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Internalizing the External Costs of Medical Device Preemption

BY DAVID CHANG*

Medical device preemption is highly controversial because it provides medical device companies with immunity from state tort claims. Congress provided medical device companies with preemption in 1976 because it was concerned that medical device companies were being overwhelmed by the costs of litigation. Congress feared that this was destroying the incentive for medical device companies to develop risky but innovative life-saving devices.

Today, the dark side of medical device preemption has come to light. Medical device preemption fails to require medical device companies to account for harms that their products create for society. Medical device companies have been able to externalize the harms caused by their defective products. Many patients harmed by medical devices have been denied the opportunity to sue for redress. Further, medical device companies have been shielded from picking up the costs of their defective products. As a result, American taxpayers have been unfairly forced to pick up the tab.

This Note argues that the United States government should force medical device companies to internalize some of the harms created by their products by creating a National Medical Device Injury Compensation Program modeled after the National Vaccine Injury Compensation Program. The government should also create a National Medical Device Insurance Fund. These two programs would force medical device companies to internalize some of the costs of their defective medical devices and provide a remedy for patients harmed by medical devices. Further, these solutions would preserve the life-saving benefits of medical device innovation.

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TABLE OF CONTENTS

INTRODUCTION.....	284
I. THE MEDICAL DEVICE ACT AMENDMENTS OF 1976 AND PREEMPTION...	287
A. THE MEDICAL DEVICE ACT AMENDMENTS OF 1976.....	287
B. MEDICAL DEVICE PREEMPTION.....	290
1. Medtronic, Inc. v. Lohr: <i>Parallel Claims and Section 510(k) Devices</i>	291
2. Rigel v. Medtronic, Inc.: <i>Non-Parallel Claims and Premarket Approval</i>	293
3. <i>Medical Device Preemption after Lohr and Riegel</i>	294
4. <i>The Lower Courts' Interpretations After Lohr and Riegel</i>	294
C. POLICY ISSUES WITH MEDICAL DEVICE PREEMPTION	295
1. <i>Medical Device Innovation</i>	295
2. <i>Opponents of Riegel and the Legislative Response</i>	296
II. THE ECONOMICS OF PREEMPTION	297
A. DEFINING EXTERNALITY	298
B. INTERNALIZING EXTERNALITIES	299
C. THE COST OF THE SPRINT FIDELIS LEAD RECALL ON MEDICARE	300
III. THE IMPACT OF MEDICAL DEVICE PREEMPTION	302
IV. INTERNALIZING THE EXTERNALITIES OF MEDICAL DEVICE PREEMPTION	304
A. CREATING A "NATIONAL MEDICAL DEVICE INJURY COMPENSATION PROGRAM"	304
B. MEDICAL DEVICE COMPANIES SHOULD BE REQUIRED TO INSURE AGAINST POSSIBLE DEFECTS	306
CONCLUSION	308

INTRODUCTION

Promoting medical device innovation is a legitimate goal that benefits the American public, and one important way for the government to achieve this goal is to protect medical device companies from unnecessary litigation. Without such protection, there is a strong likelihood that medical device companies would succumb to the high costs of litigation or be disincentivized from continuing to do business in the medical device market. This Note argues that the United States

government should develop a legal framework for medical device companies that would properly compensate harmed patients while preserving the life-saving benefits of device innovation. The creation of a new National Medical Device Injury Compensation Program and National Medical Device Insurance Fund would force device companies to internalize some of the costs of medical device defects that have historically been externalized by medical device preemption but preserve the benefits of medical device innovation.

Medical device defects can have broad social and financial implications for governments. In 2010, a public health crisis regarding silicone breast implants struck France. An unusually large percentage of women fitted with silicone breast implants made by Poly Implant Prothèse (“PIP”), a small French medical device company, experienced serious ruptures and leakages with their implants.¹ More than 1500 of the estimated 30,000 French women fitted with PIP implants experienced these serious ruptures.² This rupture rate doubled the industry average.³

After an investigation, French authorities discovered that PIP cut costs over the previous decade by using a grade of industrial silicone gel in its breast implants that was unapproved for medical use.⁴ The lower graded industrial silicone cost the company a mere fraction of the price of medical-grade silicone typically used in other breast implants.⁵ In an interview with French police, Jean-Claude Mas, the owner of PIP, admitted to deceiving European safety inspectors for thirteen years.⁶ French authorities shut down PIP in March of 2010.⁷

Health concerns over PIP’s implants further increased when a PIP silicone breast implant recipient died in November 2010 from a rare cancer called anaplastic large-cell lymphoma after her implant ruptured.⁸ The French media reported that she was the eighth woman with a PIP implant to have died of cancer.⁹ Although the cause of the deaths remained uncertain, the news alarmed French and European health

1. David Jolly & Maïa de la Baume, *France Recommends Removal of Suspect Breast Implants*, N.Y. TIMES, Dec. 23, 2011, at A6.

2. *Id.*; Maïa de la Baume, *Frenchwomen Worry About Suspect Breast Implants*, N.Y. TIMES, Jan. 17, 2012, at A11 [hereinafter *Frenchwomen Worry*].

3. Maïa de la Baume & David Jolly, *Health Fears Over Suspect French Breast Implants Spread Abroad*, N.Y. TIMES, Dec. 21, 2011, at A6.

4. Bryony Jones, *Breast Implant Scandal: What Went Wrong?*, CNN (Jan. 27, 2012, 10:41 AM), <http://www.cnn.com/2012/01/27/world/europe/pip-breast-implant-scandal-explained>.

5. *Id.*

6. *PIP Breast Implant Boss Jean-Claude Mas Faces Charges*, BBC (Jan. 26, 2012, 7:36 PM), <http://www.bbc.co.uk/news/world-europe-16736385>.

7. *Id.*

8. *Frenchwomen Worry*, *supra* note 2.

9. Jolly & de la Baume, *supra* note 1.

authorities.¹⁰ By late December 2011, the unusually high number of ruptures led French health authorities to recommend that women with silicone breast implants made by PIP have their implants removed.¹¹

Unfortunately, the scope of the silicone breast implant crisis extended well beyond the borders of France. PIP sold more than eighty percent of its silicone breast implants outside of France.¹² Some 300,000 women in sixty-five countries, including the United States, received implants made by PIP.¹³ Without the now-defunct PIP to absorb the costs of removing the implants and compensate patient losses, the French government agreed to cover the cost of removing the PIP silicone breast implants.¹⁴ The French national healthcare system estimated that it would cost approximately 60 million Euros, or about 77 million U.S. Dollars, to treat the 30,000 French women with PIP implants.¹⁵

Many countries chose to follow France's lead and absorb the costs of replacing PIP implants. Brazilian President Dilma Rousseff ordered Brazil's public health system to pay for the removal of ruptured breast implants.¹⁶ This came at a significant cost to the Brazilian government as more than 25,000 Brazilian women received PIP silicone breast implants.¹⁷ Other countries that agreed to cover the full cost of removing the implants included the United Kingdom and Venezuela.¹⁸

Medical device preemption could leave the United States government and the public on the hook for the costs associated with a medical device catastrophe similar to France's. With medical device companies immune from having to provide redress because of medical device preemption, the United States would likely have to follow the actions of countries like France and Brazil and cover the medical costs of patients harmed by medical devices.

The global medical device industry is worth \$300 billion dollars.¹⁹ The United States, the world's largest medical devices market, comprises about one-third of the global medical device market.²⁰ The United States government should not be forced to internalize the full costs of a medical

10. *Frenchwomen Worry*, *supra* note 2.

