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Julie C. Solms

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***RIEDEL V. MEDTRONIC IN LIGHT OF THE RECENT TREND IN
PREEMPTION CASES: A CASE FOR AMENDING THE MEDICAL
DEVICE ACT***

Julie C. Solms¹

The Medical Device Act of 1976 governs the Food and Drug Administration's premarket approval process for medical devices. In Riegel v. Medtronic, Inc., the United States Supreme Court held that the Act preempts state tort claims against medical device manufacturers. This Recent Development contends that the Court appropriately decided Riegel in light of its recent trend towards a more textual approach to statutory interpretation in federalism cases in the administrative context. Post-Riegel decisions, however, are improper in view of legislative intent and unfavorably deprive plaintiffs of state tort remedies. Congress should now amend the Medical Device Act in order to clarify its purpose and to produce the effect originally intended.

I. INTRODUCTION

On December 4, 2007, *Riegel v. Medtronic, Inc.*² presented the United States Supreme Court with the issue of whether premarket approval ("PMA") by the Food and Drug Administration ("FDA") preempts state claims against the manufacturer of a medical device.³ Just over two months later, the Court determined, based on the relevant language of the Federal Food, Drug and Cosmetic Act,⁴ that PMA of a device does preempt a state claim,⁵ a decision which this Recent Development contends is contrary to congressional intent.⁶ Although the modern trend of deciding

¹ J.D. Candidate, University of North Carolina School of Law, 2010.

² 128 S. Ct. 999 (2008).

³ *See id.*

⁴ Medical Device Amendments of 1976. 21 U.S.C. § 360k (2006).

⁵ *See Riegel*, 128 S. Ct. 999.

⁶ *See discussion infra* Part IV.

federalism cases according to the theory of textualism⁷ properly led to the *Riegel* decision, the legislative intent behind the Medical Device Act (“MDA”) makes it clear that legislation should be passed to invalidate the *Riegel* decision to preserve the originally envisioned protections.

Part II of this Recent Development outlines the FDA’s PMA process and discusses the *Riegel* decision. Part III describes the Supreme Court’s trend towards textualism⁸ and how this trend helps to explain the *Riegel* decision. Part IV discusses how the legislative history of the MDA⁹ would support the passage of legislation invalidating *Riegel*. Part V describes the post-*Riegel* world and explores some of the decisions’ unfavorable consequences. Part VI introduces the proposed Medical Device Amendments of 2009¹⁰ and argues that these Amendments should be passed.

II. THE FDA’S PREMARKET APPROVAL PROCESS AND *RIEGEL V. MEDTRONIC, INC.*

A. The FDA’s Premarket Approval Process

Until the MDA¹¹ was passed, the regulation of medical devices was largely left to the discretion of each state.¹² The Dalkon Shield intrauterine device was introduced in 1970, and its association with many deaths, serious infections, and pregnancies led to the filing of

⁷ See Karen A. Jordan, *The Shifting Preemption Paradigm: Conceptual and Interpretive Issues*, 51 VAND. L. REV. 1149, 1210–11 (1998). While the term “textualism” is often used to describe a method of constitutional interpretation, Jordan uses the term to describe the plain meaning of statutory language. The author of this Recent Development will use the term in this same way throughout this Recent Development.

⁸ See *id.*

⁹ 21 U.S.C. § 360k (2006).

¹⁰ Medical Device Amendments of 2009. S. 540, 111th Cong. (2009); Medical Device Amendments of 2009. H.R. 1346, 111th Cong. (2009).

¹¹ 21 U.S.C. §§ 301-95 (2006).

¹² See *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1002 (2008); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475–76 (1996).

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thousands of claims against the manufacturer.¹³ Through this disaster, many saw the failure of the common law tort system to handle the risks associated with medical devices appropriately¹⁴. Several states, including California, passed legislation requiring medical devices to be approved prior to their introduction into the market.¹⁵ In 1976, Congress passed the MDA which included an express preemption provision in § 360,¹⁶ stating that no state shall enforce any regulation “which is different from, or in addition to, any requirement applicable under this chapter to the device, and . . . 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.”¹⁷

¹³ See *Riegel*, 128 S.Ct at 1003 (citing RONALD J. BACIGAL, *THE LIMITS OF LITIGATION: THE DALKON SHIELD CONTROVERSY* 3 (1990)); *id.* at 1014–15 (Ginsburg, J., dissenting). For further discussion of the litigation related to the Dalkon Shield controversy, see Anna Birenbaum, *Shielding the Masses: How Litigation Changed the Face of Birth Control*, 10 S. CAL. REV. L. & WOMEN'S STUD. 411 (2001).

¹⁴ *Riegel*, 128 S. Ct. at 1003 (citing SUSAN FOOTE, *MANAGING THE MEDICAL ARMS RACE: INNOVATION AND PUBLIC POLICY IN THE MEDICAL DEVICE INDUSTRY*, 151–52 (1992)).

¹⁵ See *id.* (citing 1970 Cal. Stats. ch. 1573, §§ 26670–26693; see also 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) (identifying 13 state statutes governing medical devices as of 1976); Brief for Petitioners at 6, *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008) (No. 06-179) (“When drafting the MDA, Congress was informed of state regulatory programs that had stepped into the federal regulatory vacuum. Most notably, a California statute required that medical devices undergo premarket approval before commercial distribution in the state and that they comply with state good manufacturing practices regulations.” (citing H.R. REP. NO. 94-853, at 45 (1976))).

¹⁶ 21 U.S.C. § 360k(a) (2006); see also Alexandra B. Krass, *Tort Experiments in the Laboratories of Democracy*, 50 WM. & MARY L. REV. 1501, 1548 (2009) (discussing the Supremacy Clause in the U.S. Constitution and explaining federal preemption).

