



***Riegel v. Medtronic, Inc.*: Federal Preemption of State Tort Law Regarding Medical Devices with FDA Premarket Approval**

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Summary

In *Riegel v. Medtronic, Inc.*, the United States Supreme Court held in an 8 to 1 decision that if the Food and Drug Administration (FDA) grants premarket approval (PMA) to a medical device, the device manufacturer is immune from certain suits under state tort law, due to an express preemption provision in the Medical Device Amendments of 1976 (MDA). This holding establishes that FDA PMA preempts claims such as strict liability, breach of implied warranty, and negligence in design, testing, manufacturing, labeling, distribution, sale, inspection, or marketing of the device to the extent that such state law claims are “different from, or in addition to” federal PMA requirements. However, the Supreme Court held that the MDA’s express preemption provision did not prohibit state “claims premised on a violation of FDA regulation.” The Court stated that such claims “‘parallel,’ rather than add to, federal requirements.” Post-*Riegel*, the lower courts have come to differing conclusions when determining whether particular state law claims, such as manufacturing defect claims, “parallel” federal requirements, and thus are not preempted, or rather are state requirements “different from, or in addition to” federal requirements, and thus are preempted under *Riegel*.

The Supreme Court’s decision has been a cause for concern for some Members of Congress who disagree with the ruling, as well as trial lawyers and patients. However, advocates of more limited tort liability, including the previous Administration, agree with the ruling. The decision has broad implications for consumers of Class III medical devices, who are prevented from suing device manufacturers on most state common law claims, as well as manufacturers, who are shielded from many suits if their device receives FDA PMA. In the 111th Congress, bills were introduced—H.R. 1346, H.R. 4816, and S. 540—that would have overturned the Court’s decision in *Riegel* by modifying the statute at issue. As of the date of this report, similar legislation has not been introduced in the 112th Congress.

This report will provide a brief overview of federal premarket regulation of medical devices. The report then provides an overview of federal preemption of state law, as well as arguments for and against federal preemption of state law tort claims with respect to medical devices. The report explains the Supreme Court’s decision in *Riegel* and examines the concurring and dissenting opinions. Finally, the report analyzes the legal, procedural, policy, and legislative implications for Congress, consumers, and medical device manufacturers.

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In order to elucidate the Supreme Court’s decision in *Riegel v. Medtronic, Inc.*,¹ this report begins by providing background on the Food and Drug Administration’s (FDA’s) premarket regulation of medical devices and an overview of federal preemption of state law. The report discusses arguments for and against federal preemption of state law tort claims with respect to medical devices. Next, the report examines the FDA’s shifting position on federal preemption in medical device cases. The report then explains the Supreme Court’s decision in *Riegel v. Medtronic, Inc.*, as well as the concurring and dissenting opinions. Finally, the report analyzes the implications of the Court’s decision in *Riegel* for Congress, consumers, medical device manufacturers, and preemption jurisprudence.

This report focuses on Class III medical devices because it is federal preemption of state law requirements that are “different from, or in addition to” federal requirements for Class III devices with premarket approval (PMA) that was at issue in *Riegel*.²

An Overview of FDA Premarket Notification and Premarket Approval (PMA) of Medical Devices

The Federal Food, Drug, and Cosmetic Act (FFDCA)³ sets forth a detailed set of statutory requirements designed to ensure that medical devices are safe and effective. As a result, medical devices must meet certain minimum requirements before they may be marketed in the United States. For example, the device cannot be adulterated or misbranded, and there are registration, good manufacturing practices, and labeling requirements.⁴ There are also more specific requirements that a device manufacturer must follow, which are determined by the level of risk that the device poses to patients from its use or misuse.⁵

Medical devices are classified according to risk—Class I (low risk), Class II (moderate risk), and Class III (high risk)—and there are certain requirements based on that risk.⁶ Class III devices, which are those “purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health” or those that “present[] a potential unreasonable risk of illness or injury,” are generally subject to premarket approval (PMA).⁷ Examples of Class III devices include replacement heart valves, silicone gel-filled breast implants, and pacemaker pulse generators.⁸

¹ 552 U.S. 312 (2008).

² 21 U.S.C. §360k(a). Preemption of tort suits related to drugs that have received FDA approval, which was at issue in *Wyeth v. Levine*, and federal preemption of state tort claims related to generic prescription drug labeling, which was at issue in *Pliva, Inc. v. Mensing*, will not be addressed in this report.

³ 21 U.S.C. §§301 *et seq.*

⁴ 21 U.S.C. §§351-52, 360; 21 C.F.R. Parts 801, 809, and 820.

⁵ The term “manufacturer” here includes any person, organization, or sponsor that submits a PMA application to THE FDA for a medical device.

⁶ 21 U.S.C. §360c.

⁷ 21 U.S.C. §360c(a)(1)(C)(ii).

⁸ 21 C.F.R. §870.3925 (replacement heart valve); 21 C.F.R. §878.3540 (silicone gel-filled breast prosthesis); 21 C.F.R. §§870.3600, 870.3610 (respectively, external pacemaker pulse generator and implantable pacemaker pulse generator). See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008)(citing replacement heart valves and pacemaker pulse generators).

All new devices are automatically designated as Class III, and therefore must receive PMA, unless the device meets one of three exceptions: (1) the “grandfather” provision for devices on the market prior to the passage of the Medical Device Amendments of 1976 (MDA),⁹ (2) a device on the market after the passage of the MDA that has been classified as Class I or Class II or reclassified as Class I or Class II by the FDA after the manufacturer files a petition for reclassification,¹⁰ or (3) the device is “substantially equivalent” to either a grandfathered device or a Class I or Class II device.¹¹ A device is “substantially equivalent” if the FDA makes such a determination based on a comparison of the new device with a predicate device.¹² A predicate device could have been marketed either before or after 1976.¹³ The device seeking the “substantially equivalent” determination must either have (1) the same intended use¹⁴ and the same technological characteristics as the predicate device, or (2) the same intended use, different technological characteristics, and information and data that demonstrate safety and effectiveness, and cannot “raise different questions of safety and effectiveness than the predicate device.”¹⁵ The manufacturer decides which predicate device to use for the comparison with the new device. However, the FDA has discretion in determining whether the comparison is appropriate.

Premarket Notification (§510(k) Submissions)

Premarket notification is known as a Section 510(k) submission, after the section of the FDCA that requires it. Class III devices generally require a premarket notification as well as PMA. However, some Class III devices may be marketed only with a Section 510(k) submission—if the device was introduced after the passage of the MDA in 1976 and is substantially equivalent to a pre-1976 device, but there is no regulation requiring PMA.¹⁶ The majority of new Class III medical devices reach the marketplace after a Section 510k submission, as opposed to the receipt of FDA PMA.¹⁷

Premarket notification applies to new devices that are not substantially equivalent to pre-1976 devices, devices introduced after passage of the MDA in 1976 that have been reclassified as Class I or Class II, and devices that may have been or currently are on the market, but that have been significantly modified.¹⁸ At least 90 days before a manufacturer may market one of these new devices, the manufacturer must submit a notification to the FDA.¹⁹ After the FDA reviews a premarket notification under Section 510(k), the agency may find that the device either is or is

⁹ 21 U.S.C. §360c(f)(1). Approximately 1,700 different generic types of medical devices that existed on the market in 1976 were “grandfathered” in under the MDA and classified in the Code of Federal Regulations.

¹⁰ 21 U.S.C. §360c(f)(1)(A)(i)(II); 21 U.S.C. §360c(f)(1)(B); 21 C.F.R. §860.3(c)(3).

¹¹ 21 U.S.C. §360c(f)(1)(A)(ii).

¹² 21 U.S.C. §360c(i)(1)(A).

¹³ 21 U.S.C. §360c(f)(1)(A).

¹⁴ Intended use and indications for use provide the basis for risk classification and, therefore, the types of studies that are required to support approval or clearance of the device, and the stringency of the regulations with which the manufacturer will have to comply.

¹⁵ 21 U.S.C. §360c(i)(1)(A).

¹⁶ See 21 U.S.C. §§360c(f)(1), 360e(b), (i).

¹⁷ *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008).

¹⁸ 21 C.F.R. §807.81(a). Manufacturers may use a §510(k) when seeking a new indication (e.g., a new population, such as pediatric use, or a new disease or condition), or when changing the design or technical characteristics.

¹⁹ 21 U.S.C. §360(k); FDCA §510(k). The submission must contain the information required in 21 C.F.R. §807, Subpart E.

not substantially equivalent to a predicate device, request more information, withhold a decision pending the submission of certain information, or advise the submitter that the device does not require premarket notification.²⁰

Premarket Approval (PMA)

As noted above, a PMA application is required for most Class III devices, with three exceptions.²¹ In the PMA process, the FDA determines if these devices have a “reasonable assurance of ... safety and effectiveness.”²² A PMA application must include, among other facts, information regarding proposed labeling; reports of information “concerning investigations which have been made to show whether or not such device is safe and effective;” a description of the manufacturing and processing methods; samples of the device and its components; and information regarding the components, ingredients, and operating principles of the device.²³ A PMA application will be denied approval if “there is a lack of a showing of reasonable assurance that such device is safe [and effective] under the conditions of use” in the proposed labeling; if the methods of manufacturing, processing, packing, or installing the device do not conform to good manufacturing practices; if the proposed labeling is false or misleading; or if the device does not meet performance standards.²⁴ The FDA cannot disclose the existence of a PMA application file before issuing an approval order to the applicant “unless it previously has been publicly disclosed or acknowledged.”²⁵

PMA Supplements

Once a device has been approved through the PMA process, the manufacturer can market the device only for its intended use. For example, a device, such as a stent, approved to treat coronary artery disease may not be marketed for treatment of blocked biliary ducts unless the manufacturer files a PMA supplement for FDA review and approval.²⁶ The FDA must approve the PMA supplement before the manufacturer may make a “change affecting the safety or effectiveness of the device for which the applicant has an approved PMA,” such as changes to the labeling, packaging, sterilization procedures, and new indications for use of the device (as in the stent example).²⁷ However, in certain cases, a change to a device with PMA “that enhances the safety of the device or the safety in the use of the device may be placed into effect by the applicant prior to the receipt ... of a written FDA order approving the PMA supplement.”²⁸

²⁰ 21 C.F.R. §807.100(a).