11. *Id.*

12. De la Baum & Jolly, *supra* note 3.

13. *Frenchwomen Worry*, *supra* note 2.

14. Jones, *supra* note 4, at 3.

15. David Jolly & Maïa de la Baume, *British Seek Data on Suspect Breast Implants*, N.Y. TIMES, Jan. 4, 2012, at A9.

16. *Brazil: Government Will Pay to Replace Ruptured Implants*, N.Y. TIMES, Jan. 12, 2012, at A9.

17. *Id.*; see Jolly & de la Baume, *supra* note 1.

18. Q&A: *PIP breast implants health scare*, BBC (Apr. 17, 2013, 6:45 AM), <http://www.bbc.co.uk/news/health-16391522>.

19. Zacks Equity Research, *Industry Outlook*, ZACKS INV. RESEARCH (Mar. 31, 2011), <http://www.zacks.com/stock/news/50398/medical-devices-industry-outlook-%96-april-2011>.

20. *Id.*

device company's defects. Medical device recalls are common. The Food and Drug Administration ("FDA") website lists more than 160 Class I medical device (the type that receives medical device preemption) recalls in 2009 alone.²¹ Forcing the government to shoulder the full cost of device defects creates a significant cost for taxpayers.

This Note argues that the United States government should implement a National Medical Device Injury Compensation Program and National Medical Device Insurance Fund. The development of these two programs would balance the need to properly compensate harmed patients and preserve the benefits of medical device innovation. Part I examines the Medical Device Act Amendments of 1976. This Part analyzes which types of medical devices are entitled to preemption, examines the policy concerns associated with medical device preemption, and discusses the benefits of medical device innovation. Part II analyzes the economics of medical device preemption by looking at some of the costs of medical device preemption that have been borne by the government. Part III discusses the benefits of medical device preemption and considers whether the benefits of medical device preemption are worth the cost. Part IV proposes the creation of a National Medical Device Injury Compensation Program and National Medical Device Insurance Fund to provide redress for patients who have been harmed while preserving the financial ability of medical device companies to engage in medical device innovation.

I. THE MEDICAL DEVICE ACT AMENDMENTS OF 1976 AND PREEMPTION

The Food, Drug, and Cosmetic Act defines a medical device as an instrument that is intended for use in the diagnosis, cure, treatment, or prevention of disease.²² A medical device differs from medicine because it "does not achieve its primary intended purposes through chemical action within or on the body."²³ Under the Medical Device Act Amendments of 1976 (the "MDAA"), many state tort claims against medical device manufacturers are preempted because the claims are considered prohibited by the MDAA. Understanding what types of state tort claims are preempted begins with an analysis of the MDAA.

A. THE MEDICAL DEVICE ACT AMENDMENTS OF 1976

The MDAA established the regulatory system for medical devices.²⁴ The MDAA requires the FDA to approve medical devices before they

21. H. DENNIS TOLLEY, EXAMINING THE SPRINT FIDELIS EFFECT ON MEDICARE COSTS 2 (2010).

22. Food, Drug, and Cosmetic Act, 21 USC § 321(h)(2) (2012). For further discussion of the definition of medical devices, see *infra* Part I.A.

23. *Id.* § 321(h).

24. Horowitz v. Stryker Corp., 613 F. Supp. 2d 271, 278 (E.D.N.Y. 2009).

may be marketed to the general public.²⁵ For approval processing, the FDA classifies medical devices into three separate categories: Class I, Class II, and Class III.²⁶

Class I medical devices are “subject only to minimal regulation by ‘general controls’”²⁷ because “[t]hese devices present minimal potential for harm to the user and are often simpler in design than Class II or Class III devices.”²⁸ Examples of Class I medical device products include enema kits and elastic bandages.²⁹ Forty-seven percent of all medical devices are classified as Class I,³⁰ and ninety-five percent of those medical devices are exempt from the regulatory process.³¹ For exempt devices (such as stethoscopes, thermometers, and bedpans), manufacturers are only required to register and list devices with the FDA prior to marketing.³²

Class II medical devices require manufacturers to comply with “special controls” such as performance standards and post-market surveillance measures.³³ If these controls are met, the manufacturer may market these products without further approval.³⁴ Class II medical devices include powered wheelchairs and pregnancy test kits.³⁵ Forty-three percent of medical devices fall into this category.³⁶

Manufacturers of Class III medical devices must provide the FDA with a “reasonable assurance” that their medical device is safe.³⁷ The manufacturer is required to provide the FDA with all data on the medical device product’s safety, efficacy, and a proposed label.³⁸ Class III medical devices “usually sustain or support life, are implanted, or present potential unreasonable risk of illness or injury.”³⁹ Examples of Class III

25. Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified as amended at 21 U.S.C. § 360c(a)(1)(C)).

26. See 21 U.S.C. § 360c (2012); see also PREEMPTION OF PHARMACEUTICAL AND MEDICAL DEVICE CLAIMS: A SURVIVAL KIT FOR THE TRENCHES, ANN. 2008 AAJ-CLE 913 (2008).

27. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996).

28. *Learn if a Medical Device Has Been Cleared by FDA for Marketing*, U.S. FOOD & DRUG ADMIN. (Apr. 21, 2009) <http://www.fda.gov/MedicalDevices/ResourcesforYou/Consumers/ucm142523.htm>.

29. *Id.*

30. *Id.*

31. *Id.*

32. *Id.*

33. 21 U.S.C. § 360c(a)(1)(B) (2012); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316–17 (2008).

34. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996); see also *Class III Exemptions*, U.S. FOOD & DRUG ADMIN. (Dec. 5, 2012), <http://http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051549.htm>.

35. *Learn if a Medical Device Has Been Cleared*, *supra* note 28.

36. *Id.*

37. 21 U.S.C. § 360e(d)(2)(B).

38. Premarket Approval Application (“PMA”), 21 C.F.R. § 814.20 (2006); see *Martin v. Teletronics Pacing Sys., Inc.*, 105 F.3d 1090, 1095 (6th Cir. 1997).

39. *Learn if a Medical Device Has Been Cleared*, *supra* note 28.

medical devices include implantable pacemakers and breast implants.⁴⁰ Ten percent of all medical devices fall under this category.⁴¹ Most medical device litigation occurs with Class III medical devices.⁴²

Prior to receiving marketing approval, the average Class III product requires 1200 hours of testing.⁴³ Because of this stringent premarketing approval requirement, most manufacturers of Class III medical devices attempt to market their products by qualifying under an exception to the FDA's premarket approval requirement.⁴⁴

Once a Class III medical device has received premarket approval, the manufacturer is forbidden from making changes to the device's "design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness" without permission from the FDA.⁴⁵ To make a change, the manufacturer must submit an application for supplementary premarket approval.⁴⁶ The supplementary preapproval process is evaluated under a process similar to the initial application itself.⁴⁷

There are two major exceptions to the FDA's premarket approval requirements.⁴⁸ The first major exception is the "grandfathering" provision.⁴⁹ If a device was on the market before May 1976, the MDAA allows the device to be marketed without FDA approval.⁵⁰ The second major exception to the FDA's premarket approval requirements is the section 501(k) process.⁵¹ The section 510(k) process allows devices that are "substantially equivalent" to existing approved devices to undergo an expedited approval.⁵² The section 510(k) process focuses on the similarity, or equivalence, between the new device and the pre-existing device.⁵³ Thus, the section 510(k) process can usually be completed in an average of twenty hours and not the usual 1200 hours required by the FDA's premarketing approval process.⁵⁴

40. *Id.*

41. *Id.*

42. *See, e.g.*, Christopher R. Pace, *4 Views On Medical Device Preemption*, LAW360 (Mar. 24, 2011), <http://law360.com/articles/233823/print?section=appellate>.

43. *Id.* at 477.

44. *Id.* at 478–79.

45. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 319 (2008) (citing 21 U.S.C. § 360e(d)(6)(A)(i) (2012)).

46. *Id.* (citing 21 U.S.C. § 360e(d)(6); 21 C.F.R. § 814.39(c)).

47. *Id.*

48. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477–78 (1996) (citing 21 U.S.C. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1) (1995)).

49. *Id.*

50. *Id.*

51. 21 U.S.C. § 360e(b)(1)(B); *Lohr*, 518 U.S. at 478.

52. *Id.*

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

54. *Id.* at 479.

The majority of Class III medical devices are approved for marketing by way of the section 510(k) process.⁵⁵ In 2005, the FDA approved 3148 devices under the section 510(k) process.⁵⁶ That same year, the FDA approved only thirty-two devices via the premarket approval process.⁵⁷ PIP received section 510(k) approval for its saline implants from the FDA in September 1996.⁵⁸

In addition to determining which products enter the market, these standards may also determine whether an injured person can recover damages if harmed. Under the MDAA, the FDA's premarket approval allows medical device manufactures to become practically immune from state tort claims. Premarket approval by the FDA has often preempted state tort claims against medical device manufacturers and shielded medical device companies from liabilities that arise from product defects. Since medical device companies are shielded from liabilities, injured individuals often seek out other entities to redress harms caused by the medical devices—frequently the Government. This allows the medical device companies to externalize the costs of the harm caused by their products.

B. MEDICAL DEVICE PREEMPTION

Preemption derives from the Supremacy Clause of the Constitution, which provides that the Constitution and the laws made pursuant to the Constitution are the supreme law of the land.⁵⁹ The Supreme Court in *Gade v. National Solid Waste Management Association* declared that “under the Supremacy Clause . . . any state law, however clearly within a State’s acknowledged power, which interferes with or is contrary to federal law, must yield.”⁶⁰

When a statutory provision expressly preempts state law, the court must look to the text of the preemption statute and “identify the domain expressly pre-empted” by the language of the statutory provision.⁶¹ Here,

55. *Id.* (citing H.R. Rep. No. 101-808, at 14 (1990), reprinted in 1990 U.S.C.C.A.N. 6305); see *Horn v. Thoratec Corp.*, 376 F.3d 163, 167 (3d Cir. 2004).

56. See PETER B. HUTT ET AL., *FOOD AND DRUG LAW* 992 (3d ed. 2007).

57. *Id.*

58. *Breast Implant Safety: FDA Warned Poly Implant Prothese About Issues In 2000*, HUFFINGTON POST (Dec. 27, 2011, 12:12 AM), http://www.huffingtonpost.com/2011/12/27/breast-implant-safety-pip_n_1170537.html.

59. U.S. Const. art. VI (“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, anything in the constitution or laws of any state to the contrary notwithstanding.”).

60. *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 108 (1992) (citations omitted) (internal quotation marks omitted); see *De Canas v. Bica*, 424 U.S. 351, 357 (1976) (“[E]ven state regulation designed to protect vital state interests must give way to paramount federal legislation.”).

61. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).

the MDAA includes a preemption clause, so a court would first have to determine its scope.

The enactment of the MDAA triggered a great debate as to whether state tort claims (such as negligence, strict liability, and implied warranty) against medical device manufacturers are preempted by the FDA's premarketing approval process. The Medical Device Act, 21 U.S.C. § 360k, states:

[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

- (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
- (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.⁶²

The Medical Device Act did not clarify the types of medical devices bound by the Act, and the Act left companies and attorneys unsure as to the types of devices that were covered by the Act. The Supreme Court addressed the scope of 21 U.S.C. § 360k and attempted to clarify which types of medical devices were covered by preemption in *Medtronic, Inc. v. Lohr* and *Riegel v. Medtronic, Inc.*⁶³

I. *Medtronic, Inc. v. Lohr: Parallel Claims and Section 510(k) Devices*

In *Medtronic, Inc. v. Lohr*, the Supreme Court held that state law claims that parallel federal claims were not preempted.⁶⁴ In 1987, Lora Lohr had a pacemaker equipped with a Medtronic Model 4011 pacemaker lead implanted.⁶⁵ The lead had been approved through a section 510k process by demonstrating that it was “substantially equivalent” to other products on the market.⁶⁶ In 1990, Lohr's pacemaker failed and caused a “complete heart block” that required emergency surgery.⁶⁷ The suspected cause of the pacemaker's failure was Medtronic's Model 4011 lead.⁶⁸ Lohr brought an action in Florida state court against Medtronic for state law claims of negligence and strict

62. 21 U.S.C. § 360k (2011).

63. *Bausch v. Stryker Corp.*, 630 F.3d 546, 550 (7th Cir. 2010) (discussing the analysis provided by *Lohr* and *Riegel*). See generally *Lohr*, 518 U.S. 470; *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

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

65. *Id.* Pacemaker leads are the wires that conduct electrical signals to and from the pacemaker to the heart. CLEVELAND CLINIC, *Lead Placement for Defibrillator or Pacemaker Devices*, available at <http://my.clevelandclinic.org/heart/percutaneous/percutaneousDevice.aspx>.

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

67. *Id.* at 480–81.

68. *Id.* at 481.

liability.⁶⁹ Lohr's negligence claim alleged that Medtronic had breached its "duty to use reasonable care in the design, manufacture, assembly, and sale of the subject pacemaker" through its use of defective materials that may have caused the pacemaker to fail.⁷⁰ Lohr's strict liability count alleged that the pacemaker "was in a defective condition and unreasonably dangerous to foreseeable users at the time of its sale."⁷¹

The Supreme Court determined that the Medical Device Act did not preempt Lohr's state claims because they ran parallel to federal requirements and were not in addition to any federal requirements.⁷² The Court explained:

Nothing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements. Even if it may be necessary as a matter of Florida law to prove that those violations were the result of negligent conduct, or that they created an unreasonable hazard for users of the product, such additional elements of the state-law cause of action would make the state requirements narrower, not broader, than the federal requirement. While such a narrower requirement might be "different from" the federal rules in a literal sense, such a difference would surely provide a strange reason for finding pre-emption of a state rule insofar as it duplicates the federal rule. The presence of a damages remedy does not amount to the additional or different "requirement" that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing "requirements" under federal law.⁷³

The Court concluded that section 360k of the Medical Device Act does not preempt state laws that are identical to federal laws.⁷⁴ The *Lohr* Court reasoned that the device in question, Medtronic's pacemaker and the pacemaker lead, had gone through the section 510(k) "substantially equivalent" exemption and not the Food and Drug Administration's more strenuous section 360k premarketing approval process.⁷⁵ The Court held that section 510(k)'s generally applicable standards were not "requirements" under section 360k of the Medical Device Act and were therefore not sufficient to trigger preemption.⁷⁶

While the *Lohr* Court addressed the issue of preemption for section 510(k) "substantially equivalent" medical devices, the Court did not address whether the law preempts claims arising from defects in

69. *Id.*

70. *Id.*

71. *Id.*

72. *Id.* at 493-95.

73. *Id.* at 495.

74. *Id.* at 494-95.

75. *Id.* at 494.