¹⁷ 21 U.S.C. § 360k(a).

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The MDA created three classes of medical devices based on the risks of injury or illness associated with their use.¹⁸ Class III devices, such as the Evergreen Balloon Catheter in *Riegel*, discussed *infra* at Part II.B, require PMA by the FDA due to the serious risks they present.¹⁹ Manufacturers of new Class III devices must submit to the FDA a lengthy application, each of which requires approximately 1,200 hours of FDA review.²⁰ After balancing the possible benefits with the potential risks of utilizing the device, the FDA may grant PMA only if it finds “reasonable assurance of [the device’s] safety and effectiveness.”²¹

Not all Class III medical devices, however, are required to undergo this lengthy review process.²² Many devices that were on the market prior to the passage of the MDA were authorized to remain on the market without premarket approval until the FDA passed a regulation requiring PMA.²³ Other new devices “need not undergo premarket approval if the FDA finds it is ‘substantially equivalent’ to another device exempt from premarket approval.”²⁴ The FDA reviews such devices for substantial equivalence under a process described by § 510(k) of the MDA and aptly called the “section 510(k) process.”²⁵

¹⁸ See *Riegel*, 128 S. Ct. at 1003 (citing 21 U.S.C. § 360c (2006)) (“The new regulatory regime established various levels of oversight for medical devices, depending on the risks they present. Class I, which includes such devices as elastic bandages and examination gloves, is subject to the lowest level of oversight: ‘general controls,’ such as labeling requirements. Class II, which includes such devices as powered wheelchairs and surgical drapes, is subject in addition to ‘special controls’ such as performance standards and postmarket surveillance measures.”) (internal citations omitted).

¹⁹ 21 U.S.C. § 360c.

²⁰ See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996).

²¹ 21 U.S.C. § 360d(a)(1) (2006).

²² *Riegel*, 128 S. Ct. at 1004.

²³ *Id.* (citing 21 U.S.C. §§ 360c(f)(1), 360e(b)(1) (2006)).

²⁴ *Id.* (citing 21 U.S.C. § 360c(f)(1)(A) (2006)).

²⁵ *Id.* (“Most new Class III devices enter the market through § 510(k). In 2005, for example, the FDA authorized the marketing of 3,148 devices under § 510(k) and granted premarket approval to just 32 devices.” (citing 21 U.S.C. § 510(k) (2006); PETER BARTON HUTT, RICHARD A. MERRILL, & LEWIS A. GROSSMAN, *FOOD AND DRUG LAW* 992 (3d ed. 2007))).

B. *Riegel v. Medtronic, Inc.*

The FDA's PMA process under § 360, specifically the express preemption provision in § 360(k), was at issue in *Riegel*. In 1996, Charles Riegel ("Riegel") suffered a myocardial infarction²⁶ and underwent coronary angioplasty²⁷ surgery.²⁸ His surgeon used an Evergreen Balloon Catheter²⁹ in an attempt to unblock a calcified artery.³⁰ In doing so, the surgeon overinflated the balloon, and the catheter burst.³¹ Riegel then underwent emergency coronary bypass surgery after developing heart block³² and being placed on life support.³³

²⁶ A myocardial infarction is commonly known as a heart attack. U.S. Nat'l Library of Med., U.S. Nat'l Inst. of Health, *Heart Attack: MedlinePlus Medical Encyclopedia*. <http://www.nlm.nih.gov/medlineplus/ency/article/000195.htm> (last visited Aug. 6, 2009) ("A heart attack is when blood vessels that supply blood to the heart are blocked, preventing enough oxygen from getting to the heart. The heart muscle dies or becomes permanently damaged.") (on file with the North Carolina Journal of Law & Technology).

²⁷ "Angioplasty is a procedure to open narrowed or blocked blood vessels that supply blood to the heart." U.S. Nat'l Library of Med., U.S. Nat'l Inst. of Health, *Angioplasty and Stent Placement—Heart: MedlinePlus Medical Encyclopedia*. <http://www.nlm.nih.gov/medlineplus/ency/article/002953.htm> (last visited August 6, 2009) (on file with the North Carolina Journal of Law & Technology).

²⁸ See *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1005 (2008).

²⁹ A balloon catheter is a flexible tube used in a coronary angioplasty. When inserted into a blocked blood vessel and inflated, the balloon "opens the blocked vessel and restores proper blood flow to the heart." U.S. Nat'l Library of Med., U.S. Nat'l Institute of Health, *Angioplasty and Stent Placement—Heart: MedlinePlus Medical Encyclopedia*. <http://www.nlm.nih.gov/medlineplus/ency/article/002953.htm> (last visited Aug. 6, 2009) (on file with the North Carolina Journal of Law & Technology).

³⁰ See *Riegel*, 128 S. Ct. at 1005.

³¹ See *id.*

³² Heart block is the "incoordination of the heartbeat in which the atria and ventricles beat independently due to defective transmission through the [atrioventricular bundle] and which is marked by decreased cardiac output often with [deficient supply of blood to the brain]." Merriam-Webster Dictionary, <http://www2.merriam-webster.com/cgi-bin/mwmednrm?book=Medical&va=heart%20block> (last visited Sept. 8, 2009) (on file with the North Carolina Journal of Law & Technology).

³³ *Riegel*, 128 S. Ct. at 1005.