²¹ 21 U.S.C. §360e(a). The three exceptions to the PMA requirement are: (1) devices on the market prior to the enactment of the Medical Device Amendments of 1976, 21 U.S.C. §§360e, 360c(f); (2) devices for which there is an investigational device exemption, 21 U.S.C §360j(g); and (3) devices that the FDA has determined are substantially equivalent to those already on the market under the §510(k) premarket notification process, 21 U.S.C. §360e(b)(1)(B).

²² 21 U.S.C. §360c(a)(C).

²³ 21 U.S.C. §360e(c)(1). In contrast to a §510(k) submission, PMAs generally require some clinical data.

²⁴ 21 U.S.C. §360e(d)(2); 21 C.F.R. Part 814.

²⁵ 21 C.F.R. §814.9(b); *see also* 21 C.F.R. §§814.9(e)-(f). “Upon issuance of an order approving, or an order denying approval of any PMA, FDA will make available to the public the fact of the existence of the PMA.” 21 C.F.R. §814.9(e).

²⁶ 21 C.F.R. §814.39(a).

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

²⁸ 21 C.F.R. §814.39(d)(1).

Preemption

This section will first provide an overview of federal preemption of state law. It will then discuss arguments for and against preemption of state law tort claims with respect to medical devices. Finally, this section will discuss the change in the FDA's position on preemption in medical device cases.

Federal Preemption of State Law

The preemption doctrine is derived from the Supremacy Clause of the U.S. Constitution, which establishes that the laws of the United States “shall be the supreme law of the land; and the judges in every state shall be bound thereby, any thing in the Constitution or laws of any State to the contrary notwithstanding.”²⁹ In applying this constitutional mandate, courts have recognized both express and implied forms of preemption, which are “compelled whether Congress’ command is explicitly stated in the statute’s language, or implicitly contained in its structure and purpose.”³⁰ Both types of preemption may apply to state legislation, regulations, and common law. As the Supreme Court held in *Gade v. National Solid Wastes Management Association*, “the question whether a certain state action is pre-empted by a federal law is one of congressional intent. The purpose of Congress is the ultimate touchstone. To discern Congress’ intent we examine the explicit statutory language and the structure and purpose of the statute.”³¹

In the *express* preemption context, a federal statute will be deemed to supplant existing state law to the extent that it contains an explicit provision to that effect, the scope of which is determined by interpreting the language of the provision and analyzing the legislative history as necessary.³² Where express preemption provisions are not present, federal law may preempt state law implicitly. There are several different ways to conceptualize the doctrine of *implied* preemption, but it is often subdivided into three general categories for purposes of analysis: (1) federal occupation of the entire field of regulation; (2) actual conflict between federal and state requirements; and (3) state requirements that frustrate congressional purpose.³³

Courts, however, often encounter difficulty when federal law is silent as to the preemptive effect. The Supreme Court traditionally begins its analysis in this context with a presumption against preemption, an “assumption that the historic police powers of the States were not to be superseded by [a federal law] unless that was the clear and manifest purpose of Congress.”³⁴ Several decisions by the Court have strengthened this presumption, including *Maryland v. Louisiana*, which stated that “[c]onsideration under the Supremacy clause starts with the basic

²⁹ U.S. CONST. art. VI, cl. 2.

³⁰ *Gade v. National Solid Wastes Management Association*, 505 U.S. 88, 97 (1992) (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)).

³¹ *Id.* at 96 (internal quotation marks and case citations omitted).

³² *Jones*, 430 U.S. at 525.

³³ *Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002); *see also Hines v. Davidowitz*, 312 U.S. 52, 61, 77 (1941) (regarding field and frustration of purpose preemption); *Florida Lime and Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963) (regarding conflict preemption).

³⁴ *See Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 605 (1991); *see also Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

assumption that Congress did not intend to displace state law,³⁵ and *Chicago & North Western Transportation Co. v. Kalo Brick & Tile Co.*, which held that “[p]reemption of state law by federal statute or regulation is not favored ‘in the absence of persuasive reasons either that the nature of the regulated subject matter permits no other conclusion, or that the Congress has unmistakably ordained.’”³⁶ Additionally, in the Supreme Court case *Medtronic, Inc. v. Lohr*, which also addressed preemption of state tort claims under the MDA, the plurality opinion noted:

Throughout our history the several States have exercised their police powers to protect the health and safety of their citizens. Because these are “primarily, and historically, ... matter[s] of local concern,” *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 719 (1985), the “States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.” *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985) (internal quotation marks omitted).³⁷

These standards, however, are highly case specific in their application. Indeed, the Supreme Court itself has noted that “none of these expressions provide an infallible constitutional test or an exclusive constitutional yardstick. In the final analysis, there can be no crystal clear distinctly marked formula.”³⁸ Thus, cases involving federal preemption of state law often hinge on the particular factual circumstances of a given case.

Arguments for Federal Preemption of State Law Tort Claims with Respect to Devices

There are policy arguments for and against the merits of preemption in the medical device context. Arguments for federal preemption of common law in the medical device context focus on (1) uniform national standards, (2) the rigor of the PMA process, (3) the FDA’s expertise in this field, and (4) the potential for delay in the development of new products. Businesses tend to favor preemption, as regulated industries “generally prefer uniform, national regulation over varying state regulation.”³⁹

Those in favor of preemption, including the Pharmaceutical Research and Manufacturers of America (PhRMA) and trade groups for medical device makers such as the Advanced Medical Technology Association (AdvaMed), equate jury verdicts under state common law with the imposition of a state law “requirement” in addition to “requirements” that are imposed for devices under the FFDCA and FDA regulations.⁴⁰ For example, medical device manufacturers have

³⁵ 451 U.S. 725, 746 (1981).

³⁶ 450 U.S. 311, 317 (1981) (quoting *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142 (1963)).

³⁷ 518 U.S. 470, 475 (1996).

³⁸ *Hines*, 312 U.S. at 67.

³⁹ Marcia Coyle, *High Stakes for Regulated Industry in Supreme Court Pre-emption Cases*, *The National Law Journal*, Nov. 30, 2007. One court stated that “[t]he legislative history indicates that [national uniformity] was the reason the preemption provision was included within the MDA. H.R. Rep. No. 853, 45 (1976) (“If a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened.”).” *Brooks v. Howmedica*, 273 F.3d 785, 797 (8th Cir. 2001).

⁴⁰ See Samuel Loewenberg, *Lawmakers Try to Remove Tort Shield*, *Politico*, June 18, 2008; Press Release, PhRMA, PhRMA Statement on Federal Preemption (June 11, 2008), http://www.phrma.org/news_room/press_releases/phrma_statement_on_federal_preemption. The U.S. Chamber of Commerce argued that the MDA’s “express preemption provision is deliberately broad.” Coyle, *supra* note 39.

argued that in light of the rigor of the FDA's PMA process⁴¹ and its resulting "device-specific design, manufacturing, and labeling requirements," separate jury verdicts would also produce "requirements" as a practical matter with regard to a device's design, manufacture, or label.⁴² One court of appeals case explained the effect of a jury verdict this way:

The effect of a jury finding of negligent failure to warn would be that state law would require [the manufacturer] to change the label and package insert for [the medical device], but [the manufacturer] may not unilaterally make such changes under federal law. A device may not be labeled in a manner inconsistent with any conditions specified in its PMA. 21 C.F.R. § 814.80 (2000). A manufacturer must submit a Supplemental PMA for any proposed labeling changes that affect the safety of the device. *Id.* at § 814.39(a).⁴³

Others in favor of preemption, such as the George W. Bush Administration, similarly have pointed to the FDA as an agency composed of expert scientists vested with authority to undertake matters such as PMA, which should not be overruled by potentially inconsistent state juries. They argue that juries lack the FDA's expertise to engage in a balancing of the benefits and risks that products may pose.⁴⁴ Finally, preemption advocates argue that to decide differently may delay or discourage development and marketing of products with beneficial or even life-saving potential, and that recalls of medical devices are "rare."⁴⁵ They also respond to the argument that preemption does not give the manufacturer the incentive to update and improve its devices by saying that market pressures will force companies to change their products.⁴⁶

Arguments Against Federal Preemption of State Law Tort Claims with Respect to Devices

In contrast, arguments against federal preemption of common law in the medical device field focus on (1) congressional intent and legislative history; (2) protections for consumers, who may otherwise be left without a remedy; (3) the change in the FDA's view with regard to preemption, as well as the general presumption against preemption; (4) viewing FDA approval as a preliminary step—a "floor" rather than a "ceiling"—that does not hold manufacturers accountable for safety concerns; and (5) questioning the agency's capabilities in terms of resources and its reliance on industry.

⁴¹ "The FDA scrutiny process takes years and millions of dollars to prove a device's safety and efficacy. ... companies emerge only to be sued when something goes wrong, as is prone to happen in patients with serious medical conditions and with devices more technologically advanced than ever." Editorial, *Medical Double Jeopardy*, Wall Street Journal, Mar. 1, 2008, at A8.

⁴² Coyle, *supra* note 39 (discussing the arguments of Medtronic's attorneys in *Riegel*).

⁴³ *Brooks v. Howmedica*, 273 F.3d 785, 796 (8th Cir. 2001).