76. *Id.* at 492-93.

medical devices that had successfully gone through the FDA's more stringent § 360k premarketing approval process.⁷⁷ This question was later addressed in *Riegel v. Medtronic, Inc.*⁷⁸

2. *Riegel v. Medtronic, Inc.: Non-Parallel Claims and Premarket Approval*

In *Riegel v. Medtronic, Inc.*, the Supreme Court considered whether section 360k of the MDAA barred state law claims challenging the safety and effectiveness of a medical device that had received premarket approval from the FDA.⁷⁹ During Charles Riegel's heart surgery, a balloon catheter that had been inserted into his coronary artery exploded, causing blockage in his heart.⁸⁰ Riegel was immediately placed on life support and underwent emergency bypass surgery.⁸¹ Charles and Donna Riegel sued the manufacturer of the balloon catheter used in Riegel's angioplasty.

The Riegels asserted New York state law claims that included strict liability, breach of implied warranty, and negligence in design, testing, inspection, distribution, labeling, marketing, sale, and manufacture.⁸² The Riegels' complaint alleged that the catheter had been designed, labeled, and manufactured in a manner that violated New York state law and that these violations caused Riegel's injuries.⁸³

The Supreme Court held that the Medical Device Act's preemption clause did preempt the Riegels' tort claims challenging the safety and efficacy of premarket approved medical devices because the New York state laws imposed requirements that were "different from, or in addition to" federal ones.⁸⁴ The Court noted that the FDA's premarket approval process was a "rigorous" and time-intensive process that requires the FDA to reasonably assure the medical device's "safety and effectiveness."⁸⁵ The Court determined that "the attributes that *Lohr* found lacking in section 510(k) review are present here."⁸⁶

The Court found that New York's negligence and strict liability laws included requirements that may differ or complement those imposed by federal law.⁸⁷ "[T]he state tort law underlying the Riegels' claims would require a manufacturer's device to be safer (but perhaps less effective)

77. PREEMPTION OF PHARMACEUTICAL AND MEDICAL DEVICE CLAIMS, *supra* note 26.

78. 552 U.S. 312 (2008)

79. *Id.* at 315.

80. *Id.* at 320.

81. *Id.*

82. *Id.*

83. *Id.*

84. *Id.* at 322.

85. *Id.* at 317–18.

86. *Id.* at 323.

87. PREEMPTION OF PHARMACEUTICAL AND MEDICAL DEVICE CLAIMS, *supra* note 26.

than the model device approved by the FDA, those requirements would ‘disrupt[] the federal scheme no less than state regulatory law to the same effect.’”⁸⁸ Thus, the Court found that New York’s state requirements were not parallel to the federal requirements of the Medical Device Act and were preempted under section 360k.⁸⁹

3. *Medical Device Preemption after Lohr and Riegel*

After *Lohr*, claims regarding Class III section 510(k)-approved devices are not preempted and are subject to state tort claims.⁹⁰ Although the majority of Class III medical devices are approved for marketing through the section 510(k) process,⁹¹ many Class III section 360k devices still enter the market each year.⁹² After *Riegel*, these section 360k-approved devices are entitled to preemption and are not open to state tort claims.⁹³ These section 360k-approved devices are subject to most of the medical device preemption controversy.

The section 510(k) approval process is based on pre-existing devices.⁹⁴ Thus, these devices have been previously tested and have a history of product safety.⁹⁵ Section 360k devices are the newest and most untested devices on the market. Thus, the most untested devices receive medical device preemption from state law tort claims.

4. *The Lower Courts’ Interpretations After Lohr and Riegel*

After *Lohr* and *Riegel*, courts have generally followed a three-step process to determine if a state tort claim is preempted: (1) identify the conduct that allegedly provides the right to damages under state law; (2) determine if that conduct is prohibited by the Food, Drug, and Cosmetic Act (if the conduct is not prohibited under the act, the claim is expressly prohibited under section 360k(a)); and (3) determine if that conduct would give rise to liability under state law even if the Food, Drug, and Cosmetic Act had never been enacted; if not, it is likely that the claim is impliedly preempted.⁹⁶

The lower courts have been divided as to the application of the second prong of the test.⁹⁷ If the conduct is not prohibited by the Food,

88. *Bausch v. Stryker Corp.*, 630 F.3d 546, 552 (7th Cir. 2010) (citing *Riegel*, 552 U.S. at 325).

89. *Id.*

90. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 492–94 (1996).

91. *See id.* at 479 (citing H.R. REP. NO. 101-808, at 14 (1990), *reprinted in* 1990 U.S.C.C.A.N. 6305); *Horn v. Thoratec Corp.*, 376 F.3d 163, 167 (3d Cir. 2004).

92. HUTT ET AL., *supra* note 56, at 992.

93. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323 (2008).

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

95. *Id.* at 493–94.

96. *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 776–77 (D. Minn. 2009).

97. 2 JAMES T. O’REILLY, *FOOD AND DRUG ADMINISTRATION* § 26:63 (3d ed. 2012).

Drug, and Cosmetic Act, the claim can be considered parallel and is not expressly prohibited under section 360k(a).⁹⁸ If the conduct is prohibited by the Act, however, the claim is preempted under section 360k(a).⁹⁹ Courts have also differed as to what constitutes a “parallel claim.” Neither *Lohr* nor *Riegel* provides much guidance as to what constitutes a parallel claim, so the district courts have largely defined what constitutes a parallel claim on their own.¹⁰⁰

C. POLICY ISSUES WITH MEDICAL DEVICE PREEMPTION

Legal scholars and legislators have long debated whether medical device preemption should exist. Supporters of preemption argue that it is necessary to encourage medical device innovation.¹⁰¹ Opponents counter that after *Riegel*, manufacturers of dangerous medical devices are practically immune from lawsuits initiated by victims who have been injured by the manufacturers’ devices.¹⁰² Those against preemption continually try to eliminate preemption through legislative means. This Part first discusses the primary benefit of medical device preemption—innovation. Next, this Part discusses the opponents of preemption and their legislative efforts to eliminate medical device preemption.

I. Medical Device Innovation

Proponents of preemption argue that subjecting medical device manufacturers to tort litigation imposes high levels of regulatory and litigation risk. Proponents assert that the threat of litigation discourages investors from providing the capital necessary to develop and manufacture life-saving medical devices. Legislation that eliminates medical device preemption would “impair the health and lead to the death of Americans.”¹⁰³ The establishment of a uniform set of rules to promote

98. *Id.*

99. *Id.*

100. See *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2009) (“The contours of the parallel claim exception were not addressed in *Riegel* and are as-yet ill-defined.”); *Prudhel v. Endologix*, No. S-09-0661, 2009 WL 2045559, at *6, *9 (E.D. Cal. July 9, 2009) (“Districts courts have divided on what constitutes a ‘parallel claim’ under *Riegel*” and “[c]ourts are further divided as to what *Twombly* requires of a plaintiff seeking to plead a parallel claim.”); *White v. Stryker*, 818 F. Supp. 2d 1032, 1036 (W.D. Ky. 2011) (“[W]hile establishing a framework for . . . preemption, *Riegel* also raised many new questions.”).

101. See Hans A. von Spakovsky, *Killing Americans by Stifling Medical Innovation: The Medical Device “Safety” Act of 2009*, 46 LEGAL MEMORANDUM, Aug. 4, 2009, at 5.

102. See generally Demetria D. Frank-Jackson, *The Medical Device Federal Preemption Trilogy: Salvaging Due Process for Injured Patients*, 35 S. ILL. U. L.J. 452 (2011).

103. von Spakovsky, *supra* note 101, at 1.

medical device innovation, as the Food and Drug Administration did via the MDAA, has been important to the development of new medical devices.¹⁰⁴

Proponents of preemption argue that medical device preemption increases stability by encouraging investors who are weary of the risks associated with products liability litigation. Hans von Spakovsky of the Heritage Foundation writes that “[t]his uniformity is the result of federal preemption and a federal regulatory system administered through the FDA that protects the health and safety of the public while allowing innovation and providing incentives for investors to fund the huge development costs.”¹⁰⁵ Investors are encouraged to support the development of new medical devices because their investments will not be subject to reduced returns as a result of litigation costs. Additionally, reduced litigation against medical device companies encourages innovation because these companies can pursue the development of new and potentially life-saving products without the risk that these products will be subject to litigation if something goes wrong.

In *Riegel*, Justice Scalia acknowledged Congress’ concern that permitting state tort claims against manufacturers for FDA-approved devices might stifle innovation.¹⁰⁶ Justice Scalia wrote that Congress considered “those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 states to all innovations.”¹⁰⁷ This factor contributed to the Court’s final decision to uphold preemption.¹⁰⁸

However, not all of the Justices shared this concern. In his concurrence, Justice Stevens cautioned against the idea that tort remedies stifled the innovation and development of medical devices.¹⁰⁹ Justice Stevens stated “[t]hat is a policy argument advanced by the Court, not by Congress.”¹¹⁰ Justice Stevens found no evidence in the pre-enactment history of the Medical Device Act to suggest that Congress believed that state tort remedies would impede future medical device development.¹¹¹ The Supreme Court remains divided on the question of whether preemption actually promotes medical device innovation.

2. *Opponents of Riegel and the Legislative Response*

Opponents of medical device preemption assert that medical device companies are receiving a free pass from state tort violations as a result

104. *Id.* at 3.

105. *Id.*

106. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 326 (2008).

107. *Id.*

108. *Id.*

109. *Id.* at 331 (Stevens, J., concurring in part and concurring in judgment).

110. *Id.*

111. *Id.*

of preemption. Analyzing *Riegel*, Judge Brody of the United States District Court for the Eastern District of Pennsylvania wrote that *Riegel* is “loud and clear: if a manufacturer complies with the premarket approval, it gets a free pass on those two claims. No state common-law claim can survive if it allows a claimant to proceed without showing a departure from federal standards. There simply is no wiggle room to find otherwise.”¹¹²

Opponents of medical device preemption have attempted to remedy this “free pass” through legislative attempts to change section 360k of the Medical Device Amendments.

Since the *Riegel* decision in 2008, Congress repeatedly introduced legislation to amend section 360k of the Medical Device Safety Act of 1976, without success.¹¹³ In April of 2008, Senator Edward Kennedy of Massachusetts introduced the Medical Device Safety Act.¹¹⁴ This act attempted to bring medical device preemption back to the pre-*Riegel* standard by amending section 360k so that it could not be interpreted to preempt state law claims.¹¹⁵ The bill died when it was referred to Committee.¹¹⁶ The 111th Congress reintroduced the bill as the Medical Device Safety Act of 2009.¹¹⁷ This bill also died in Committee.¹¹⁸ To date, no proposed amendments to section 360k of the Medical Device Safety Act of 1976 have passed Congress. However, the economics of preemption make it likely that Congress will revisit efforts to amend § 360k.

The legislature and judiciary must address medical device preemption because the outcome could decide whether individuals harmed by medical devices are entitled to partial or total compensation for their injuries. To properly answer this question, courts must evaluate the benefits and consequences of medical device preemption. In making a cost-benefit analysis, it is important to first consider the economics of preemption.

II. THE ECONOMICS OF PREEMPTION

Externalities are costs or benefits from an economic activity that impact parties outside of those engaged in the actual transaction.¹¹⁹ The central goal of tort law is to impose liability on the party or parties that

112. *Williams v. Cyberonics, Inc.*, 654 F. Supp. 2d 301, 306 (E.D. Pa. 2009), *aff'd*, 388 F. App'x 169 (3d Cir. 2010).

113. See Medical Device Safety Act of 2008, H.R. 6381, 110th Cong. (2d Sess. 2008); Medical Device Safety Act of 2009, H.R. 1346, 111th Cong. (1st Sess. 2009).

114. H.R. 6381.

115. See PREEMPTION OF PHARMACEUTICAL AND MEDICAL DEVICE CLAIMS, *supra* note 26.

116. H.R. 6381.

117. H.R. 1346.

118. *Id.*

119. Matthew Bishop, *Economics A-Z terms beginning with E*, THE ECONOMIST, <http://www.economist.com/economics-a-to-z/e> (“Externality”) (last visited Oct. 31, 2013) (emphasis omitted).

are responsible for causing the harm.¹²⁰ This operates as a way to internalize harmful externalities to the parties that cause the injury.¹²¹

Harmful externalities arise when injurers do not account for the loss that they inflict on others as a result of their actions.¹²² The injuring party does not have to account for the harm because they do not suffer any consequences.¹²³ This distorts economic resources and leads to economic inefficiency.¹²⁴ Internalizing the externality, on the other hand, ensures that the perpetrators of the harm are suffering the consequences.¹²⁵ In tort law, internalizing the externality is a way to prevent or deter harmful actions from occurring.¹²⁶

This Part first defines the term externality and then reviews the concept of internalizing externalities. This Part concludes with a look at how the costs of the Sprint Fidelis Lead failure were externalized to the United States government.

A. DEFINING EXTERNALITY

Externalities “are costs or benefits arising from an economic activity that affect somebody other than the people engaged in the economic activity and are not reflected fully in prices.”¹²⁷ Classic examples of externalities include air pollution from fossil fuels damaging public health¹²⁸ and bees kept to produce honey pollinating plants belonging to a nearby farmer, thus boosting that farmer’s crop.¹²⁹ In the air pollution example, the public suffers health consequences without any of the economic benefits that are enjoyed by the producer of the pollution. In the bee example, the farmer benefits from the bees pollinating her crops but experiences none of the costs of maintaining the bees.

120. Israel Gilead, *Tort Law and Internalization: The Gap Between Private Loss and Social Cost*, 17 INT’L REV. L. & ECON. 589, 589 (1997).

121. *Id.*; see Tibor Scitovsky, *The Concept of External Economics*, 62 J. POL. ECON. 143 (1954), reprinted in EXTERNALITIES: THEORETICAL DIMENSIONS OF POLITICAL ECONOMY 77 (Robert J. Staaf & Francis X. Tannian eds., Dunellen 1973) (noting the concept of externalities is “one of the most elusive in economic literature” because it can be defined in many ways); WILLIAM J. BAUMOL & WALLACE E. OATES, *THE THEORY OF ENVIRONMENTAL POLICY* 15–18 (2d ed. 1988).

122. Gilead, *supra* note 120, at 589.

123. *Id.*

124. *Id.*

125. *Id.* at 589–90.

126. *Id.*; see Frank B. Cross, *Tort Law and the American Economy*, 96 MINN. L. REV. 28, 30 (2011); David Partlett, *Economic Analysis and Some Problems in the Law of Torts*, 13 MELB. U. L. REV. 398, 401 (1982).

127. Bishop, *supra* note 119 (emphasis omitted).

128. *Other Impacts: Ecosystems and Biodiversity*, in EUROPEAN COMM’N PUBL’NS OFFICE, EXTERNALITIES OF ENERGY: METHODOLOGY 2005 UPDATE 229–237 (Peter Bickel & Rainer Friedrich eds., 2004).

129. See Bishop, *supra* note 119.

Here, medical device preemption externalizes the harms produced by medical devices from the manufacturers to the government and general public. When medical devices fail, like in the case of the pacemaker lead in *Lohr* or the balloon catheter in *Riegel*, serious consequences result. Great harm and costs can be borne by the government and general public if these harms are not internalized by the medical device companies themselves.

B. INTERNALIZING EXTERNALITIES

Courts have generally required businesses to absorb all the harms and costs associated with production.¹³⁰ Courts have applied this concept in determining liability.¹³¹ A.C. Pigou, a leading early twentieth century economist, labeled this general economic principle as “internalization.”¹³²

Under Pigou’s principle of internalization, firms must pay for all of the costs associated with production.¹³³ If firms do not, the market prices of their goods will become distorted and not reflect the true cost and use of resources that were necessary to produce the goods.¹³⁴ Thus, some goods would be overpriced while others would be underpriced.¹³⁵ The following example illustrates this concept of market inefficiency:

[S]uppose that in the course of production a firm pollutes an adjacent river which has the effect of increasing the costs of production to a farmer downstream. If the firm is not forced to pay for those increased costs, then the farmer must absorb them. Due to these higher costs the farmer will have to charge higher prices in order to produce the same level of output as he did before the pollution. Because of these higher prices, however, consumers will purchase less of the farmer’s goods than they did previously. A new equilibrium for the farmer can be achieved only at higher prices and lower levels of production. At the same time, since the firm is not required to absorb its pollution costs, it will have lower costs of production and thus will be able to charge lower prices to produce the same level of output. Because of these lower prices consumers are willing to purchase more of the firm’s goods. The firm’s equilibrium will consist of lower prices and greater output when it does not pay for the pollution effects as compared with when it does.¹³⁶

In the example above, the economics of the marketplace have been distorted. The firm has externalized the costs of the pollution to the

130. Barbara White, *Coase and the Courts: Economics for the Common Man*, 72 IOWA L. REV. 577, 580 (1987).

131. *Id.*

132. *Id.* at 580. See generally A.C. PIGOU, *THE ECONOMICS OF WELFARE* (4th ed. 1932).

133. See White, *supra* note 130, at 580.

134. *Id.*

135. *Id.*

136. *Id.*

disadvantage of the farmer, who is forced to bear the burden of the firm's pollution. The firm can now charge a lower price for its products and sell more products, while the farmer has to charge a higher price and sell fewer products. This encourages the firm to continue to pollute the river to the detriment of the farmer. Pigou argues that this distortion of the marketplace is economically inefficient.¹³⁷

Here, similar to the example of the firm and farmer, the danger of medical device preemption is that it fails to require medical device companies to account for the harms to society that are produced by their products. Permitting medical device manufacturers to externalize the harms that are produced by their devices promotes poor corporate behavior and fails to force companies to act quickly and appropriately when their products harm consumers. Companies have no economic incentive to be good corporate citizens because they suffer no consequences if they fail to act in a responsible manner. The case of *Medtronic, Inc.'s Sprint Fidelis Lead* exemplifies this scenario.

C. THE COST OF THE SPRINT FIDELIS LEAD RECALL ON MEDICARE

In re Medtronic Inc. Sprint Fidelis Leads Products Liability Litigation illustrates the economic and societal damages that arise when the company causing harm does not suffer the consequences of that harm.¹³⁸ Anna Bryant and other patients sued Medtronic in 2007 after the company announced a recall of its defective Sprint Fidelis lead.¹³⁹ The Sprint Fidelis Lead is a wire that allowed cardiac defibrillators to detect abnormal heart rhythms.¹⁴⁰ When abnormal heart rhythms occurred, the Sprint Fidelis Lead delivered a shock to help the heart return to its normal rhythm.¹⁴¹ The patients asserted twenty state law tort and breach of warranty claims for injuries allegedly caused by Medtronic's defective leads.¹⁴² Applying the preemption principle from *Riegel* that medical devices receiving premarket approval from the FDA are entitled to preemption, the Eighth Circuit held that the MDA preempts the patient's claims.¹⁴³ Thus, the court affirmed Medtronic's motion to dismiss.¹⁴⁴

Medtronic's Sprint Fidelis Lead is a Class III medical device.¹⁴⁵ In December 1993, the FDA granted Medtronic Inc. premarket approval

137. *Id.* at 580–81.

138. 623 F. 3d 1200 (8th Cir. 2010).

139. *Id.* at 1203.

140. *Id.*

141. *Id.*

142. *Id.*

143. *Id.* at 1209.

144. *Id.*

145. *Id.* at 1203.

for the Transvene Lead System.¹⁴⁶ In June 2004, the FDA approved a premarket approval supplement for the Sprint Fidelis Lead.¹⁴⁷

Shortly after the Sprint Fidelis lead entered the market, patients implanted with the Sprint Fidelis device began experiencing unnecessary shocks.¹⁴⁸ An investigation by Dr. Robert G. Hauser and the Minneapolis Heart Institute discovered that the Sprint Fidelis Leads fractured more frequently than other types of leads.¹⁴⁹ Dr. Hauser and his colleagues published a “report finding that the Sprint Fidelis Lead was more likely to fracture than other types of leads, met with Medtronic to voice their concerns, and advised the FDA of those concerns.”¹⁵⁰ Despite receiving this information from the Minneapolis Heart Institute, Medtronic vigorously defended its product and assured doctors that the Sprint Fidelis Lead was safe.¹⁵¹ Medtronic sent a “Dear Doctor” letter to physicians and other medical practitioners defending the safety of the Sprint Fidelis Lead.¹⁵² Medtronic asserted that the fractures were a result of improper surgical technique and assured physicians that the Sprint Fidelis Lead was as safe as other Medtronic leads.¹⁵³

In May 2007, Medtronic filed for a premarket approval (“PMA”) supplement for its Sprint Fidelis Lead.¹⁵⁴ Medtronic sought FDA approval for design and manufacturing changes to the Sprint Fidelis Leads.¹⁵⁵ The plaintiffs in *Sprint Fidelis Leads* asserted that Medtronic did this without advising the FDA about the high rate of failures experienced by patients with the Sprint Fidelis Lead.¹⁵⁶ Medtronic’s PMA supplement for its Sprint Fidelis Lead was approved by the Food and Drug Administration in July 2007.¹⁵⁷

In September 2007, less than two months after receiving PMA supplement approval, Medtronic filed 120 adverse events with the Sprint Fidelis Lead with the FDA.¹⁵⁸ On October 15, 2007, Medtronic announced a worldwide recall.¹⁵⁹ Shortly after, the FDA issued a Class I recall, the most serious level of medical device recalls.¹⁶⁰

146. *Id.*

147. *Id.*

148. *Id.*

149. *Id.*

150. *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1203 (8th Cir. 2010).

151. *Id.* at 1203–04.

152. *Id.* at 1204.

153. *Id.*

154. *Id.*

155. *Id.*

156. *Id.*

157. *Id.*

158. *Id.*

159. *Id.*

160. *Id.*

At the time of the recall more than 150,000 patients had been treated with Sprint Fidelis leads.¹⁶¹ It is estimated that more than eighty-five percent of the patients receiving pacemakers and leads are sixty-five years or older and are thus covered under Medicare.¹⁶² Because the majority of the people who received the Sprint Fidelis Lead were on Medicare, the Medicare program has paid millions of dollars to address problems that patients have faced as a result of the defective Sprint Fidelis Leads.¹⁶³

The Eighth Circuit's decision *In re Medtronic Inc. Spring Fidelis Leads Products Liability Litigation* absolved Medtronic, Inc. of any responsibility for these damages caused by its Sprint Fidelis Lead and externalized the costs to Medicare.¹⁶⁴ In his actuarial analysis of the cost of Medtronic's defective Sprint Fidelis Leads for pacemakers to the Medicare program, Dr. Dennis Tolley concluded that Medicare will pay up to one billion dollars in additional claims as a direct result of the damage caused by Medtronic placing the defective leads on the market.¹⁶⁵

The *In re Medtronic Inc. Spring Fidelis Leads Products Liability Litigation* case is evidence that the Supreme Court's decision in *Riegel* has fully externalized the costs of device failures from medical device companies. The medical device companies have externalized the costs of medical device failures to the government and created "a very costly present and future liability for Medicare, Medicaid, and private health insurance companies."¹⁶⁶

III. THE IMPACT OF MEDICAL DEVICE PREEMPTION

With the large number of annual medical device recalls, the potential costs of medical device preemption on the American public are enormous. The FDA website lists over 160 Class I medical device recalls in 2009 alone.¹⁶⁷ Although claims involving ninety percent of medical devices are arguably not preempted because they involve Class III medical devices that have been approved through the 510(k) "substantially equivalent process," the majority of litigation involves the remaining ten percent of medical device products that may be entitled to preemption.¹⁶⁸ In the case of Medtronic's defective Sprint Fidelis Leads, the immunity

161. Robert G. Hauser & David L. Hayes, *Increasing Hazard of Sprint Fidelis Implantable Cardioverter-Defibrillator Lead Failure*, 6 HEART RHYTHM 605, 605 (2009).

162. Arshad Jahangir et al., *Relation Between Mode of Pacing and Long-Term Survival in the Very Elderly*, 33 J. AM. COLL. CARDIOLOGY 1208, 1214 (1999).

163. TOLLEY, *supra* note 21, at 3.

164. *Id.* at 5.

165. *Id.* at 2.

166. *Id.* at 3.

167. *Id.* at 2.

168. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477-78 (1996).

from liability provided by *Riegel v. Medtronic* externalized an estimated one billion dollars worth of harm from Medtronic to the government, Medicare, and ultimately the American people.¹⁶⁹

It is important to weigh the benefits of medical device preemption against the significant costs associated with the act. One of the major goals behind the concept of medical device preemption is to promote medical device innovation by providing incentives for investors to fund the large amount of capital needed to develop medical devices.¹⁷⁰ The medical device industry in the United States is a roughly \$98 billion industry dominated by small medical device companies.¹⁷¹ Many small medical device companies face continual financial challenges, creating a need for third-party investors.¹⁷²

Promoting medical device innovation is a legitimate goal that provides tangible health benefits to the American people through the development of life-prolonging and life-saving devices. It reasonably follows that protecting small medical device companies from cumbersome litigation is an important way for the government to encourage medical device innovation. Without such protection, there is a strong likelihood that small medical device companies would be harmed by the high cost of litigation or be disincentivized from continuing in the medical device market. This is one of the primary reasons Congress passed the Medical Device Amendments in 1976.

However, providing blanket medical device preemption externalizes the harm of developing defective and improperly functioning medical devices because medical device companies do not face the consequences of their actions. As evidenced by *Sprint Fidelis Leads*, when devices are provided full preemption, medical device companies have no incentive to vigilantly promote the safety of their products. These companies can delay responses and ignore claims of injury absent enforceable consequences

169. See TOLLEY, *supra* note 21, at 2.

170. See von Spakovsky, *supra* note 101.

171. Marisa A. Trasatti et al., *Preemption in Medical Device Litigation: What Has Changed Since Riegel?*, (July 28, 2012) available at http://www.semmed.com/publications_archive/litigation/medical-device-litigation.asp (citing LEWIN GRP., INC., STATE IMPACTS OF MEDICAL TECHNOLOGY INDUSTRY (June 7, 2010)).

172. See, e.g., Greg Avery, *MicroPhage Files for Bankruptcy Protection*, DENVER BUS. J., Jan. 7, 2013, <http://www.bizjournals.com/denver/news/2013/01/02/microphage-files-for-bankruptcy.html>; Patricia Miller, *Otologics Files for Bankruptcy*, ST. LOUIS BUS. J., July 30, 2012, <http://www.bizjournals.com/stlouis/blog/BizNext/2012/07/otologics-files-for-bankruptcy.html>; Luke Timmerman, *Archus Orthopedics, Spine Device Maker that Raised \$60M, Shuts Down Amid Cash Crunch*, XCONOMY (Sept. 3, 2009), <http://www.xconomy.com/seattle/2009/09/03/archus-orthopedics-spine-device-maker-that-raised-60m-shuts-down-amid-cash-crunch>; *Update 1-NMT Medical Says to Liquidate Assets*, REUTERS, Apr. 19, 2011, available at <http://www.reuters.com/assets/print?aid=USL3E7FJ3SC20110419>; *Update 1-Xtent Board Approves Liquidation*, REUTERS, May 15, 2009, available at <http://www.reuters.com/assets/print?aid=INBNG38436220090515>.

for being irresponsible because the externalization of risks encourages medical device companies to take unnecessary risks.

In the case of Medtronic's Sprint Fidelis Lead, Medtronic had no incentive to expediently address the issues associated with the Sprint Fidelis because medical device preemption allowed the company to externalize the cost of the defect to the government to the tune of one billion dollars.¹⁷³ Had medical preemption not existed and Medtronic been forced to internalize the potential costs of its product's defects, it is likely that Medtronic would have acted much more quickly to address the problem. This would have benefitted the public, as quick action by Medtronic could have saved a large number of the 150,000 people¹⁷⁴ implanted with the Sprint Fidelis Lead from the life-threatening health consequences, and thousands of people from the inconvenience of having the Sprint Fidelis Lead device removed. Additionally, quicker action would have saved Medicare and the American taxpayers some of the one billion dollars¹⁷⁵ that was spent to remedy problems with the Sprint Fidelis Lead device.

A solution is needed that balances the need for small medical device manufacturers to have an incentive to innovate and forces medical device companies to internalize some of the costs that arise out of their defective devices.

IV. INTERNALIZING THE EXTERNALITIES OF MEDICAL DEVICE PREEMPTION

This Note proposes that the government should develop a system that would force medical device companies to internalize some of the costs of medical device defects that have been externalized as a result of medical device preemption. The following two-part plan attempts to balance the desire for more medical device innovation and force medical device companies to internalize some of the costs associated with defects in their products.

A. CREATING A "NATIONAL MEDICAL DEVICE INJURY COMPENSATION PROGRAM"

Congress should place a small tax on medical device manufacturers for each medical device sold. Revenue from the tax would go into a fund run by FDA called the "National Medical Device Injury Compensation Program" for the purposes of providing redress for patients who have been harmed by defective products. In turn, state tort claims against

173. See TOLLEY, *supra* note 21, at 2.

174. See Hauser & Hayes, *supra* note 161.

175. See TOLLEY, *supra* note 21, at 2.

medical device companies would be severely restricted. While this incrementally drives up cost of medical devices for the consumers, this fund simultaneously benefits consumers because the fund would be available to cover the harmed patients' costs immediately. The creation of the National Medical Device Injury Compensation Program would internalize some of the costs of defects to the medical device companies. This solution is similar to the National Vaccine Injury Compensation Program, which was enacted in 1986 "to encourage and improve childhood vaccination programs, coordinate record keeping, and standardize vaccine-specific warnings."¹⁷⁶ An amendment to the act created the National Vaccine Injury Compensation Program ("NVICP").¹⁷⁷ One of the main purposes of the NVICP was "to safeguard the nation's supply of vaccines by insulating manufacturers from liability claims and to provide prompt and adequate compensation for victims of unpreventable adverse effects of vaccination."¹⁷⁸

To accomplish this goal, the government implemented a no-fault government compensation program to limit the damages that individuals who suffered injuries attributed to vaccinations may collect.¹⁷⁹ The compensation plan was funded by a vaccine excise tax:¹⁸⁰ Individuals receiving the vaccine were charged a small tax starting at seventy-five cents per vaccine dose.¹⁸¹ The largest per dose charge was for diphtheria-tetanus-pertussis ("DTP") vaccinations.¹⁸² DTP doses were taxed at a rate of \$2.25 per dose, or approximately fifteen percent of the wholesale cost of vaccine.¹⁸³

The NVICP was the first national industry-wide effort at creating a no-fault strict product liability scheme that balanced the need for innovation from vaccine manufacturers and the rights of consumers.¹⁸⁴ This model has been proposed as an example for insuring other products or services like pharmaceuticals or medical care.¹⁸⁵ Since the NVICP's implementation, instances of large vaccine injury awards have been

176. Derry Ridgway, *No-Fault Vaccine Insurance: Lessons from the National Vaccine Injury Compensation Program*, 24 J. HEALTH POL. POL'Y & L. 59, 62 (1999).

177. *Id.*

178. *Id.* (citing Lisa J. Steel, *National Childhood Vaccine Injury Compensation Program: Is This the Best We Can Do for Our Children?*, 63 GEO. WASH. L. REV. 144, 173 (1994)).

179. Ridgway, *supra* note 176, at 62.

180. *Id.*

181. *Id.*

182. *Id.*

183. *Id.*

184. *Id.* at 83. See generally Theodore H. Davis, Jr. & Catharine B. Bowman, *No-Fault Compensation for Unavoidable Injuries: Evaluating the National Childhood Vaccine Injury Compensation Program*, 16 U. DAYTON L. REV. 277 (1991).

185. See Ridgway, *supra* note 176, at 83; Davis & Bowman, *supra* note 184, at 321.

eliminated.¹⁸⁶ This was not the trend before the implementation of the NVICP.¹⁸⁷ The NVICP's success "in protecting both manufacturers and consumers is certain to attract the attention of legislators anxious to protect other commercial interests, to promote consumers' chances of compensation after injury, or simply to combat the public perception of tort law as a system out of control."¹⁸⁸

Similarly, the FDA should develop a "National Medical Device Injury Compensation Program" modeled after the NVICP. The NVICP was successful at balancing protection of manufacturers with the patients' right to compensation. Like the NVICP, the National Medical Device Injury Compensation Program would successfully balance costs of faulty medical device companies through small surcharges on their products and preserve the ability of medical device companies to innovate. The key to the success of a potential tax would be to set the tax rate at a level high enough to fulfill the redress requirements of the patient who has been hurt by the medical device, but low enough to not stifle medical innovation.

B. MEDICAL DEVICE COMPANIES SHOULD BE REQUIRED TO INSURE AGAINST POSSIBLE DEFECTS

Under the second part of the plan, Congress should revise medical device preemption and pass new legislation that requires medical device companies to purchase insurance that protects the companies from state tort claims based on defective products. This should be required for each new device brought to market by medical device companies. Such a requirement would also provide a remedy for individuals who have been harmed by defective medical devices. Additionally, the insurance requirement would preserve medical device companies' ability to innovate while providing redress for those who have been harmed by faulty devices. This solution, implemented concurrently with the National Medical Device Injury Compensation Fund, will provide some remedy for patients harmed by medical devices.

The type of insurance required should be similar to the stop-loss insurance that is used by many companies for their ERISA liabilities. Stop-loss insurance allows companies to protect themselves from the costs associated with major losses.¹⁸⁹ There are two main types of stop-loss insurance.¹⁹⁰ Specific stop-loss insurance covers against the risk that

186. See Ridgway, *supra* note 176, at 77.

187. *Id.*

188. *Id.* at 83.

189. Troy Paredes, Note, *Stop-Loss Insurance, State Regulation, and ERISA: Defining the Scope of Federal Preemption*, 34 HARV. J. ON LEGIS. 233, 249 (1997).

190. *Id.*

the insurance purchaser's claims will exceed a certain threshold.¹⁹¹ "For example, if the insurance kicks in when an individual's claims exceed \$20,000 per year and a participant has claims of \$30,000, the plan's stop-loss insurer covers \$10,000 of the person's claims."¹⁹² The other type of stop-loss insurance is aggregate stop-loss insurance, which covers the insured party against the risk that the sum of all claims against it will exceed a certain threshold.¹⁹³ "For example, if the insurance kicks in when aggregate claims exceed \$2 million per year and claims under the plan total \$2.5 million, the stop-loss insurer covers \$500,000 of the claims."¹⁹⁴ Companies should be required to purchase one of these two types of stop-loss insurance.

To account for the differing sizes of medical device companies, the amount of coverage required should depend both on the financial size of the company and the potential size of the device's market. The insurance requirements should become part of the FDA's premarket approval process.

The purpose of insurance is to protect risk adverse groups from suffering the full consequences of non-foreseeable actions that affect them unfavorably.¹⁹⁵ Requiring medical device companies to purchase insurance would internalize some of the external costs of defective products to the medical device company. Medical device companies would pay a premium to spread the potential costs of defective products to the entire medical device industry. Insurance premiums are dependent on the level of risk posed by the companies being insured. An insurance requirement would encourage medical device companies to minimize their own risks because companies with a history of safer devices would be charged lower premiums than companies with a history of producing defective devices. Thus, such a requirement would encourage medical device companies to minimize the harms caused by their devices.

Currently, under medical device preemption, the entire cost of the defects is externalized from medical device companies to consumers, private insurers, Medicare, and the government. Under the insurance requirement, the costs would be internalized by the medical device industry and spread throughout the entire medical device industry. An insurance requirement, while increasing the costs of medical device companies, would not cost the companies as much as the complete removal of the medical device preemption. Together, these two proposals would internalize some of the costs of medical device defects

191. *Id.*

192. *Id.*

193. *Id.*

194. *Id.*

195. Michael Spence & Richard Zeckhauser, *Insurance, Information, and Individual Action*, 61 AM. ECON. REVIEW, 380, 380 (1971).

without subjecting medical device companies to litigation that could curtail innovation.

CONCLUSION

Promoting medical device innovation is a legitimate goal that benefits the American public. Protecting small medical device companies from unnecessary litigation is an important way for the government to achieve this goal. Providing blank medical device preemption is not the solution because it enables medical device companies to externalize the harms caused by their devices.

To solve this conundrum, Congress must develop a system that internalizes some of the costs of medical device preemption. Such a requirement would encourage medical device companies to take fewer risks and promote medical device safety without stifling medical innovation. This can be achieved by forcing medical device companies to participate in an industry-wide insurance system and imposing a small tax to fund the cost of possible defects. The plan proposed by this Note would provide harmed patients with an avenue to remedy the harms that they have suffered, promote medical device safety, and allow medical device companies to continue to develop life-enhancing products.