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Riegel and his wife brought suit against Medtronic in April 1999,³⁴ alleging that Medtronic had violated New York common law by negligently designing, manufacturing, and labeling the catheter.³⁵ Through this negligence, the Riegels claimed, Medtronic had caused Riegel to suffer serious and permanent injuries.³⁶ The District Court held that the FDA approval of the Evergreen Balloon Catheter preempted the Riegels' claims of strict liability, breach of implied warranty, and "negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the catheter."³⁷ The Second Circuit Court of Appeals affirmed the District Court's decision because the Riegels' claims, "if successful[,] would impose state requirements 'different from, or in addition to' those imposed via PMA process."³⁸

Mrs. Riegel then appealed the case to the United States Supreme Court, which focused its decision on § 360k(a), the MDA's express preemption clause. The clause reads as follows:

[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.³⁹

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.* at 1006 (citing App. to Pet. for Cert. 68a; Complaint 3–4). Additionally, the District Court held that the MDA preempted the negligent manufacturing claim because this claim was not based on an alleged violation of federal law. *Id.* The MDA also preempted Mrs. Riegel's loss of consortium claim due to the fact that this claim was based on the other preempted claims. *Id.* The District Court also granted summary judgment to Medtronic on claims of breach of express warranty, negligent manufacturing based on a lack of compliance with federal standards, and Donna Riegel's claim of derivative consortium. *Id.* n.2. These claims did not come before the United States Supreme Court, and they will not be discussed further in this Recent Development.

³⁸ *Id.* at 1003 (quoting 21 U.S.C. §§ 360k(a), 521(a) (2006)).

³⁹ 21 U.S.C. § 360k(a).

Justice Scalia, writing for the majority, divided the issue into two parts: 1) whether the FDA regulations applied to the Medtronic catheter, and if so, 2) whether the Riegels' claims are based on New York regulations that are "different from, or in addition to" the FDA requirements, and whether the New York regulations "relate to safety and effectiveness."⁴⁰ The Court addressed the first issue by following the precedent established by *Medtronic, Inc. v. Lohr*,⁴¹ determining that the PMA process established by § 360k(a)(1) focuses on the safety of a particular device, thus imposing "requirements."⁴² The Evergreen Balloon Catheter was approved via the PMA process, and therefore the safety of the Catheter had presumably been closely inspected. As such, Justice Scalia determined that the Riegels' claims were preempted by the MDA. Justice Scalia also adhered to the precedent set by *Lohr* when he discussed the second issue, stating that "common-law causes of action for negligence and strict liability do impose 'requirement[s]' and would be pre-empted by federal requirements specific to a medical device."⁴³

⁴⁰ *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1006 (2008) (citing § 360k(a)).

⁴¹ *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). In *Lohr*, the Class III device was a pacemaker that was approved by the FDA via the § 510(k) process because it was substantially similar to one that had already been approved. *Id.* 21 U.S.C. § 510 does not have an express preemption provision, and thus, FDA approval under § 510 does not preempt state tort claims of negligent manufacture. *Id.*

⁴² See *Riegel*, 128 S. Ct. at 1006–07 (describing what is meant by "requirements," since 21 U.S.C. § 360k(a) only preempts state requirements "different from, or in addition to, any requirement applicable . . . to the device" under federal law). Justice Scalia also noted that the MDA does not preempt state tort claims concerning devices approved by the FDA under 510(k) because those devices are not individually tested for safety by the FDA. *Id.*

⁴³ *Id.* at 1007 (citing *Lohr*, 518 U.S. at 512 (O'Connor, J., joined by Rehnquist, C.J., and Scalia and Thomas, J.J., concurring in part and dissenting in part)); *Lohr*, 518 U.S. at 503–05 (Breyer, J., concurring in part and concurring in the judgment); see also *Bates v. Dow Agrisciences LLC*, 544 U.S. 431, 443 (2005) (finding that a provision of the Federal Insecticide, Fungicide, and Rodenticide Act stated that certain States "shall not impose or continue in effect any requirements . . . in addition to or different from those required under this subchapter," preempts common-law claims. (citing 7 U.S.C. § 136v(b) (2000))).

Justice Ginsburg dissented, focusing on the legislative intent of the MDA, and stating that “Congress, in [her] 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.”⁴⁴ She also focused on policy, stating that “[p]reemption analysis starts with the assumption that ‘the historic police powers of the States [a]re not to be superseded . . . unless that was the clear and manifest purpose of Congress.’”⁴⁵ The goal of this assumption was to ensure that neither the courts nor Congress would inadvertently disturb the balance between federal and state laws.⁴⁶ The health and safety of citizens has generally been the concern of state governments,⁴⁷ and the federal government has traditionally deferred to state police powers “to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.”⁴⁸

Justice Stevens concurred in part and concurred in the judgment based on a reconciliation of the majority opinion and the dissent.⁴⁹ While he agreed that Justice Ginsburg accurately laid out the historical foundation for and the congressional intent behind the MDA, Justice Stevens believed that “it is ultimately the provisions of our laws rather than the principal concerns of our legislators by which we are governed.”⁵⁰ He therefore concurred

⁴⁴ *Riegel*, 128 S. Ct. at 1013 (Ginsburg, J., dissenting).

⁴⁵ *Id.* (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

⁴⁶ *Id.* (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977) (internal citation omitted)).

⁴⁷ *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996); *see also Hillsborough County v. Automated Med. Lab., Inc.*, 471 U.S. 707, 719 (1985) (“The regulation of health and safety matters is primarily and historically a matter of local concern.”).

⁴⁸ *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985) (quoting *Slaughter-House Cases*, 83 U.S. 36, 62 (1873)).

⁴⁹ *Riegel*, 128 S. Ct. at 1011–13 (Stevens, J., concurring in part and concurring in the judgment).

⁵⁰ *Id.* at 1011 (Stevens, J., concurring in part and concurring in the judgment) (quoting *Oncale v. Sundowner Offshore Services, Inc.*, 523 U.S. 75, 79–80 (1998)).

with the majority in the judgment, believing that the text of the federal statute preempts the state claims.⁵¹

III. MODERN TREND IN FEDERALISM CASES: THE REASONING BEHIND *RIEGEL*

Although Part VI argues that the MDA should be amended in order to avoid the preemption of legitimate state claims against medical device manufacturers in the future,⁵² this Recent Development does not contend that the Supreme Court was out of line in deciding *Riegel* as it did. While the *Riegel* decision does not fall in line with a legislative intent approach to statutory interpretation,⁵³ the Supreme Court appropriately decided the case in light of its recent trend of taking a textualist approach to statutory interpretation in federalism cases. The issue of federalism in the administrative context has recently drawn more notice than usual due to the Supreme Court's decision of several such cases since 2000, most recently in the 2009 term.⁵⁴ In the context of state tort law, the Court has been increasingly willing to allow federal regulations to override state claims by utilizing a more textual approach to statutory interpretation since the late 1980's.⁵⁵ This is in contrast to the Court's approach between the 1930's and the early 1980's during which it broadly accepted the

⁵¹ *Id.* at 1011–13 (Stevens, J., concurring in part and concurring in the judgment).

⁵² See *infra* Part VI.

⁵³ See *infra* Part V.

⁵⁴ See Stuart Minor Benjamin, *Tennis with the Net Down: Administrative Federalism Without Congress*, 57 DUKE L.J. 2111, 2133 n.83 (2008). Note that the “two new cases” discussed in this footnote have been decided since the article was published in May 2008: *Altria Group, Inc. v. Good*, 129 S. Ct. 538 (2008) (decided December 15, 2008) and *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (decided March 4, 2009) (See *infra* note 121).

⁵⁵ See Jordan, *supra* note 7, at 1211 n.287. It is no coincidence that this trend began just after Justice Scalia joined the Court in 1986, as Scalia “urged the Court to adopt textualism as its interpretive regimen.” Thomas A. Bishop, *The Death and Reincarnation of Plain Meaning in Connecticut: A Case Study*, 41 CONN. L. REV. 825, 841 (2009).

originalist approach.⁵⁶ For a century before the late 1980's, the court participated only minimally in the review of state tort claims.⁵⁷ The FDA in particular has long enjoyed a successful record in the Supreme Court due to the justices' remarkable deference to the agency's expertise in promoting public health.⁵⁸ *Riegel* appears to fit the Supreme Court's trend of deciding modern preemption cases on the basis of textualism.⁵⁹

In *Riegel*, Justice Scalia lays out a careful path, interpreting the preemption provision of the MDA strictly from the language of the statute, without much consideration of the legislative intent behind the provision. As noted *supra* Part II(B), the *Riegel* Court found that common law causes of action imposed "requirements" that were preempted by the FDA requirements of § 360k.⁶⁰ The Court then placed emphasis on the definition of the term "requirement" so as to give Congress notice of how the Court will interpret that term under similar circumstances in the future.⁶¹ Justice Scalia clearly asserted that "[a]bsent other indication, reference to a State's 'requirements' includes its common-law duties."⁶²

The *Riegel* approach sharply contrasts with the Court's approach to similar issues in the past, as it has formerly said that though the "starting point is the language of the statute,"⁶³ "in expounding a statute, we [are] not . . . guided by a single sentence or member of a sentence, but look to the provisions of the whole

⁵⁶ See Jordan, *supra* note 7, at 1202 (describing originalism as "the tradition of striving to discover original legislative intent or purpose.").

⁵⁷ See Krass, *supra* note 16, at 1543 ("Notably, after more than one hundred years of minimal involvement in reviewing state tort law the Court has in the past two decades been increasingly willing to allow Congress and federal agencies to override state tort law as a matter of constitutional law, statutory interpretation, and agency deference.").

⁵⁸ See Lars Noah, *The Little Agency that Could (Act with Indifference to Constitutional and Statutory Strictures)*, 93 CORNELL L. REV. 901 (2008).

⁵⁹ See Jordan, *supra* note 7.

⁶⁰ See *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1007 (2008).

⁶¹ See *id.* at 1008.

⁶² *Id.*

⁶³ *Schreiber v. Burlington Northern, Inc.*, 472 U.S. 1, 5 (1985).

law, and to its object and policy.”⁶⁴ The Court would have come to a very different conclusion had it given more weight to the congressional intent of the MDA when it was originally passed in 1976.⁶⁵

IV. LEGISLATIVE INTENT OF THE MDA

Justice Ginsburg stated in her dissent that the “purpose of Congress is the ultimate touchstone of pre-emption analysis,”⁶⁶ and provided enough evidence to convince Justice Stevens that “the overriding purpose of the legislation was to provide additional protection to consumers, not to withdraw existing protections.”⁶⁷ As briefly discussed in Part II(A),⁶⁸ Congress adopted the MDA in response to the numerous injuries and deaths caused by a series of defective medical devices, including the Dalkon Shield intrauterine device.⁶⁹ “Given the publicity attending the Dalkon Shield litigation and Congress’ awareness of the suits at the time the MDA was under consideration, [Justice Ginsburg found] informative the absence of any sign of a legislative design to preempt state common-law tort actions.”⁷⁰ Put simply, Justice Ginsburg believed that, had legislators intended the MDA to have a preemptive effect

⁶⁴ *Massachusetts v. Morash*, 490 U.S. 107, 115 (1989) (quoting *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 51 (1987) (alteration in original)).

⁶⁵ See *infra* Part IV.

⁶⁶ *Riegel*, 128 S. Ct. at 1013 (Ginsburg, J., dissenting) (quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992)).

⁶⁷ *Id.* at 1012 (Stevens, J., concurring in part and concurring in the judgment) (citing *Riegel*, 128 S. Ct. at 1013–20 (Ginsburg, J., dissenting)).

⁶⁸ See *supra* notes 11–17 and accompanying text.

⁶⁹ *Riegel*, 128 S. Ct. at 1014–15 & nn.5–6 (Ginsburg, J., dissenting).

⁷⁰ *Id.* at 1015 (Ginsburg, J., dissenting) (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 491 (1996)); S.Rep. No. 94-33, at 6 (1975), *reprinted in* 1976 U.S.C.C.A.N. 1070, 1076 (“Some 10,000 injuries were recorded, of which 731 resulted in death. For example, 512 deaths and 300 injuries were attributed to heart valves; 89 deaths and 186 injuries to heart pacemakers; 10 deaths and 8,000 injuries to intrauterine devices.”); 122 CONG. REC. 5859 (1976) (remarks of Rep. Waxman) (“A 10-year FDA death-certificate search found over 850 deaths tied directly to medical devices.”); 121 CONG. REC. at 10689–90 (1975) (remarks of Sen. Nelson); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996)).

in the context of state tort claims, they could have made that intention clear in the text of the statute.⁷¹

The stated purpose of the MDA, noted in the Act's preamble is "to provide for the safety and effectiveness of medical devices intended for human use."⁷² During the debate of S. 510,⁷³ the bill that later became the MDA, Senator Edward M. Kennedy, as a sponsor of the bill, stated that "[t]he 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."⁷⁴ In an effort to describe the intent of Congress in passing the MDA, Sen. Kennedy and Representative Henry A. Waxman submitted an amici curiae brief in support of the petitioner in *Riegel*. Sen. Kennedy indicated in his brief that in § 360k(b), Congress allowed for exemptions from preemption when the state or local requirement is more strict than the federal regulation.⁷⁵ Sen. Kennedy continued, indicating that Congress specifically pointed out California's stringent requirements and noted that those requirements should still be observed following the passage of federal legislation. Sen. Kennedy then spoke directly to the congressional intent behind § 360k(b), stating that "consistent with the focus on public safety in the MDA, Congress favored patient protection over nationwide uniformity."⁷⁶

Justice Ginsburg noted Sen. Kennedy's views during the *Riegel* oral arguments, explaining:

[T]here's an argument that what [the preemption provision] was intended to do was to cut out State pre-market approval, where States like California⁷⁷ came in when there was a Federal void and said we

⁷¹ See *Riegel*, 128 S. Ct. at 1015 (Ginsburg, J., dissenting).

⁷² Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (preamble) (1976).

⁷³ S. 510, 94th Cong. (1975) (enacted).

⁷⁴ *Riegel*, 128 S. Ct. at 1014 n.4 (Ginsburg, J., dissenting) (quoting 121 CONG. REC. 10688 (Apr. 17, 1975) (Statement of Sen. Kennedy)).

⁷⁵ See Brief for Edward M. Kennedy et al. as Amici Curiae Supporting Petitioner, *Riegel v. Medtronic, Inc.* 128 S. Ct. 999 (2008) (No. 06-179) (citing H.R. Rep. No. 94-85 at 4) (1976)).

⁷⁶ *Id.* at 6.

⁷⁷ See Brief for Petitioners, *supra* note 15, at 2.

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shouldn't let the manufacturers put out whatever they'd like. Let's have a pre-market approval. And the argument . . . which was presented in Senator Kennedy's brief, [is that] that's what [Congress] meant to do with the preemption provision. Nothing more.⁷⁸

Justice Ginsburg supports this argument in her dissent, opining that the legislature's intention in § 360k(a) was not to "effect a radical curtailment" of state tort claims.⁷⁹

Upon hearing of the *Riegel* decision, Sen. Kennedy stated that "Congress never intended that F.D.A. approval would give blanket immunity to manufacturers from liability for injuries caused by faulty devices."⁸⁰ Rep. Waxman responded similarly, saying "[t]he Supreme Court's decision strips consumers of the rights they've had for decades. This isn't what Congress intended, and we'll pass legislation as quickly as possible to fix this nonsensical situation."⁸¹ While these statements alone do not give irrefutable evidence of the legislative intent of the MDA, "surely Kennedy and Waxman, leaders in the enactment of the [MDA], are more privy to congressional deliberations on congressional aims than Justice Scalia[.]"⁸²

⁷⁸ Transcript of Oral Argument at 25–26, *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2007) (No. 06-179) (internal footnote added).

⁷⁹ *Riegel*, 128 S. Ct. at 1013 (Ginsburg, J., dissenting). *But see* Ashley W. Warren, *Preemption of Claims Related to Class III Medical Devices: Are the Federal Objectives of Public Health and Safety Furthered or Hindered?*, 49 SMU L. REV. 619, 633 (1996) (citing Lars Noah, *Amplification of Federal Preemption in Medical Device Cases*, 49 FOOD & DRUG L.J. 183, 185 (1994) ("Congress left no question that its intent was for the MDA to have a broad preemptive effect.")).

⁸⁰ Linda Greenhouse, *Justices Shield Medical Devices from Lawsuits*, N.Y. TIMES, Feb. 21, 2008, at A1 (internal quotation marks omitted), available at <http://www.nytimes.com/2008/02/21/washington/21device.html>.

⁸¹ *Id.* (internal quotation marks omitted).

⁸² Robert L. Rabin, *Territorial Claims in the Domain of Accidental Harm: Conflicting Conceptions of Tort Preemption*, 74 BROOK. L. REV. 987, 997 n.56 (2009) (describing the following as Justice Scalia's "armchair commentary": "it is implausible that the MDA was meant to 'grant greater power (to set state standards 'different from, or in addition to' federal standards) to a single state jury than to state officials acting through state administrative or legislative

For those who are not persuaded that the legislative intent of the MDA evidences intent to preempt state tort claims, consider the modern view of preemption that evolved in response to the post-1930 reformation of American federalism in light of changing interpretations of the Commerce Clause.⁸³ According to this view, there is a “presumption that state laws would survive unless Congress clearly manifested its intent that a federal statute would preempt state law.”⁸⁴ Two notable cases exemplify this view of preemption—*Rice v. Santa Fe Elevator Corp.*⁸⁵ and *Mintz v. Baldwin*.⁸⁶ *Rice* reiterated the presumption against preemption in traditional areas of state control when clear congressional intent is absent.⁸⁷ In *Mintz*, the legislative intent of the federal Cattle Contagious Diseases Acts was held to be not clear enough to preempt a state law designed to prevent contagious cattle diseases.⁸⁸ Thus, according to the modern view of preemption, state law should not be preempted in traditional areas of state control absent clear congressional intent.

V. THE POST-*RIEGEL* WORLD

Post-*Riegel* customer claims against medical device manufacturers have not produced desirable results.⁸⁹ Consideration of the consequences of *Riegel* strengthens the argument that Congress should implement the amendments introduced by H.R. 1346 and S. 540, as the Court’s interpretation of the MDA “cut[s]

lawmaking processes.’ 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.” (quoting *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1008 (2008) (citation omitted)).

⁸³ See Jordan, *supra* note 7, at 1156 (citing Bruce Ackerman, *Constitutional Politics/Constitutional Law*, 99 YALE L.J. 453, 510–15 (1989)).

⁸⁴ See *id.*

⁸⁵ 331 U.S. 218 (1947).

⁸⁶ 289 U.S. 346 (1933).

⁸⁷ *Rice*, 331 U.S. at 237.

⁸⁸ *Mintz*, 289 U.S. at 352.

⁸⁹ See *infra* notes 94–104 and accompanying text.

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deeply into a domain historically occupied by state law.”⁹⁰ In the post-*Riegel* world, state claims against manufacturers of premarket approved medical devices will be preempted by the FDA’s PMA of those devices unless Congress amends the MDA.⁹¹

In deciding *Riegel*, the Court approved a system in which some consumers harmed by medical devices will not be compensated.⁹² Courts across the country have already been faced with *Riegel*-like issues, and they have largely followed the Supreme Court’s lead.⁹³ As long as the manufacturers in these cases have obtained PMA prior to marketing their device and have not made any changes to their device after acquiring PMA, the state claims have regularly been preempted. Courts now apply the *Riegel* reasoning set out by Justice Scalia⁹⁴ in deciding whether a particular claim is preempted

⁹⁰ *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1013 (2008) (Ginsburg, J., dissenting).

⁹¹ Tort claims will continue, however, to provide relief in cases of manufacturer noncompliance, even when those devices have PMA. See Harvard Law Review Association, *Preemption of State Common Law Claims*, 122 HARV. L. REV. 405, 412 (2008). Manufacturers must submit a supplemental application to the FDA and wait for FDA approval prior to changing anything that “affects safety and effectiveness.” 21 U.S.C. § 360e(d)(6)(A)(i) (2006). Should a manufacturer make a change in the design or labeling of a device after receiving PMA without disclosing that change to the FDA, that manufacturer violates FDA regulations, and thus will not be protected by preemption. A successful claim, however, would be based on federal rather than state law. See Harvard Law Review Association, *Preemption of State Common Law Claims*, 122 HARV. L. REV. 405, 412 (2008)). In *Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919 (5th Cir. 2006), for example, the Fifth Circuit reversed in part the judgment of the district court due to the fact that the plaintiff’s claims of defective manufacturing were not preempted by the MDA to the extent that the defendant manufacturer did not comply with FDA-approved specifications. However, the Fifth Circuit correctly affirmed in part the district court’s holding that the state defective design claims were preempted by the MDA.

⁹² See Harvard Law Review Association, *supra* note 91, at 412.

⁹³ For a fuller discussion of post-*Riegel* medical device case law, see Gregory J. Wartman, *Life After Riegel: A Fresh Look at Medical Device Preemption One Year After Riegel v. Medtronic, Inc.*, 64 FOOD & DRUG L.J. 291 (2009).

⁹⁴ See *supra* note 60–62 and accompanying text.

by the MDA.⁹⁵ Two questions must be answered according to *Riegel*: 1) whether the device is subject to federal government requirements, and 2) whether the plaintiff's claims are based on state regulations that qualify as regulations that are "different from, or in addition to" such federal requirements and that "relate[] to . . . safety and effectiveness."⁹⁶

The Supreme Court of New York in Madison County, for example, granted summary judgment to a medical device manufacturer in *Lake v. Kardjian*⁹⁷ on December 17, 2008. The medical device involved was the Targis transurethral microwave therapy system, used to treat an enlarged prostate.⁹⁸ The plaintiff, William Lake, alleged that the device damaged both his urethra and his urinary sphincter, and caused him to undergo numerous surgeries.⁹⁹ The Madison County court found that Lake's negligence claim, breach of implied warranty claim, and strict liability claim were preempted by the MDA.¹⁰⁰ The court found that the MDA also preempted a claim that the defendant manufacturer was required by state common law to provide warnings in addition to those approved by the FDA.¹⁰¹ Thus, although Lake has suffered myriad injuries allegedly caused by the Targis system, the fact that the FDA approved the Targis system as safe and effective within the meaning of § 360e denies Lake any compensation that might otherwise be due.¹⁰² Several other post-

⁹⁵ See, e.g., *Bausch v. Stryker Corp.*, 2008 WL 5157940 (N.D. Ill. Dec. 9, 2008).

⁹⁶ *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1006 (2008) (quoting 21 U.S.C. § 360k(a) (2006)).

⁹⁷ 874 N.Y.S.2d 751 (N.Y. Sup. Ct. 2008).

⁹⁸ *Id.*

⁹⁹ See *id.* at 753.

¹⁰⁰ See *id.* at 754.

¹⁰¹ See *id.*

¹⁰² Other avenues may be found through which plaintiffs like the one in *Lake* will find relief, but they will not get compensation through a state tort claim.

Riegel state claims against medical device manufacturers have had similar results.¹⁰³

Even manufacturers of medical devices that are recalled after PMA are immune from state tort claims.¹⁰⁴ In *Bausch v. Stryker Corp.*, the Northern District of Illinois decided that a total hip replacement prosthesis produced by the defendant corporation, though recalled “due to dimensional anomalies,”¹⁰⁵ had still acquired PMA from the FDA, and was thus not subject to liability on the basis of a state tort claim. As Justice Ginsburg pointed out in *Riegel*, “[t]he Court's holding does not reach an important issue outside the bounds of this case: the preemptive effect of § 360k(a) where evidence of a medical device's defect comes to light only *after* the device receives premarket approval.”¹⁰⁶

Physicians also fear the repercussions of *Riegel*, having expressed concerns that this decision will negatively impact consumer health and safety. The necessity of amending the MDA has also been expressed by physicians.¹⁰⁷ A recently published article in the *New England Journal of Medicine* discusses the injustice of preemption and declares that it “will . . . result in the reduced safety of drugs and medical devices for the American people.”¹⁰⁸ As the authors of the article explain, tort litigation provides information to the FDA about the safety of drugs and

¹⁰³ See, e.g., *Despain v. Bradburn*, 282 S.W.3d 814 (Ark. 2008); *Mullin v. Guidant Corp.*, 970 A.2d 733 (Conn. App. Ct. 2009); *Troutman v. Curtis*, 185 P.3d 930 (Kan. 2008); *Blunt v. Medtronic, Inc.*, 760 N.W.2d 396 (Wis. 2009).

¹⁰⁴ But note that “parallel claims” may escape preemption. See Beck Herrmann, (New) Medical Device Preemption Scorecard. <http://druganddevicelaw.blogspot.com/2008/08/new-medical-device-preemption-scorecard.html> (last visited August 7, 2009) (on file with the North Carolina Journal of Law & Technology).

¹⁰⁵ Trial Pleading, Complaint, *Bausch v. Stryker Corp. et al.*, No. 108-CV-04248, 2008 WL 4227478 (N.D. Ill. 2008).

¹⁰⁶ *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1013 n.1 (2008) (Ginsburg, J., dissenting) (emphasis in original).

¹⁰⁷ See *House Bill Would Declare Medical Device Claims Not Preempted*, 44-SEP JTLATRIAL 10 (2008).

¹⁰⁸ Gregory D. Curfman et al., *Why Doctors Should Worry about Preemption*, 359 NEW ENG. J. MED. 1, 2 (2008), available at <http://content.nejm.org/cgi/content/full/359/1/1>.

medical devices, and it acts in conjunction with FDA regulations to encourage safer practices by manufacturers.¹⁰⁹ Preemption would do away with this source of information, ultimately resulting in a decrease in device safety.¹¹⁰

VI. PROPOSED AMENDMENTS TO THE MDA

The disconnect between the *Riegel* holding, the legislative intent of the MDA, and public policy, presents a significant problem.¹¹¹ Looking at *Riegel* as part of the modern trend of determining federalism issues on basic statutory interpretation, it seems that the majority appropriately decided the case based on the text of the MDA. Despite the frustration of uncompensated plaintiffs in trial level tort suits, it is not the place of the Court to make the policy determinations¹¹² that would be necessary to prevent FDA approval of medical devices from preempting state tort claims. It is now for Congress to determine whether policy dictates that MDA amendments are necessary.

Following the *Riegel* decision, on June 26, 2008, Congressman Frank Pallone, Jr. (“Rep. Pallone”) of New Jersey, along with 71 co-sponsors, introduced H.R. 6381¹¹³ to the House. The bill proposed amending the MDA to clarify that Congress did not

¹⁰⁹ See *id.*; see also Brief of Amici Curiae Members of Congress in Support of Respondent in *Wyeth v. Levine*, Senator Arlen Specter, *Senate Regulatory Preemption Hearing* at 133–34 (discussing the possible preemption of state tort claims against drug manufacturers by FDA approval of drug labels). See generally Matthew S. Reid, *Vermont Supreme Court Rules that Food and Drug Administration Regulations Do not Preempt State Failure-to-Warn Claims—Levine v. Wyeth*, 944 A.2d 179 (VT. 2006), 4 J. HEALTH & BIOMEDICAL L. 413 (2008).

¹¹⁰ See Curfman et al., *supra* note 108.

¹¹¹ See *supra* Part V.

¹¹² See *Valley Forge Christian Coll. v. Americans United for Separation of Church and State, Inc.*, 454 U.S. 464, 472 (1982) (“The constitutional role of the courts, however, is to decide concrete cases—not to serve as a convenient forum for policy debates.”). But see *Dole v. United Steelworkers of Am.*, 494 U.S. 26, 35 (1990) (stating that the Court is “not guided by a single sentence or member of a sentence, but look[s] to the provisions of the whole law, and to its object and policy.”) (citations and internal quotation marks omitted)).

¹¹³ Medical Device Safety Act of 2008. H.R. 6381, 110th Cong. (2008).

intend for § 360k to be an express preemption provision.¹¹⁴ An identical bill, S. 3398, was introduced in the Senate on July 31, 2008 by Sen. Kennedy,¹¹⁵ together with fifteen co-sponsors.¹¹⁶ If passed, this legislation would have invalidated *Riegel* and allowed state tort claims to escape preemption by the MDA. Neither bill was passed during the 110th session of Congress, and Rep. Pallone and Sen. Kennedy reintroduced identical bills, H.R. 1346¹¹⁷ and S. 540,¹¹⁸ respectively, on March 5, 2009,¹¹⁹ the day after the *Wyeth v. Levine*¹²⁰ decision. As of this writing, neither of these bills has been passed into law.¹²¹

¹¹⁴ *Id.*

¹¹⁵ It is noteworthy that Senator Kennedy sponsored S. 3398, as he was involved in the passage of the original MDA in 1976.

¹¹⁶ Medical Device Amendments of 2009. S. 3398, 110th Cong. (2009).

¹¹⁷ Medical Device Amendments of 2009. H.R. 1346, 111th Cong. (2009).

¹¹⁸ Medical Device Amendments of 2009. S. 540, 111th Cong. (2009).

¹¹⁹ As of July 7, 2009, H.R. 1346 has been referred to the Subcommittee on Health within the House Committee on Energy and Commerce and a subcommittee hearing has been held. <http://thomas.loc.gov/cgi-bin/query/z?c111:S.540>. As of the same date, S. 540 has been referred to the Senate Committee on Health, Education, Labor, and Pensions. *Id.*

¹²⁰ *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (determining that premarket approval by the FDA under the Federal Food, Drug, and Cosmetic Act does not preempt a state failure-to-warn claim against a drug manufacturer). Note that 21 U.S.C. § 352 (2006) (the relevant statute in *Wyeth*), unlike the MDA, does not contain an express preemption provision, making *Wyeth* a less complicated case. *Id.* at 1196 (“And when Congress enacted an express pre-emption provision for medical devices in 1976, see § 521, 90 Stat. 574 (codified at 21 U.S.C. § 360k(a)), it declined to enact such a provision for prescription drugs.”). The Court notes that Congress could have enacted an express preemption provision for prescription drugs had it so desired. *See Wyeth*, 129 S. Ct. at 1200.

¹²¹ Plaintiffs’ attorneys have already attempted to use S. 3398 and H.R. 6381 to their advantage. *See McCutcheon v. Zimmer Holdings, Inc.*, 586 F. Supp.2d 917, 923–24 (N.D. Ill. 2008) (stating in response to plaintiff’s counsel’s urging that the District Court “act, not as taught by *Riegel* . . . , but rather according to a bill recently introduced in the House of Representatives that, if enacted, would overturn *Riegel*” that it would be “irresponsible [for the District Court] to ignore controlling Supreme Court and Seventh Circuit precedent in favor of prospective legislation”); *Link v. Zimmer Holdings, Inc.*, 604 F. Supp.2d 1174, 1179–80 (N.D. Ill. 2008) (declining to decide the case “based upon alleged congressional motivations in conflict with the Supreme Court’s ruling or upon a potential law

The bills would add clear language to § 360k, specifically stating that § 360k should have “[n]o [e]ffect on [l]iability [u]nder [s]tate [l]aw,” and that “[n]othing in this section shall be construed to modify or otherwise affect any action for damages or the liability of any person under the law of any State.”¹²² This legislation appears more closely aligned to Congress’s intentions for the MDA, and from a policy standpoint, would result in more favorable outcomes in future state tort claims against medical devices manufacturers.¹²³ Should the Supreme Court continue to follow the modern trend of using basic statutory construction to interpret statutes in federalism cases, Congress must replace the current language of § 360k with an unambiguous statement in order to avoid the MDA’s preemption of future state tort claims.

VI. CONCLUSION

While the U.S. Supreme Court appropriately decided *Riegel* based on a basic statutory construction approach to interpreting § 360k, the legislative intent of the statute is contrary to the majority’s decision, and the decision has produced unfavorable outcomes in post-*Riegel* state tort suits against medical device manufacturers. Congress now has the opportunity to look at the disconnect between the intent of the statute and its interpretation by the Court and to amend the preemption provision of the MDA to reflect the policy by which it wants the judicial system to abide.

that may or may not be passed by Congress at an unknown point in the future”). Similarly, the *Riegel* Court noted, “it is not our job to speculate upon congressional motives. If we were to do so, however, the only indication available—the text of the statute—suggests that 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.” *Riegel*, 128 S. Ct. at 1009.

¹²² Medical Device Amendments of 2009, S. 540, 111th Cong. (2009); Medical Device Amendments of 2009, H.R. 1346, 111th Cong. (2009).

¹²³ See discussion *supra* Part V (describing the lack of judicial recourse for patients harmed by medical devices and the concerns of physicians that federal preemption of state tort claims against medical device manufacturers will ultimately result in reduced safety of these devices).

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By passing H.R. 1346 and S. 540, Congress can effectively invalidate the *Riegel* decision and elucidate the legislative intent of the MDA for the Court. In doing so, it will prevent FDA PMA from preempting future state tort claims and provide much needed relief to patients injured by medical devices.