⁴⁴ Shannon P. Duffy, *Pre-emption Issue Weighed in Label Cases*, The Legal Intelligencer, Dec. 14, 2007; Linda Greenhouse, *Supreme Court Hears Medical Device Case*, N.Y. Times, Dec. 5, 2007; Anna Edney, *High Court Case Will Define Parameters of 1976 Medical Law*, Congress Daily AM; Sam Baker, *Supreme Court Hears Arguments in FDA Preemption Case; Breyer Seen as Swing Vote*, FDA Week. At oral argument in *Riegel*, Justice Kennedy "noted that the FDA is 'specifically charged with weighing the risks against the probable benefits,' and in a state product liability case, 'the jury is doing the same thing that the FDA did.'" Laurel Newby, *Supreme Court Argument Report: Justices Mull Pre-emption of Product Liability Claims*, Law.com, Dec. 5, 2007.

⁴⁵ Greenhouse, *supra* note 44; Edney, *supra* note 44; Newby, *supra* note 44; *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), Amicus Brief for AdvaMed and DRI, 2007 U.S. S. Ct. Briefs LEXIS 1290, at *1.

⁴⁶ Baker, *supra* note 44.

With regard to congressional intent, some commentators have noted that “Congress did not directly address tort suits in the MDA, despite decades of lawsuits against drug manufacturers.”⁴⁷ Opponents of federal preemption of state common law claims in the device area, such as Senator Kennedy and Representative Waxman, have argued that Congress’s silence on the issue evidences “its intent not to preempt the suits,”⁴⁸ or alternately, that the discussions in the legislative history do not provide evidence of such intent.⁴⁹ In *Riegel*, discussed below, the plaintiffs’ attorney also questioned whether Congress would “have really intended to protect the manufacturer from liability,” since the passage of the MDA occurred in the wake of the Dalkon Shield cases,⁵⁰ in which an intrauterine device “was linked to serious infections and several deaths, not to mention a large number of pregnancies.”⁵¹

Some who are against preemption view tort law as an “important and necessary adjunct to the regulatory process”⁵² and cite the FDA’s view prior to 2004 that federal law did not preempt product liability lawsuits.⁵³ While proponents of preemption see it as a way to protect orderly business functions, others assert that “industry has been pushing to expand federal pre-emption for the past 25 years as a wholesale, get-out-of-jail-free card.”⁵⁴ The Riegels’ counsel and others have argued that FDA PMA should be seen as “a preliminary judgment of safety and effectiveness that did not relieve a manufacturer of an obligation to make a device better and safer.”⁵⁵

Moreover, as the Justices explored at oral argument in *Riegel*, preemption could shield manufacturers who discover a risk or problem with their FDA-approved device, if the FDA has not yet learned of the problem or has not taken action as a result of the risk.⁵⁶ It could be argued that the FDA is dependent on manufacturers to provide information regarding devices, that “[t]here is no opportunity for public comment or for any public challenge to the information presented to the FDA by the device manufacturer” in the PMA application, and to allow the common law tort claims to go forward may reveal information in the discovery process that manufacturers withheld from the FDA in the PMA process.⁵⁷ This view sees the state tort law

⁴⁷ Baker, *supra* note 44.

⁴⁸ *Id.*

⁴⁹ Brief for Amici Curiae Senator Kennedy and Congressman Waxman, *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); 2007 U.S. S. Ct. Briefs LEXIS 644, at *3.

⁵⁰ Newby, *supra* note 44.

⁵¹ *Riegel v. Medtronic*, 552 U.S. 312, 315 (2008).

⁵² Duffy, *supra* note 44.

⁵³ Greenhouse, *supra* note 44. Deputy solicitor general Edwin S. Kneedler argued that the FDA’s policy change on preemption “recognized that there would be a serious undermining of F.D.A.’s approval authority and its balancing of the risks and benefits if a state jury could reweigh those.” *Id.* At oral argument in *Riegel*, the government asserted that it “filed a brief in - - late 1997 taking a position that PMA approval did *not* ... have preemptive effect.” (emphasis added). Transcript of Oral Argument at 45, *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), http://www.supremecourt.gov/oral_arguments/argument_transcripts/06-179.pdf. According to the government, at approximately the same time the agency issued a proposed rule—that it withdrew seven months later—and that proposed rule asserted that PMA approval did *not* have preemptive effect. *Id.*

⁵⁴ Coyle, *supra* note 39.

⁵⁵ Greenhouse, *supra* note 44; Baker, *supra* note 44.

⁵⁶ Greenhouse, *supra* note 44; *see infra* notes 146-48.

⁵⁷ *Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1456 (9th Cir. 1995); Baker, *supra* note 44; *see also* Editorial, *Our View on Pharmaceutical Safety: If a drug has FDA’s OK, should you be able to sue?*, USA Today, Apr. 25, 2008 (noting that Merck, which made Vioxx, “apparently downplayed evidence that the medicine tripled the death risk in Alzheimer’s-prone patients”).

system as a backstop, as safety concerns may “have been uncovered not by the agency but during the course of litigation.”⁵⁸ Concerns have been raised that companies may also not “respond to safety concerns that arise after a product is on the market,” if federal law preempts state tort claims, or even attempt to manufacture new devices that are safer or better because suits related to marketing previously approved devices would be preempted.⁵⁹ Those who view the agency as overburdened may also similarly view the agency’s PMA process as inadequate to protect patients.⁶⁰

The FDA’s Position on Preemption in Medical Device Cases

Over the years, the FDA’s position on preemption of state tort law claims in medical device cases has shifted.⁶¹ This section will discuss the express preemption provision, as well as the FDA’s positions since the provision was first enacted in 1976.

The FFDCA contains an express preemption provision with respect to medical devices. This provision was included as part of the MDA, which was enacted in 1976. The statute, 21 U.S.C. Section 360k(a), which was at issue in *Riegel*, provides:

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from or in addition to, any requirement applicable under [federal law] 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 [relevant federal law].⁶²

However, the agency may exempt state requirements that are “more stringent” and state requirements “required by compelling local conditions” if “compliance with the requirement would not cause the device to be in violation of any applicable requirement under” the FFDCA.⁶³

The FDA subsequently issued regulations interpreting this preemption provision in 1978, which were amended after the Supreme Court issued its decision in *Medtronic, Inc. v. Lohr*.⁶⁴ In that

⁵⁸ Lawrence O. Gostin, *Reply*, J. AM. MED. ASS’N 1882 (Oct 23, 2008).

⁵⁹ Baker, *supra* note 44; *see infra* notes 146-48.

⁶⁰ See Gardiner Harris, *Justices Add Legal Complications to Debate on F.D.A.’s Competence*, N.Y. Times, Feb. 21, 2008, at C4; Karl Thiel, *Supreme Court Actions Add Pressure to Beleaguered FDA*, Bioworld Today, Vol. 19, Issue 42, Mar. 3, 2008. Congress has held multiple hearings on the FDA’s lack of resources as compared to its obligations. *See, e.g., Should FDA Drug and Medical Device Regulation Bar State Liability Claims?: Hearing Before the H. Comm. on Oversight and Gov’t Reform*, 110th Cong., May 14, 2008.

⁶¹ Former FDA Commissioner Donald Kennedy has argued that the “notion of preemption has taken on an entirely new guise, also involving the FDA, but in a far more troubling way than the older use of preemption in the regulatory sense.” Donald Kennedy, Editorial, *Misbegotten Preemptions*, 320 SCIENCE 585 (May 2, 2008). He asserts that the FDA used preemption in the late 1970s, when he was commissioner of the agency, in a way that prevented states from establishing their own requirements, such as “net weight requirements for packaged foods” that may “disfavor our-of-state competition,” or their “own drug approval agenc[ies].” *Id.*

⁶² 21 U.S.C. §360k(a); FFDCA §521(a).

⁶³ 21 U.S.C. §360k(b).

⁶⁴ 43 Fed Reg. 18665 (May 2, 1978); 45 Fed. Reg. 67336 (Oct. 10, 1980); 61 Fed. Reg. 52606, 52654 (Oct. 7, 1996).

case, the Court concluded that state common law negligence actions against manufacturers of devices found by the FDA to be “substantially equivalent” under the Section 510(k) process were not preempted. In the agency’s post-*Lohr* 1996 final rule amending the regulations, the FDA noted that “the new quality system regulation does not preempt State tort and common law remedies.”⁶⁵ The regulations presently provide:

State or local requirements are preempted *only* when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from or in addition to, the specific Food and Drug Administration requirements.

...

Section 521(a) [21 U.S.C. § 360k(a)] does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices ... or to unfair trade practices in which the requirements are not limited to devices.⁶⁶

As indicated by these regulations, the FDA’s position, prior to the early 2000s, was of a “long-standing presumption against preemption in implementing section 521” of the FFDCA (21 U.S.C. §360k).⁶⁷ The agency’s outlook with regard to the scope of the preemption provision was that it “should be interpreted narrowly, with a presumption against preemption.”⁶⁸ With regard to whether the preemption provision applied to state tort claims, the “FDA did not have occasion to address the precise issue of whether [21 U.S.C. § 360k] preempts state tort claims before that issue was litigated in private lawsuits.”⁶⁹ In 1997, the then-Chief Counsel of the FDA argued that “although the agency had not formally expressed its position on the precise issue, it is clear from the views it expressed in many other contexts [such as a 1984 advisory opinion, a response to a 1980 request from California for an exemption from preemption, and a response to “a congressional request for an opinion on the preemptive status of another California statute”] that it did not believe that state tort claims were preempted under” 21 U.S.C. §360k.⁷⁰ She referred to the statute’s legislative history, the exemption procedure, and the lack of congressional mention of its intent to preempt state common law claims when noting the agency’s “belie[f] that Congress intended to restrict preemption to positive enactments (for example, legislation or regulations) that apply to the marketing of medical devices within a state.”⁷¹

Meanwhile, in *Lohr*, the agency had argued in an *amicus* brief that “state tort claims generally are not preempted under” 21 U.S.C. §360k.⁷² After the Supreme Court’s decision in *Lohr*, the then-Chief Counsel for the FDA, Margaret J. Porter, stated:

FDA regulation of a device cannot anticipate and protect against all safety risks to individual consumers. Even the most thorough regulation of a product such as a critical medical device

⁶⁵ 61 Fed. Reg. 52601, 52603 (Oct. 7, 1996).

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

⁶⁷ Margaret J. Porter, *The Lohr Decision: FDA Perspective and Position*, 52 FOOD & DRUG L.J. 7, 7 (1997).

⁶⁸ *Id.*

⁶⁹ *Id.* at 8.

⁷⁰ *Id.*

⁷¹ *Id.* at 8-9.

⁷² *Id.* at 10.

may fail to identify potential problems presented by the product. Regulation cannot protect against all possible injuries that might result from use of a device over time. Preemption of all such claims would result in the loss of a significant layer of consumer protection, leaving consumers without a remedy for injuries caused by defective medical devices. Moreover, FDA's regulation of devices would have been accorded an entirely different weight in private tort litigation than its counterpart regulation of drugs and biologics. This disparity is neither justified nor appropriate, nor does the agency believe it was intended by Congress when section 521 [21 U.S.C. § 360k] was enacted.⁷³

The FDA's view on preemption in medical device cases appeared to shift in 2004, when the agency filed an appellate brief in *Horn v. Thoratec Corp.*, in which the plaintiff sued the medical device manufacturer alleging negligence, defective design, defective manufacture, and failure to warn.⁷⁴ In *Horn*, the FDA submitted an *amicus curiae* letter brief to the court, which the court referenced, in which the agency "unequivocally expressed the opinion that state common law claims such as those made by Horn against a PMA-approved device are preempted."⁷⁵

However, the shift may have occurred earlier. As the court in *Horn* noted, the FDA argued in a 2003 statement of interest in a Tennessee circuit court case that PMA "triggers preemption of a wide array of requirements imposed under state tort law."⁷⁶ Others have argued that the agency's support of preemption began even prior to the change of presidential Administrations from Bill Clinton to George W. Bush, although this assertion was not limited to medical device cases.⁷⁷ One scholar has characterized preemption "as a fundamentally political issue."⁷⁸

In its 2004 *amicus* brief in *Horn*, the agency specifically acknowledged that it was disclaiming its previous view that 21 U.S.C. Section 360k "does not preempt a state tort law claim concerning an FDA-approved device,"⁷⁹ which the agency had articulated in a 1997 *amicus* brief.⁸⁰ The agency gave several reasons for its change in position. The FDA previously asserted that its approval of a manufacturer's design did not "convert the features of that design into federal requirements," but now stated that such a "proposition does not adequately account for the highly detailed ... nature of the PMA process."⁸¹ The agency also noted that its past position viewed the PMA process as a

⁷³ Brief for Amici Curiae Senator Kennedy and Congressman Waxman, *Riegel v. Medtronic*, 552 U.S. 312 (2008); 2007 U.S. S. Ct. Briefs LEXIS 644, at *20-*21 (quoting Porter, *supra* note 67, at 11). Justice Ginsburg also quoted portions of the above paragraph in her dissent in *Riegel*, noting that "the FDA's long-held view on the limited preemptive effect of §360k(a) better comports with the presumption against preemption of state health and safety protections, as well as the purpose and history of the MDA." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 338 n.8 (2008) (Ginsburg, J. dissenting).

⁷⁴ 376 F.3d 163, 165 (3d Cir. 2004).

⁷⁵ *Id.* at 171.

⁷⁶ *Id.* at 171 n. 13; *see also id.* at 178.

⁷⁷ Drug and Device Law, The FDA's Amicus Curiae Briefs on Preemption—Redux, http://druganddevicelaw.blogspot.com/2007_10_01_archive.html.

⁷⁸ Samuel Raymond, *Judicial Politics and Medical Device Preemption After Riegel*, 5 NYU J. L. & LIBERTY 745, 752 (2010). *See generally* Jennie Holman Blake, *Presidential Power Grab or Pure State Might? A Modern Debate Over Executive Interpretations on Federalism*, 2000 B.Y.U.L. Rev. 293 (discussing executive orders issued by Presidents Reagan and Clinton on federal preemption of state law).

⁷⁹ Brief for Amicus Curiae U.S. Dep't of Justice, *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2000) (No. 02-4597), at 3, 28.

⁸⁰ *Smiths Industries Medical Systems, Inc. v. Kernats*, *cert. denied*, 522 U.S. 1044 (1998).

⁸¹ Brief for Amicus Curiae U.S. Dep't of Justice, *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2000) (No. 02-4597), at 28.

minimum standard, which “should not displace state common law that may provide additional protection to consumers,” but said in its 2004 *amicus* brief that PMA “sets a ceiling as well as a floor.”⁸² Finally, the FDA noted that its position change “reflects in part the decisions applying *Lohr* issued by the federal courts” since the Supreme Court issued that opinion.⁸³

The agency’s view under the George W. Bush Administration was that state common law tort claims, such as those at issue in *Horn* and *Riegel*, are preempted under 21 U.S.C. Section 360k because the FDA granted PMA, which imposes specific federal requirements on the Class III medical device at issue, and the state common law claims “would impose a requirement different from, or in addition to, the requirements imposed by FDA in granting pre-market approval.”⁸⁴ The agency previously stated that even though it does not issue specific federal regulations for a device, “the agency’s approval of this device through the PMA process does impose specific requirements for the product, including requirements for its design, manufacturing, performance, labeling, and use,” which are based on the manufacturer’s PMA application.⁸⁵ Additionally, the agency asserted that five Justices in *Lohr* “concluded that a state common law tort judgment is a ‘requirement’ under Section 360k(a).”⁸⁶ Therefore, under the agency’s view of preemption during the Bush Administration, “any finding of liability based upon [a device manufacturer’s] failure to satisfy a standard different from those approved by the FDA in the PMA process would necessarily rest upon an implicit requirement that this device be designed, manufactured, or marketed in a way that differs from the way approved by FDA.”⁸⁷

Though the *Riegel* decision was issued before the start of the Obama Administration, the President announced his policy on preemption in a 2009 memorandum, which stated that “preemption of State law by executive departments and agencies should be undertaken only with full consideration of the legitimate prerogatives of the States and with a sufficient legal basis for preemption.”⁸⁸ The memorandum explicitly addressed the inclusion of preemption statements in regulatory preambles and said such statements should not be included unless the preemption provision is included in the regulation itself. Additionally, such provisions should not be included in the regulation unless they were “justified under legal principles governing preemption,” including those in President Clinton’s Executive Order 13132 on federalism.⁸⁹ That executive order requires agencies to “construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.”⁹⁰ When addressing preemption in terms of federal requirements in recent regulations, the FDA has cited President Clinton’s executive order on federalism as well as the Supreme Court’s holding in *Riegel*.⁹¹

⁸² *Id.* at 29.

⁸³ *Id.* at 30.

⁸⁴ Brief for Amicus Curiae U.S. Dep’t of Justice, *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2000) (No. 02-4597), at 1-2, 15.

⁸⁵ *Id.* at 15-16.

⁸⁶ *Id.* at 19.

⁸⁷ *Id.* at 18.

⁸⁸ President Obama, Memorandum for the Heads of Executive Departments and Agencies, Preemption (May 20, 2009).

⁸⁹ *Id.*

⁹⁰ Exec. Order No. 13132, 64 Fed. Reg. 43255 (Aug. 10, 1999).

⁹¹ See, e.g., FDA, Medical Devices; Ovarian Adnexal Mass Assessment Score Test System; Labeling; Black Box Restrictions, 76 Fed. Reg. 82129, 82131 (Dec. 30, 2011).

The Obama memorandum also called upon agencies to review regulations issued in the previous 10 years that included statements in the preamble or the regulation itself with regard to preemption of state law.⁹² A 2008 *Associated Press* article noted that 51 regulations proposed or adopted since 2005 had placed limits on lawsuits and that a combined 41 of those 51 came from the FDA and the National Highway Traffic Safety Administration.⁹³ In 2011, the FDA issued its preemption review. The FDA concluded that its position on preemption that had been articulated in the preamble to a rule on supplemental applications for labeling changes for prescription drugs, biologics, and devices—a position also referenced in rules on nonprescription drugs and food labeling—could not “be justified under legal principles governing preemption.”⁹⁴ These legal principles included the Supreme Court’s decision in *Wyeth v. Levine*, which explicitly addressed the FDA’s preemption position in that labeling rule.⁹⁵

Riegel v. Medtronic, Inc.

This section will discuss the Supreme Court’s 2008 decision in *Riegel*, as well as the concurrence and the dissent. The *Riegel* case involved preemption of state common law tort suits regarding medical devices that have been FDA-approved under the PMA process.

The U.S. Supreme Court Decision

The *Riegel* case involved a catheter that had received PMA from the FDA to be marketed by Medtronic, Inc. as a Class III device.⁹⁶ The “device’s labeling stated that use was contraindicated for patients with ... calcified stenoses,” in other words, narrowed or constricted passages.⁹⁷ The patient, Charles Riegel, had a “diffusely diseased and heavily calcified” right coronary artery.⁹⁸ Riegel’s doctor inflated the “catheter five times, to a pressure of 10 atmospheres,” although the device’s labeling “warned that the catheter should not be inflated beyond its rated burst pressure of eight atmospheres.”⁹⁹ The catheter burst on the fifth inflation, and “Riegel developed a heart block, was placed on life support, and underwent emergency coronary bypass surgery.”¹⁰⁰ The patient and his wife raised New York state common law claims of “strict liability; breach of implied warranty; and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the catheter.”¹⁰¹

⁹² President Obama, Memorandum for the Heads of Executive Departments and Agencies, Preemption (May 20, 2009).

⁹³ Pete Yost, *Bush Administration Uses Bureaucracy to Limit Lawsuits*, Law.com, May 14, 2008, <http://www.law.com/jsp/law/LawArticleFriendly.jsp?id=1202421377252>. An FDA spokesperson stated that “[t]he preambles to these rules do not seek to preempt, but instead describe the scope of preemption under operation of federal law. *Id.* According to the article, “[j]udges have cited the FDA’s regulatory preamble in its prescription drug rule in more than a dozen favorable rulings for pharmaceutical companies,” although “judges have ruled for the consumers’ right to sue about as often as they have ruled against them in cases touching on the regulatory preamble for prescription drug labels.” *Id.*

⁹⁴ FDA, Preemption Review, 76 Fed. Reg. 61565 (Oct. 5, 2011).

⁹⁵ *Id.* at 61565.

⁹⁶ *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 310 (2008).

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ 552 U.S. at 320.

¹⁰¹ *Id.*

The Supreme Court found that the Medical Device Amendments of 1976 (MDA) preempted state tort law claims because the common law negligence and strict liability claims fell into the category of “any requirement” in the bolded language below. Section 360k(a) of Title 21, United States Code (FFDCA §521) reads:

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use **any requirement—**

(1) **which is different from or in addition to**, any requirement applicable under [federal law] 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 [relevant federal law].

In other words, the Court held that the federal government had established requirements in the PMA process for medical devices in the MDA. The Court said that the New York state common law claims were “different from or in addition to” the federal MDA requirements because “reference to a State’s ‘requirements’ includes its common-law duties.”¹⁰²

To reach its holding, the Court addressed two questions: (1) Has the federal government established requirements applicable to the medical device? and (2) If the answer to the first question is yes, are the plaintiffs’ common law claims (such as negligence in the design, labeling, and marketing of the catheter) based on state requirements that are “different from, or in addition to” the federal requirements, “and that relate to safety and effectiveness”?¹⁰³

First, the Court held that the federal government had “established requirements applicable to” the device at issue, Medtronic’s catheter, and that PMA “imposes ‘requirements’ under the MDA.”¹⁰⁴ In making its determination, the Court distinguished its earlier decision in *Medtronic, Inc. v. Lohr*, which held that “federal manufacturing and labeling requirements” do not preempt common law claims of negligence and strict liability in instances where (1) any federal requirements are not specific to the device at issue; and (2) the FDA finds that a device “is ‘substantially equivalent’ to another device exempt from premarket approval,”¹⁰⁵ because this constituted an exemption, not a “requirement.”¹⁰⁶ The Court found that, unlike the substantial equivalence process, PMA is device-specific and is not an exemption, but rather a “requirement.”¹⁰⁷ The Court differentiated from *Lohr* by reasoning that PMA is focused on safety, rather than equivalence; that PMA is a formal FDA review, as opposed to the lack of formal review that the device subject to premarket notification in *Lohr* received; and that devices that receive PMA may not deviate from the FDA-approved specifications in the PMA application.¹⁰⁸

¹⁰² *Id.* at 324, 335.

¹⁰³ *Id.* at 321-22.

¹⁰⁴ *Id.* at 322-23.

¹⁰⁵ *Id.* at 317, 322.

¹⁰⁶ *Id.* at 322.

¹⁰⁷ *Id.* at 322-23.

¹⁰⁸ *Id.*

Second, the Court held that “New York’s tort duties constitute ‘requirements’ under the MDA”¹⁰⁹ and that these “requirements” were “different from, or in addition to” the federal requirements. The Court began by noting that five Justices in *Lohr* “concluded 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.”¹¹⁰ The *Lohr* Court had said that it did “not believe that [the MDA’s] statutory and regulatory language necessarily precludes ... ‘general’ state requirements from ever being pre-empted.”¹¹¹ In other words, the MDA could potentially preempt general state “requirements,” or general state common law under circumstances such as strict liability, negligence, and implied warranty claims.¹¹²

The Court also addressed the Riegels’ argument that general common law duties are not “requirements” specific to medical devices, and therefore should not be preempted. This argument depended on the FDA regulation 21 C.F.R. Section 808.1(d)(1), which states “that MDA pre-emption does not extend to ‘[s]tate or local requirement of general applicability [whose] purpose ... relates either to other products in addition to devices.’”¹¹³ However, the regulation also “states that the MDA sets forth a ‘general rule’ pre-empting state duties ‘having the force and effect of law (whether established by statute, ordinance, regulation, or court decision).”¹¹⁴ It was this subsection of the regulation that prompted the Court to note that only common law duties are established by court decision.¹¹⁵

Additionally, the Court undertook a discussion of the statutory text and informed Congress of the meaning that “this Court will assign to terms regularly used” in congressional enactments: “Absent other indication, reference to a State’s ‘requirements’ includes its common-law duties.”¹¹⁶ The Court then remarked that “[i]n the present case, there is nothing to contradict the normal meaning” that the term “requirements” will include state common-law duties.¹¹⁷ The Court then indicated that state tort law was perhaps “less deserving of preservation” than state statutes or state regulations, as one state jury could potentially “set state standards ‘different from, or in addition to’ federal standards.”¹¹⁸

The Court held that New York’s common law causes of action were preempted by the MDA “only to the extent that they are ‘different from, or in addition to’ the requirements imposed by federal

¹⁰⁹ *Id.* at 323.

¹¹⁰ *Id.* at 323-24 (emphasis added).

¹¹¹ *Id.* at 328 n.6 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 500 (1996)).

¹¹² *Id.* at 327. The *Riegel* Court also referred to two other cases—*Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), and *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992)—in which the Court held that statutory language regarding preemption of state “requirements” was the equivalent of preemption of state common law. *Riegel*, 552 U.S. 312, 324. In *Bates*, the Court stated: “A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement.” 544 U.S. at 445. In *Cipollone*, the Court held that a preemption provision, which prohibited states from imposing any requirement or prohibition based on smoking and health with respect to the advertising or promotion of cigarettes that are labeling in conformity with the Federal Cigarette Labeling and Advertising Act, was intended to preempt some common law claims.

¹¹³ 21 C.F.R. §808.1(d)(1).

¹¹⁴ 21 C.F.R. §808.1(b).

¹¹⁵ *Riegel*, 552 U.S. at 329.

¹¹⁶ *Id.* at 324.

¹¹⁷ *Id.*

¹¹⁸ *Id.* at 325.

law.”¹¹⁹ To the extent that the lawsuit raises claims that “‘parallel’ rather than add to, federal requirements,” such as a state “damages remedy for claims premised on a violation of FDA regulations,” it does not appear that such suits would be preempted.¹²⁰

Justice Stevens’s Concurrence

Justice Stevens agreed with the dissent’s “description of the actual history and principal purpose of the pre-emption provision at issue” and observed that the text of the provision “cover[s] territory not actually envisioned by its authors.”¹²¹ He also dispensed with congressional intent in this case: “we have frequently concluded that ‘it is ultimately the provisions of our laws rather than the principal concerns of our legislators by which we are governed.’”¹²² However, he agreed with the majority that New York common law duties “constitute requirements with respect to the device at issue that differ from federal requirements relating to safety and effectiveness.”¹²³ He found that the preemption provision’s language “encompasses other types of ‘requirements’” and that “common-law rules administered by judges ... create and define legal obligations, [therefore] some of them unquestionably qualify as ‘requirements.’”¹²⁴

Justice Ginsburg’s Dissent

Justice Ginsburg’s dissent focused on the intent of Congress in enacting the MDA, as well as previous Supreme Court cases emphasizing congressional intent as the “ultimate touchstone of pre-emption analysis.”¹²⁵ The dissent tracks the Court’s presumption against preemption analysis outlined earlier in this report and stated that “[w]here the text of a preemption clause is open to more than one plausible reading, courts ordinarily ‘accept the reading that disfavors pre-emption.’”¹²⁶

Beginning with the majority’s holding that “[a]bsent other indication, reference to a State’s ‘requirements’ includes its common law duties,” she stated that “other indication[s]” exist in the MDA and its legislative history that preclude the Court’s conclusion that the MDA preempts state common law claims.¹²⁷ Justice Ginsburg noted the act’s consumer-oriented purpose, as well as congressional awareness of over 500 lawsuits related to the Dalkon Shield medical device: “I find informative the absence of any sign of a legislative design to preempt state common-law tort actions.”¹²⁸ She pointed to the absence of a federal compensation scheme for consumers injured by FDA-approved medical devices as evidence that Congress did not intend to preempt state

¹¹⁹ *Id.* at 330.

¹²⁰ *Id.* The Court declined to address whether the Riegels raised parallel claims, as the Riegels did not make that argument in their briefs to the Second Circuit or in their petition for certiorari. *Id.*

¹²¹ *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 331 (Stevens, J. concurring). Justice Stevens also noted that the majority opinion advanced several policy arguments regarding impediments to development of devices.

¹²² *Id.* (quoting *Oncale v. Sundowner Offshore Services, Inc.*, 523 U.S. 75, 79-80 (1998)).

¹²³ *Riegel*, 552 U.S. at 332 (Stevens, J. concurring).

¹²⁴ *Id.*

¹²⁵ *Riegel*, 552 U.S. at 334 (Ginsburg, J. dissenting) (quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992)).

¹²⁶ *Id.* at 335 (quoting *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005)).

¹²⁷ *Id.* at 335.

¹²⁸ *Id.* at 336-37.

common law suits.¹²⁹ Furthermore, she referenced the Court’s plurality in *Lohr*, which stated: “[N]othing in the hearings, the Committee reports, or the debates ... suggest[ed] that any proponent of the legislation intended a sweeping pre-emption of traditional common-law remedies against manufacturers and distributors of defective devices.”¹³⁰ Justice Ginsburg also cited remedies provided by the MDA—such as the FDA’s ability to order a device manufacturer to repair or recall the device—and a provision stating that compliance with an FDA order to recall or repair a device “shall not relieve any person from liability under Federal or State law,” as evidence that Congress did not intend to preempt state common law suits.¹³¹

With regard to the FDA’s shift in its position on preemption, she took note of the FDA’s pre-2003 view, as described by a former FDA counsel, that “FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection ... [as] [e]ven the most thorough regulation of a product ... may fail to identify potential problems.”¹³² The dissent then addressed the deference that should be granted to the FDA’s new position on preemption, finding that the agency’s announcement of its position shift in an *amicus* brief would be entitled to little deference when compared with the FDA’s previous view, the presumption against preemption, and the MDA itself.¹³³

The dissent next examined the history of federal regulation of medical devices, and in part, federal regulation of drugs and additives. Justice Ginsburg noted that, prior to the enactment of the MDA in 1976, the defense of state common law claims for defective design or drug labeling either did not involve preemption or, if preemption was asserted as a defense, it was unsuccessful.¹³⁴ She argues that Congress included the preemption provision 21 U.S.C. Section 360k “to empower the FDA to exercise control over state premarket approval systems installed at a time when there was no preclearance at the federal level,” such as the California PMA system.¹³⁵ Moreover, unlike devices, states had not developed PMA processes for drugs or additives.¹³⁶

The dissent also quotes the FDA’s former counsel as observing the disparity that would arguably arise if preemption of state common law suits existed for devices with PMA, but not drugs or biologics: “This disparity is neither justified nor appropriate, nor does the agency believe it was intended by Congress.”¹³⁷ Medtronic had argued that “Congress would not have wanted state juries to second-guess the FDA’s finding that a medical device is safe and effective when used as directed,” however the dissent noted that the PMA process for drugs is “at least as rigorous” as that for devices, and that courts “have overwhelmingly held that FDA approval of a new drug

¹²⁹ *Id.* at 337.

¹³⁰ *Riegel*, 552 U.S. at 337 n.7 (Ginsburg, J. dissenting) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 491 (1996)).

¹³¹ *Id.* at 339.

¹³² *Id.* at 337-38 (quoting Porter, *supra* note 67, at 11).

¹³³ *Id.* at 338 n.8 (examining the deference that should be accorded to the FDA’s position in light of the seminal Supreme Court administrative law cases *Skidmore v. Swift & Co.* and *United States v. Mead Corp.*).

¹³⁴ *Id.* at 340 n.11.

¹³⁵ *Id.* at 341-42.

¹³⁶ *Id.* at 342.

¹³⁷ *Id.* at 340 n.12 (quoting Porter, *supra* note 67, at 11). The FDCA is a statute with many similarities in how it regulates food, drugs, and devices. For example, the act’s enforcement provisions are based on findings that a food, drug, or device is adulterated or misbranded. If a product is adulterated or misbranded, criminal and civil penalties may apply, and the agency may seek injunctions, seizures, and debarment.

application does not preempt state tort suits.”¹³⁸ The decades in which state product liability suits for drugs and FDA approval coexisted may also be seen as an indication of congressional intent not to preempt such claims, according to the dissent.¹³⁹

Finally, Justice Ginsburg notes that device manufacturers may have two defenses to state common law suits: implied preemption under the actual conflict theory (in other words a conflict between FDA PMA of a device and the plaintiff’s case theory), and “a regulatory compliance defense based on the FDA’s approval of the premarket application.”¹⁴⁰ FDA approval could be used as “evidence that [the manufacturer] used due care in the design and labeling of the product.”¹⁴¹

Legal Implications

This section addresses the types of cases that may be affected by the Court’s decision in *Riegel*, identifies areas that would not be affected by this opinion, and discusses similar cases that the *Riegel* Court noted may arise in the future. The *Riegel* Court held that state common law tort claims “premised on a violation of FDA regulations,” such as claims that a medical device was not manufactured according to the FDA specifications or safety processes, were not preempted by 21 U.S.C. Section 360k since “the state duties in such a case ‘parallel,’ rather than add to, federal requirements.”¹⁴² For example, individuals would be able to bring suits alleging that a device manufacturer failed to comply with FDA requirements and that there manufacturer was negligent in designing, labeling, or manufacturing the device because the manufacturer did not follow what the FDA had approved.¹⁴³

Riegel did not alter the Court’s holding in *Lohr* that the FDA’s determination that a device was substantially equivalent to one on the market did not preempt state common law claims regarding defective or negligent design or damages remedies “for violations of common-law duties when those duties parallel federal requirements.”¹⁴⁴ The Court did not address preemption in the investigational device exemption context. Nor did the Court discuss preemption in the context of PMA supplements, which are applications “required for any change to a device subject to an approved application under [21 U.S.C. § 360e] that affects safety or effectiveness, unless such a change is a modification in a manufacturing procedure or method of manufacturing and the holder of the approved application submits a written notice” detailing the change.¹⁴⁵

¹³⁸ *Id.* at 343-44.

¹³⁹ *Id.*

¹⁴⁰ *Id.* at 344-45.

¹⁴¹ *Id.* at 345.

¹⁴² *Riegel*, 552 U.S. at 330; Linda Greenhouse, *Justices Shield Medical Devices from Lawsuits*, N.Y. Times, Feb. 21, 2008, at A1.

¹⁴³ Transcript of Oral Argument at 33-34, *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), http://www.supremecourtus.gov/oral_arguments/argument_transcripts/06-179.pdf.

¹⁴⁴ *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996).

¹⁴⁵ 21 U.S.C. §360e(d)(6)(A)(i). Devices with PMA supplements include devices such as Medtronic’s Sprint Fidelis pacemaker lead, which was recalled by the company since it was “more prone to developing potentially deadly fractures than an older lead called the Quattro.” Barnaby J. Feder, *Medical Device Ruling Redraws Lines on Lawsuits*, N.Y. Times, Feb. 22, 2008, at C2.

Justice Ginsburg noted that “[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.”¹⁴⁶ This issue was also mentioned by Chief Justice Roberts and Justices Kennedy, Stevens, and Souter at oral argument: “[There could be a newly discovered risk that the FDA never knew about. And, nevertheless, the claim would be preemptive.”¹⁴⁷ Justice Ginsburg also argued that manufacturers may lack the incentive to make their devices safer once they receive PMA because they “have permission to market this product as is.”¹⁴⁸ Medtronic’s counsel responded by arguing that the FDA could withdraw approval of a device already on the market if there was a safer device in existence or allow both the newer and safer device to coexist on the market with the older device that may have more risks for some patients.¹⁴⁹ Congressional critics argue that the FDA’s initiation of withdrawal proceedings “can be a time consuming process,” as the FDA “must establish that the product no longer meets the statute’s safety and efficacy requirements.”¹⁵⁰ Relatedly, these Members note that medical device clinical trials “will not identify all of the significant risks involved in the use of the device,” and that rare risks “will emerge only when a device is released into a larger and more heterogeneous population.”¹⁵¹

Preemption Jurisprudence

One preemption scholar, who commented that litigants and scholars alike see preemption jurisprudence as “a muddle, a mess,” saw the ruling as part of a “framework for pre-emption jurisprudence” that the Supreme Court may be attempting to create.¹⁵² An appellate and Supreme Court practice attorney also indicated that *Riegel* and similar cases “raise recurring issues, such as whether there is a presumption against pre-emption and, if so, when it applies and how strong it is, and how much deference courts should give to the federal agency’s position.”¹⁵³ Although the majority opinion in *Riegel* did not address the presumption against federal preemption of state law, the Court had addressed the presumption against preemption in *Lohr*:

Although our analysis of the scope of the pre-emption statute must begin with its text ... our interpretation of that language does not occur in a contextual vacuum. Rather that interpretation is informed by two presumptions about the nature of pre-emption.... First,

¹⁴⁶ *Riegel*, 552 U.S. at 333 n.1 (Ginsburg, J. dissenting).

¹⁴⁷ Transcript of Oral Argument at 28 (Stevens, J. speaking), *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), http://www.supremecourtus.gov/oral_arguments/argument_transcripts/06-179.pdf; *see also id.* at 29 (Souter, J. speaking); *id.* at 26-27 (Chief Justice Roberts: “What if the FDA hasn’t done it [weighed safety and effectiveness of a device versus availability]? How are newly discovered flaws dealt with? I mean, say where you have this catheter, and the FDA didn’t look at the possibility of allergic reactions to the balloon plastic, and all of a sudden it turns out to be a serious problem. How can you say that that’s preemptive?” Mr. Olson [Counsel for Medtronic, Inc.]: “This is a continuous process. Information must be given by the manufacturer. There is a process by which doctors report consequences to the FDA. Citizens may report information.” Justice Kennedy: “Is the manufacturer free to continue to sell the device after newly discovered risks ... pending the FDA’s acting on the same information?” Mr. Olson: “Yes, Justice Kennedy.”)

¹⁴⁸ *Id.* at 35-36.

¹⁴⁹ *Id.* at 36.

¹⁵⁰ Brief for Amici Curiae Senator Kennedy and Congressman Waxman, *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); 2007 U.S. S. Ct. Briefs LEXIS 644, at *19-*20.

¹⁵¹ *Id.* at *19.

¹⁵² Coyle, *supra* note 39.

¹⁵³ *Id.*

because the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action.... Second, our analysis of the scope of the statute's pre-emption is guided by our oft-repeated comment ... that 'the purpose of Congress is the ultimate touch-stone' in every pre-emption case.¹⁵⁴

Given that the *Riegel* Court did not address this traditional presumption against preemption, it could be argued that the presumption may not be as strong as previously considered.¹⁵⁵ However, it is important to note that the Court did not explicitly repudiate this presumption.

The Riegels had argued "that the justices have relied repeatedly on the presumption that a federal statute does not pre-empt the historic police powers of the state absent a finding of Congress' 'clear and manifest intent' to do so," and that the statutory language did not contain such intent.¹⁵⁶ However, "a review of the Supreme Court's various preemption holdings demonstrates that the presumption is not applied in 'all pre-emption cases,' ... and that congressional intent is certainly not the 'ultimate touchstone' in every preemption case."¹⁵⁷

The FDA and Preemption Cases

This section will examine the type of deference that the agency's shifting position on preemption would likely receive if addressed by a reviewing court. The Court looked to the text of the statute when considering the FDA's own interpretation of the statute's meaning. Initially, commentators on the case predicted that the amount of deference that the Court would give to the agency's position, given the FDA's reversal in favor of preemption circa 2003-2004, would be a key question, as an agency interpretation "which conflicts with the agency's earlier interpretation is 'entitled to considerably less deference than a consistently held agency view.'"¹⁵⁸ However, jurists may use various tools of interpretation, and the Supreme Court appeared to circumvent this question by finding clear congressional intent in favor of preemption. The Court "found it unnecessary to rely upon th[e] agency view [in support of preemption] because we think the statute itself speaks clearly to the point at issue."¹⁵⁹ Thus, the FDA regulation did not appear to affect how the Court chose to interpret the statute.

¹⁵⁴ *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485-86 (1996).

¹⁵⁵ While Justice Ginsburg's dissent does not criticize the Court for omitting a discussion of this presumption, she outlines the Court's typical method of analyzing cases with this presumption. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 334-35 (2008) (Ginsburg, J. dissenting).

¹⁵⁶ Coyle, *supra* note 39.

¹⁵⁷ See Jodie M. Gross and Judi Abbott Curry, *The Federal Preemption Debate in Pharmaceutical Labeling Product Liability Actions*, 43 TORT TRIAL & INSURANCE PRACTICE L. J. 35, 42 (Fall 2007), (quoting *Retail Clerks Int'l Ass'n Local 1625 v. Schermerhorn*, 375 U.S. 96, 103 (1963) ("[T]he purpose of Congress is the ultimate touchstone."); Raymond, *supra* note 78, at 749 (arguing that "the Court has inconsistently approved the use of a background canon of interpretation providing for a 'presumption against preemption'" and stating that while the Court did not address the presumption in *Riegel*, it "relied heavily upon it" in a subsequent Supreme Court case involving preemption of tort suits related to drugs that have received FDA approval, "to deny preemption.").

¹⁵⁸ *Immigration & Naturalization Serv. v. Cardoza-Fonseca*, 480 U.S. 421, 447 n.30 (1987); see, e.g., Greenhouse, *supra* note 44. With regard to the FDA's views on preemption in drug labeling products liability cases, see Gross and Curry, *supra* note 157, at 39, which discusses the conclusions of several courts "that FDA interpretations of its own statutes, as expressed in numerous amicus briefs as well as the preamble [to the regulation in which the FDA stated its belief that FDA approval of drug labeling preempts state law that conflicts or contradicts approved labeling], do not warrant *Chevron* deference."

¹⁵⁹ *Riegel*, 552 U.S. at 326.

However, the Court noted (and the dissent agreed with the type of deference that would be given) that if it “had found the statute ambiguous, and had accorded the agency’s current position deference ... *Skidmore* deference would seemingly be at issue.”¹⁶⁰ Under *Skidmore v. Swift & Co.*, “the weight of [an administrative agency’s interpretation] will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.”¹⁶¹ The agency’s lack of consistency in this area may have been a potential cause for concern, because while the FDA under the Bush Administration supported the concept of preemption, under previous Administrations the agency had taken the opposite view.¹⁶²

Additionally, as noted above, since the Court’s decision in *Riegel* was issued, the Obama Administration has directed executive departments and agencies to avoid including statements regarding intent to preempt state law through regulations or preambles to regulations.¹⁶³ It seems likely that courts will continue to address the scope of preemption with regard to FDA statutes and regulations. In two 2011 cases, the Supreme Court addressed deference to agency interpretations generally, although preemption was not at issue in these cases.¹⁶⁴

Procedural Implications

In the wake of the *Riegel* decision, cases involving medical devices that received PMA from the agency have been dismissed for failure to state a “legally cognizable claim” that would “overcome[] a preemption defense.”¹⁶⁵ These post-*Riegel* cases appear to have been affected by two other Supreme Court cases that address pleadings standards—*Bell Atlantic Corp. v. Twombly*,¹⁶⁶ which was decided a few months prior to *Riegel*, and *Ashcroft v. Iqbal*,¹⁶⁷ which was decided after *Riegel*. These two cases have been hailed by attorneys for defendant manufacturers and bemoaned by plaintiffs’ attorneys for raising the plausibility requirements for pleadings.¹⁶⁸ Courts have found that plaintiffs with parallel state law claims did not “plead enough facts to ‘state a claim that is plausible on its face’” and survive a motion to dismiss.¹⁶⁹ According to one

¹⁶⁰ *Id.* at 326.

¹⁶¹ 323 U.S. 134, 140 (1944).

¹⁶² *See, e.g., Riegel*, 552 U.S. at 326-27.

¹⁶³ President Obama, Memorandum for the Heads of Executive Departments and Agencies, Preemption (May 20, 2009).

¹⁶⁴ In *Pliva, Inc. v. Mensing*, the Court deferred to THE FDA’s interpretation of its regulations on drug labeling. 564 U.S. ___ (2011), 131 S. Ct. 2567 (2011). In *Talk America, Inc. v. Michigan Bell Telephone Co.*, the Court stated, “we defer to an agency’s interpretation of its regulations, even in a legal brief, unless the interpretation is ‘plainly erroneous or inconsistent with the regulation[s]’ or there is any other ‘reason to suspect that the interpretation does not reflect the agency’s fair and considered judgment on the matter in question.’” 564 U.S. ___ (2011), 131 S. Ct. 2254 (2011)(quoting *Auer v. Robbins*, 519 U.S. 452, 461, 462 (1997)).

¹⁶⁵ *See, e.g., Funk v. Stryker Corp.*, 631 F.3d 777, 779, 783 (5th Cir. 2011); Raymond, *supra* note 78, at 766-72.

¹⁶⁶ 550 U.S. 544 (2007).

¹⁶⁷ 556 U.S. 662 (2009).

¹⁶⁸ *See, e.g., Drug and Device Law Blog*, <http://druganddevicelaw.blogspot.com/search?q=TwIqbal+>; Demetria D. Frank-Jackson, *The Medical Device Federal Preemption Trilogy: Salvaging Due Process for Injured Patients*, 35 S. ILL. U. L. J. 453 (2011).

¹⁶⁹ *Stryker Corp.*, 631 F.3d at 782 (quoting *Ashcroft v. Iqbal*); *see* Frank-Jackson, *supra* note 168, at 477-79 (stating that “claims are dismissed because the pleaders lack details in their allegations about what specific federal law the medical device manufacturer violated,” and that “courts readily dismiss claims where the plaintiff’s complaint fails to [establish a causal] link [between] the federal violation [and] the injury sustained by the device recipient”).

circuit judge from the United States Court of Appeals for the Eighth Circuit, “[t]he combination of the rigid application of *Twombly* and the now-articulated parallel claim exception to § 360k preemption have, in these cases, led to the dismissal of over two hundred potentially meritorious lawsuits on a technicality.”¹⁷⁰ The significance of the pleading requirements in the context of medical device PMA preemption cases decided after *Riegel* has led one pro-plaintiff law professor to argue that Congress should amend the MDA to address “what is required for proper pleading” and *Twombly*’s “effect on plaintiff’s claims.”¹⁷¹ Additionally, if a case survives a motion to dismiss, medical device manufacturers have argued that they should receive summary judgment from the courts under *Riegel*.¹⁷²

In terms of the frequency of preemption post-*Riegel*, one law review article examined 75 post-*Riegel* lower court cases involving medical devices with FDA PMA.¹⁷³ The author defined rulings that “maintain[ed] a cause of action” as findings of no preemption, while preemption rulings were defined as (1) those that “dismiss[ed] all claims arising from the design, manufacture, and labeling of a medical device” and (2) dismissals of cases with claims that were “insufficiently pled” in terms of the necessary factual showings.¹⁷⁴ According to this study, courts found preemption in 77.3% of the cases.¹⁷⁵

In terms of the types of claims that have survived post-*Riegel*, according to the article, in the 17 cases in which the courts did not find preemption, the courts considered three types of claims as “sufficiently parallel and not preempted”: (1) “complaints arising from injuries suffered because of a design change without FDA approval”; (2) “claims that the manufacturer made express warranties to the consumer”; and (3) “claims of manufacturing defect.”¹⁷⁶ While these types of claims were successful in some lower courts, they were not successful in others.¹⁷⁷ The author found that the first type of claim was an “infrequent factual occurrence” and that most plaintiffs would not be able to use this claim.¹⁷⁸ The second type of claim is based on contractual theories

¹⁷⁰ In re: Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig., 23 F.3d 1200, 1210 (8th Cir. 2010)(Melloy, J. concurring in part and dissenting in part). The judge argued that “[i]f plaintiffs must allege that the defendant violated a particular FDA-approved specification before discovery, then it is difficult to appreciate how any plaintiff will ever be able to defeat a Rule 12(b)(6) motion [to dismiss]. In essence, application of *Twombly* in this manner eliminates the remaining exception to §360(k) preemption.” *Id.* at 1212.

¹⁷¹ Frank-Jackson, *supra* note 168, at 495.

¹⁷² See, e.g., *Dorsey v. Allergan, Inc. and Allergan Sales, LLC*, 2009 U.S. Dist. LEXIS 26235 (D. Tenn. Mar. 11, 2009) (awarding summary judgment to the breast implant manufacturer on a strict liability claim because the silicone implants, a Class III device, later received FDA PMA, even though they had not received PMA at the time of the patient’s surgery). *But see Kavalir v. Medtronic, Inc.*, 2008 U.S. Dist. LEXIS 82979 (N.D. Ill. Aug. 27, 2008) (denying the medical device manufacturer’s motion to dismiss the patient’s claims of strict liability, breach of warranty, and breach of implied warranty with regard to an implantable cardioverter defibrillator device (ICD), a Class III device, because there was not a sufficient basis to determine whether the forms of the ICDs that received PMA were the same as the ones implanted in the plaintiff or whether the plaintiff’s state tort claims were different from or in addition to FDA requirements).

¹⁷³ Raymond, *supra* note 78, at 757 (analyzing lower court cases from the date of the *Riegel* decision on February 20, 2008 through July 15, 2010).

¹⁷⁴ *Id.* at 758, 770-71.

¹⁷⁵ *Id.* at 760. The article also found that one state court “rejected” the *Riegel* decision in an opinion “explicitly calling for” congressional action. *Id.* at 756.

¹⁷⁶ *Id.* at 748, 766.

¹⁷⁷ *Id.* at 766.

¹⁷⁸ Raymond, *supra* note 78, at 766-67.

and may involve statements made by the manufacturer.¹⁷⁹ The “largest number of unpreempted parallel cases” were cases based on the third type of claim, such as those in which courts “determine[d] that the device at issue was not manufactured in conformance with the FDA’s Current Good Manufacturing Practice and Quality System Regulation.”¹⁸⁰ However, at least one federal appellate court found that such claims were preempted.¹⁸¹

The types of parallel claims that may survive in the lower courts may differ from circuit to circuit. The United States Court of Appeals for the Eighth Circuit has stated that “the contours of the parallel claim exception were not addressed in *Riegel* and are as-yet ill-defined.”¹⁸² However, there may be some commonalities, and as more courts issue decisions on parallel claims post-*Riegel*, it may be easier to predict the types of parallel claims that courts will allow. According to one law review article, in five of the federal circuit courts, “in order for a parallel cause of action to be properly alleged, the claims must be premised on a violation of federal law or deviation from federal standard. Essentially, the circuit courts conclude the common law claims must go beyond alleging violation of federal statute, and the pleadings should contain sufficient detail of how the federal regulations were violated.”¹⁸³

Regulatory Implications

The Court’s decision in *Riegel* has potential implications for the agency’s responsibilities, regulatory authorities, and reliance on industry-provided information. The FDA’s responsibilities have increased over the years, not only in the device area, but in other regulatory areas as well, including food, drugs, and tobacco. At the same time, the agency has been identified as strapped for resources and under strain because of the large amounts of responsibility it possesses.¹⁸⁴ While the *Riegel* decision does not grant the FDA greater responsibilities or authorities per se, it provides the FDA with more complete control over medical devices in the sense that the FDA’s approval and regulatory requirements carry greater weight than state law requirements.¹⁸⁵ The Court’s finding that the MDA preempts state common law claims related to devices that receive FDA PMA could conceivably pressure the FDA to more stringently examine devices undergoing the PMA process.¹⁸⁶ However, the FDA is not required to alter its considerations of devices undergoing the PMA process due to the effect that its approval would have in terms of preempting later consumer lawsuits, such as those with regard to defectively designed devices.

¹⁷⁹ *Id.* at 767-68.

¹⁸⁰ *Id.* at 768-69.

¹⁸¹ *Id.* at 769-70; In re: Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig., 623 F.3d 1200 (8th Cir. 2010). Interestingly, the Eighth Circuit’s decision was issued after Medtronic settled “all pending U.S. claims alleging product liability defects in its Sprint Fidelis defibrillator leads” in pacemakers. Alison Frankel, 8th Circuit Affirms Pre-emption Dismissal of Defibrillator Cases Against Medtronic, American Lawyer, Oct. 21, 2010.

¹⁸² *Sprint Fidelis*, 623 F.2d at 1204.

¹⁸³ Frank-Jackson, *supra* note 168, at 472.

¹⁸⁴ “The Institute of Medicine, the Government Accountability Office and the FDA’s own science board have all issued reports concluding that poor management and scientific inadequacies have made the agency incapable of protecting the country against unsafe drugs, medical devices and food.” Harris, *supra* note 60. The agency has countered that it is “responding to reports of its deficiencies and improving.” *Id.*

¹⁸⁵ Supporters of the ruling, such as the Advanced Medical Technology Association, emphasize the FDA’s “ultimate regulatory authority” with regard to medical devices, as opposed to multiple state regulation schemes and jury verdicts. Stephen Langel, *Democrats Threaten Legislation to Overturn Medical Device Ruling*, Congress Now, Feb. 21, 2008.

¹⁸⁶ Supporters have argued that the decision prevents “unscientific state juries second-guessing F.D.A.’s science-based decisions.” Harris, *supra* note 60.

The agency's reliance on industry-provided information in the medical device area has led some to argue that consumers are more vulnerable post-*Riegel*.¹⁸⁷ The agency may decide to address the issue of notification from manufacturers who have discovered problems with their devices after receiving PMA. One former FDA Commissioner argues that once an FDA-approved product such as a drug has a wider distribution than in controlled clinical trials, it "may have a thousand times as many users," which can lead to increased numbers of adverse events such as illness or death, necessitating new warning labels or the withdrawal of the product from the market.¹⁸⁸ At oral argument, Justice Kennedy discussed the possibility of a notification requirement, along the lines of an adverse event reporting requirement,¹⁸⁹ for device manufacturers who have discovered safer alternatives: "If the manufacturer finds just from its own laboratory experiments and not because of any data it's [sic] received from doctors and patients that there's a better way to do this, does it have the obligation to notify the FDA? Mr. Olson: I don't think so, Justice Kennedy. I think that there may be marketplace incentives."¹⁹⁰

Legislative Implications

Three potential legislative implications stem from the *Riegel* case. First, some Members of Congress introduced legislation in the 111th Congress to overturn the Court's decision. Second, if Congress decided not to nullify the effect of the *Riegel* decision through legislation, one congressional approach to offer a remedy to those injured by a medical device that has received FDA PMA would be to create a victim's compensation fund. Third, future legislation that references a state's "requirements" and state common law may be affected by the Court's statements in *Riegel*.

Legislative Proposals

In the 111th Congress, bills were introduced that would have overturned the Court's decision in *Riegel* by modifying the statute at issue: H.R. 1346, H.R. 4816, and S. 540. The House Energy and Commerce Committee's Subcommittee on Health held a hearing on H.R. 1346 in the 111th Congress. Similar legislation has not been introduced in the 112th Congress.

In response to the Supreme Court's decision in *Riegel*, Representative Pallone and Senator Kennedy introduced H.R. 1346/S. 540, the Medical Device Safety Act of 2009. The bill would have effectively overturned the Court's decision in *Riegel*. The bill would have modified 21 U.S.C. Section 360k by adding a provision stating that "[n]othing in this section shall be

¹⁸⁷ Harris, *supra* note 60.

¹⁸⁸ Donald Kennedy, *Misbegotten Preemptions*, 320 SCIENCE 585 (May 2, 2008).

¹⁸⁹ See, e.g., 21 C.F.R. Part 803, Medical Device Reporting (For example, 21 C.F.R. §803.50(a) requires manufacturers to report to the FDA, within 30 calendar days, information that the manufacturer "receive[s] or otherwise become[s] aware of ... from any source, that reasonably suggests that a device that [the manufacturer] market[s]: (1) May have caused or contributed to a death or serious injury; or (2) Has malfunctioned and this device or a similar device that [the manufacturer] market[s] would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.").

¹⁹⁰ Transcript of Oral Argument at 36, *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), http://www.supremecourtus.gov/oral_arguments/argument_transcripts/06-179.pdf. Chief Justice Roberts noted that manufacturers must "disclose unpublished reports of data from clinical investigations or nonclinical laboratory studies involving the device"; however, this appears to differ from Justice Kennedy's observation regarding the obligation of a device manufacturer that has discovered or created a safer device than the one already on the market. *Id.* at 35-37.

construed to modify or otherwise affect any action for damages or the liability of any person under the law of any State.” The addition of that clause stated that the bill would “take effect as if included in the enactment of the [MDA],” and would “apply to any civil action pending or filed on or after the date of enactment of” the legislation, if passed. The language in H.R. 1346/S. 540 was incorporated in H.R. 4816, the Food and Drug Administration Improvement Act of 2010, in the 111th Congress, which was referred to committee but did not see further action.

The AARP, the American Association for Justice, the National Conference of State Legislatures, Public Citizen, state attorneys general, consumer groups, and several Members of Congress either supported the Riegels’ case and/or support overturning the Court’s decision, which some have argued impacts patients and states with strong consumer protection laws.¹⁹¹ A former FDA chief counsel and the American Tort Reform Association opposed the legislation, and the latter reportedly called the bill “little more than an economic stimulus for personal injury lawyers.”¹⁹²

Creating a Victim’s Compensation Fund

If Congress does not overturn the *Riegel* decision, but is interested in providing a remedy for injured medical device consumers, one approach would be to establish a compensation fund. In *Riegel*, the dissent argued that Congress would not have, “‘without comment, remove[d] all means of judicial recourse’ for consumers injured by FDA-approved devices.”¹⁹³ The majority opinion responded by stating:

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.¹⁹⁴ (emphasis added)

It could be argued that if Congress had intended to preempt state common law claims, it may have considered a victims’ compensation fund of some sort.

In the past, Congress has created compensation schemes when it has removed an individual’s ability to sue. For example, the National Vaccine Injury Compensation Program prohibits suits under state tort law against manufacturers and administrators of specified vaccines unless the claimant first files a claim for limited no-fault compensation with the National Vaccine Injury Compensation Program. Congress also created the September 11th Victim Compensation Fund of 2001, under which a victim or a victim’s estate could seek no-fault compensation from the

¹⁹¹ Coyle, *supra* note 39; