grants broad immunity to "an entire industry that in the judgment of Congress, needed more stringent regulation."<sup>207</sup>

Moreover, Justice Ginsburg believes that Congress' experience in regulating drugs and food and color additives under the Federal Food, Drug, and Cosmetic Act (FDCA) provided the model for its regulation of medical devices.<sup>208</sup> Much like Congress did for medical devices, it also enacted premarket approval requirements between 1938 and 1976 for drugs and additives.<sup>209</sup> Like the MDA, Congress implemented these federal premarket regulations at a time when there was a dramatic increase in personal injury litigation under common law.<sup>210</sup> However, in contrast to the MDA, the FDCA did not include a pre-emption clause.<sup>211</sup> Justice Ginsburg finds the reason for this distinction to be evident: at the time the FDCA was enacted, "[s]tates had not installed comparable control regimes in those areas."<sup>212</sup> She notes that Congress included a pre-emption provision in the MDA not to proscribe tort suits, but to prevent conflicts between state regulation schemes that were already in place and the regulatory scheme found in the MDA.<sup>213</sup>

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

207. *Id.* at 1016 (quoting *Lohr*, 518 U.S. at 487).

208. *Id.* at 1016. See Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*

209. *Riegel*, 128 S. Ct. at 1017-18.

210. *Id.* at 1017 (Ginsburg, J., dissenting).

211. *Id.*

212. *Id.* at 1018.

213. *Id.* To emphasize the different situation that existed for medical devices at the time the MDA was passed, Justice Ginsburg quotes the House Report:

In the absence of effective Federal regulation of medical devices, some States have established their own programs. The most comprehensive State regulation of which the committee is aware is that of California, which in 1970 adopted the Sherman Food, Drug, and Cosmetic Law. This law requires premarket approval for all new medical devices, requires compliance of device manufacturers with good manufacturing practices and authorizes inspection of establishments which manufacture devices. Implementation of the Sherman Law has resulted in the *requirement* that intrauterine devices are subject to premarket clearance in California.

Lastly, Justice Ginsburg addresses the Court's argument that "Congress would not have wanted state juries to second-guess the FDA's finding that a medical device is safe and effective when used as directed."<sup>214</sup> She argues that because the premarket approval process for drugs is "at least as rigorous" as it is for medical devices, and common law claims have not been pre-empted for drugs, then "Congress did not regard FDA regulation and state tort claims as mutually exclusive."<sup>215</sup>

### 3. Justice Ginsburg Explains that her Reading of § 360k(a) Would Not Render the FDA's Premarket Approval Irrelevant to the Riegels' Common Law Claims.

In Part III, Justice Ginsburg notes that despite her disagreement with the Court's opinion, her dissenting opinion does not render premarket approval irrelevant to the Riegels' claims against Medtronic.<sup>216</sup> First, she states that a manufacturer can still argue that there is a conflict between the plaintiff's theory and the FDA's premarket approval of the device.<sup>217</sup> She refers to this possible defense as "conflict preemption."<sup>218</sup> Second, she notes that a manufacturer can defend its position by arguing that it complied with the FDA's premarket application.<sup>219</sup> Justice Ginsburg notes that states generally treat the manufacturer's compliance with the FDA's premarket approval process as one factor taken into account by the jury.<sup>220</sup>

Finally, Justice Ginsburg finishes her dissent with a conclusion that captures the implications of the Court's opinion:

The Court's broad reading of § 360k(a) saves the manufacturer from any need to urge these defenses. Instead, regardless of the strength of a plaintiff's case, suits will be barred *ab initio*. The constriction of state authority ordered today was not mandated by Congress

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*Id.* (quoting H.R. Rep. No. 94-853 at 45 (emphasis added)).

214. *Id.* at 1018-19 (Ginsburg, J., dissenting).

215. *Riegel*, 128 S. Ct. at 1018-19.

216. *Id.* at 1019.

217. *Id.* at 1019-20.

218. *Id.* at 1020.

219. *Id.*

220. *Id.*

and is at odds with the MDA's central purpose: to protect consumer safety.<sup>221</sup>

## V. IMPACT

It took Medtronic nearly nine months to recall its product – a small lead wire that connects an implantable cardiac defibrillator to the heart – after first receiving reports that its product was defective and dangerous to its users.<sup>222</sup> This means that for nine months Medtronic continued to sell the defective Sprint Fidelis lead, a lead that upon fracture would either shock patients with painful electric jolts or would fail to provide a life saving shock when a patient's heart needed one.<sup>223</sup> Even when Medtronic recalled the product, 257,000 leads remained implanted in patients.<sup>224</sup> The *Riegel* decision leaves patients with no remedy when they are injured in the period between when a manufacturer first learns of the defect and when the FDA recalls the product.<sup>225</sup> If the FDA wrongfully grants premarket approval to a Class III device, *Riegel* places the risk of injuries or death caused by the device on its user.<sup>226</sup>

According to *Riegel*, if the FDA has granted premarket approval to a Class III device, then this approval imposes federal requirements on the device that pre-empt any common law claim brought by injured plaintiffs that are “different from, or in addition to” the requirements under the premarket approval process.<sup>227</sup> In the majority opinion, Justice Scalia concentrates on the “rigorous regime” that the pre-market

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221. *Riegel*, 128 S. Ct. at 1020.

222. *In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig.*, No. 08-1905, slip op. at 9-12 (D. Minn. filed Jan. 5, 2009).

223. Barnaby J. Feder, *Medtronic Predicts Drop in Sales*, N. Y. TIMES, Oct. 15, 2007, available at <http://www.nytimes.com/2007/10/15/business/15cnd-device.html> (last visited Oct. 25, 2009).

224. *In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig.*, No. 08-1905, slip op. at 12 (D. Minn. filed Jan. 5, 2009).

225. *Riegel*, 128 S. Ct. at 999. See *In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig.*, No. 08-1905, (D. Minn. filed Jan. 5, 2009); *In re Guidant Corp. Implantable Defibrillators Prod. Liab. Litig.*, No. 05-1708, 2007 WL 1725289 (D. Minn. June 12, 2007).

226. See *Riegel*, 128 S. Ct. at 999.

227. 21 U.S.C. § 360k. See *Riegel*, 128 S. Ct. 999.



approval process has created for new Class III devices.<sup>228</sup> Furthermore, he explains that manufacturers are subject to reporting requirements even after the device has been approved.<sup>229</sup> If the FDA finds the device is unsafe or ineffective based on the reports submitted, then the FDA can withdraw the product.<sup>230</sup> However, the MDA's current FDA premarket approval process makes two assumptions that have left injured plaintiffs with no remedy.<sup>231</sup> First, the current regime assumes that the premarket approval process is sufficient to protect users from unsafe products.<sup>232</sup> Next, it assumes that if a defect arises after the devices is marketed, then the FDA will immediately take the product off the market by utilizing its recall authority.<sup>233</sup> To the contrary, the FDA does make errors in granting premarket approval to devices, and there is a prolonged period of time before these products are recalled.<sup>234</sup>

The inadequacies of the premarket approval process, and the time lag that *Riegel* did not account for, became apparent on January 5, 2009.<sup>235</sup> The District Court of Minnesota interpreted *Riegel*, and held that plaintiff's common law claims for injuries or death, resulting from Medtronic's Sprint Fidelis leads, were pre-empted by the Medical Device Amendments.<sup>236</sup> The Sprint Fidelis received premarket

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228. *Riegel*, 128 S. Ct. at 1004-05.

229. *Id.* at 1005.

230. *Id.*

231. *See* Medical Device Amendments, 21 U.S.C. § 360 *et seq.*

232. World Health Organization, *Medical Device Regulations: Global Overview and Guiding Principles* 12 (2003), available at [www.who.int/medical-devices/publications/en/MD\\_Regulations.pdf](http://www.who.int/medical-devices/publications/en/MD_Regulations.pdf). "No amount of rigour in the pre-marketing review process can predict all possible device failures or incidents arise from device misuse. It is through actual use that unforeseen problems related to safety and performance can occur." *Id.*

233. *See In re* Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig., No. 08-1905, (D. Minn. filed Jan. 5, 2009); *In re* Guidant Corp. Implantable Defibrillators Prod. Liab. Litig., No. 05-1708, 2007 WL 1725289 (D. Minn. June 12, 2007).

234. *In re* Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig., No. 08-1905 (D. Minn. filed Jan. 5, 2009).

235. *Id.* Following the recall of the Sprint Fidelis leads, plaintiffs began suing Medtronic for strict liability and negligence. *Id.* at 12. Plaintiffs filed a Master Consolidated Complaint against Medtronic containing 21 claims in this multidistrict litigation. *Id.*

236. *Id.* Medtronic submitted the premarket approval application for the Sprint Fidelis Leads in November of 2004. *Id.* at 10. According to the plaintiffs,

approval by the FDA in June of 2004.<sup>237</sup> In 2006, patients with implantable cardiac defibrillators (ICDs) began to suffer painful shocks and began submitting reports to Medtronic.<sup>238</sup> After medical investigation, a physician concluded that the shocks were caused by fractures in the leads.<sup>239</sup> It was not until May of 2007 that Medtronic filed a supplemental premarket approval application with the FDA containing design and manufacturing changes to the product in order to fix the defect.<sup>240</sup> The application was approved by the FDA in July of 2007.<sup>241</sup> However, Medtronic continued to sell the previously manufactured Sprint Fidelis leads to hospitals, and they were implanted into patients.<sup>242</sup> Further, it was not until September 10, 2007 that Medtronic filed 120 adverse reports with the FDA concerning the product, and not until October 15, 2007 that Medtronic voluntarily recalled the Sprint Fidelis leads and the FDA issued a Class I recall.<sup>243</sup>

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the leads were 2.1 inches wide. *In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig.*, No. 08-1905, slip op. at 10 (D. Minn. filed Jan. 5, 2009).

237. *Id.* at 11. An example of a patient who suffered painful shocks from the defect in the Sprint Fidelis leads is a sixty-eight year old grandmother, Liz Fossum. Janet Moore, *Seeking Relief from Medical Device Makers*, STAR TRIBUNE, Feb. 7, 2009, <http://www.startribune.com/business/39232102.html> (last visited Oct. 25, 2009). The article states: "For about an hour early that November morning two years ago, Fossum's implanted defibrillator repeatedly shocked her heart – 54 times all told. It felt like a horse was kicking her in the chest." *Id.* Fossum brought a lawsuit against Medtronic, but her case was dismissed under *Riegel. Id.*

238. *In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig.*, No. 08-1905, slip op. at 11 (D. Minn. filed Jan. 5, 2009). This investigation was done by a physician at the Minneapolis Heart Institute. *Id.* The physician concluded that the shocks were caused by fractures in the lead. *Id.* Another physician at Cornell University agreed with this conclusion. *Id.*

239. *Id.* Plaintiffs alleged in their complaint that Medtronic was filing the new application to correct the defects in the leads. *Id.* However, Plaintiffs also alleged that Medtronic did not notify the FDA that it was filing the new application because of the lead failures. *Id.*

240. *In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig.*, No. 08-1905, slip op. at 11 (D. Minn. filed Jan. 5, 2009).

241. *Id.* at 12.

242. *Id.*

243. Barnaby J. Feder, *Medtronic Predicts Drop in Sales*, N. Y. TIMES, Oct. 15, 2007, available at <http://www.nytimes.com/2007/10/15/business/15cnd-device.html> (last visited Oct. 25, 2009). Doctors say that the Sprint Fidelis leads were often used in children because of its "narrow girth." Anna Wilde Mathews & Thomas M. Burton, *Heart Wires May Pose Risk for the Young*, WALL ST. J.,

Yet by the time the leads were recalled, approximately 257,000 Sprint Fidelis leads had already been implanted into patients.<sup>244</sup> According to research, 4,000 to 5,000 of these patients will experience lead fracture within thirty months of implantation.<sup>245</sup>

All 257,000 patients are left without some form of remedy.<sup>246</sup> The patients who have experienced a lead malfunction are unable to recover damages under *Riegel*.<sup>247</sup> The patients who have consulted their doctor and have been advised to undergo explant surgery, must be subjected to a dangerous surgery in order to replace the lead.<sup>248</sup> According to experts, the surgery is so dangerous that they believe patients are better off leaving the lead in place unless it has “stopped functioning properly.”<sup>249</sup> The remaining patients are in danger of being one of the 4,000 to 5,000 patients who will experience fracture within thirty months of implantation.<sup>250</sup> According to *Riegel*, Medtronic is immune from liability for any of these consequences, simply because the FDA granted its device premarket approval.<sup>251</sup> Because of the Court’s decision in *Riegel*, patients are left with no remedy even though Medtronic knew for nearly nine months that its product was dangerous to its users.<sup>252</sup>

The adverse effects of the current recall system is also illustrated when considering Guidant Corporation’s Prizm 2 implantable cardiac

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October 19, 2007, at A4. There are studies showing that the leads will be more likely to fracture in younger patients because their hearts tend to beat faster, and they are more active. *Id.* There were 265,000 Sprint Fidelis leads implanted into patients, and 2,085 of them were implanted into patients under the age of twenty-one. *Id.* Doctors say that the failure rate of younger patients is higher than that of older patients. *Id.*

244. See *In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig.*, No. 08-1905, (D. Minn. filed Jan. 5, 2009).

245. *Id.*; *Riegel*, 128 S. Ct. 999.

246. Anna Wilde Mathews & Thomas M. Burton, *Heart Wires May Pose More Risk For The Young*, WALL ST. J., October 19, 2007, at A4.

247. *Id.* According to doctors, removing the lead can be more dangerous than having the lead fracture. *Id.*

248. Feder, *Medtronic Predicts Drop in Sales*, *supra* note 243.

249. *Riegel*, 128 S. Ct. at 999.

250. Feder, *Medtronic Predicts Drop in Sales*, *supra* note 243.

251. *In re Guidant Corp. Implantable Defibrillators Prod. Liab. Litig.*, No. 05-1708, 2007 WL 1725289 at 1 (D. Minn. June 12, 2007).

252. *Id.*

defibrillator (ICD).<sup>253</sup> In August of 2000, the FDA granted premarket approval to the defibrillator as a Class III device.<sup>254</sup> In February of 2002, Guidant received reports of an “arcing,” or short-circuiting in the device.<sup>255</sup> After the device was explanted from the patient, Guidant tested the Prizm 2 and found that the short-circuiting was caused by polyimide deterioration in the header and inadequate wire spacing.<sup>256</sup> In April of 2002, Guidant instituted a design and manufacturing change plan to solve the short-circuiting problem.<sup>257</sup> However, Guidant continued to sell the pre-April Prizm, and failed to notify the public of the device’s tendency to short-circuit.<sup>258</sup> It was not until the New York Times published an article in March of 2005, detailing the death of a twenty-one year old college student, which resulted from a Prizm 2 failure, that Guidant finally issued a public notice in May of 2005.<sup>259</sup> In this notice, Guidant confirmed that they had received reports that twenty-six Prizm devices have resulted in at least one death and at least two cases of bodily injury.<sup>260</sup> Guidant finally recalled the device on June 17, 2005, and thousands of patients had the device explanted shortly thereafter.<sup>261</sup> Guidant agreed to pay for replacement devices and other minor incidental costs, but refused to pay for the explant surgeries or costs associated with the surgeries.<sup>262</sup>

As the two preceding examples illustrate, users of Class III devices are being left with no remedy. They are denied remedy even when they are injured after the time the manufacturer learns of the risks. Additionally, the time it takes to recall the products after reports start surfacing leaves consumers in great danger, as they are not notified of

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253. *Id.* at 14-20.

254. *Id.* at 2.

255. *Id.*

256. *Id.* at 14-20.

257. *In re* Guidant Corp. Implantable Defibrillators Prod. Liab. Litig., No. 05-1708, 2007 WL 1725289 (D. Minn. June 12, 2007).

258. *Id.*

259. *Id.*

260. *Id.*

261. *See In re* Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig., No. 08-1905, (D. Minn. filed Jan. 5, 2009); *In re* Guidant Corp. Implantable Defibrillators Prod. Liab. Litig., No. 05-1708, 2007 WL 1725289 (D. Minn. June 12, 2007).

262. *See* H.R. REP. NO. 94-1090, at 1 (1976) (Conf. Rep.); H.R. REP. NO. 94-853, at 6-12.

the risks. The injustice that results from denying any remedy to patients is magnified when the device involved is implanted.<sup>263</sup> This result is inconsistent with Congress' purpose in enacting the MDA: to protect consumers from dangerous devices and to prevent the distribution of dangerous devices.<sup>264</sup>

Additionally, it is at odds with the savings clause codified in the MDA, 21 U.S.C. § 360(h), which states: “[c]ompliance with an order issued under this section shall not relieve any persons from liability under Federal or State law.”<sup>265</sup> The MDAs were enacted in order to provide consumers with an extra layer of protection before Class III devices are marketed.<sup>266</sup> Yet, the Supreme Court's decision in *Riegel*, and its interpretation of 21 U.S.C. § 360k of the MDA, takes away all consumer protection.<sup>267</sup> When the MDAs were introduced on the Senate Floor, Senator Edward Kennedy stated: “The legislation is written so that the benefit of the doubt is always given to the consumer. After all, it is the consumer who pays with his health and his life for medical device malfunctions.”<sup>268</sup> Instead of protecting consumers as Congress intended, *Riegel* strips away the common law remedies that were once available, and gives manufacturers immunity so long as the FDA has granted premarket approval to its device.<sup>269</sup>

## VI. CONCLUSION

The Court's decision in *Riegel* decision affects the regulation of the most risky and complex medical devices: Class III devices. These life sustaining devices, such as catheters, pacemakers, and implantable cardiac defibrillators are those in which our loved ones rely upon. Yet because the Court's decision in *Riegel* gives manufacturers immunity from liability for later discovered defects, consumers are left unsure of how reliable their medical devices really are. Though the *Riegel*

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263. See *In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig.*, No. 08-1905, (D. Minn. filed Jan. 5, 2009); *In re Guidant Corp. Implantable Defibrillators Prod. Liab. Litig.*, No. 05-1708, 2007 WL 1725289 (D. Minn. June 12, 2007).

264. See H.R. REP. NO. 94-1090, at 1; H.R. REP. NO. 94-853, at 6-12.

265. 21 U.S.C. § 360(h).

266. See *Riegel*, 128 S. Ct. at 999.

267. See *id.*

268. 121 CONG. REC. 9, 10688 (1975).

269. See generally *Riegel*, 128 S. Ct. at 999.

decision provides courts with a bright line rule to interpret the pre-emption statute in the MDA, it leaves consumers with less certainty as to whether the device implanted inside of them is actually safe. The impact of this decision can already be seen as thousands of patients have been injured by Medtronic's Sprint Fidelis leads and Guidant Prizm 2 defibrillator, and are left with no remedy.<sup>270</sup> Further, because most Class III devices are implanted into patients, the FDA cannot quickly alleviate the situation when a defect is discovered. Instead of giving consumers an extra layer of protection, the Supreme Court has interpreted the MDA to take away a plaintiff's right to seek judicial recourse, and has disrupted the American tort law system.

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270. See *In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig.*, No. 08-1905, (D. Minn. filed Jan. 5, 2009); *In re Guidant Corp. Implantable Defibrillators Prod. Liab. Litig.*, No. 05-1708, 2007 WL 1725289 (D. Minn. June 12, 2007).

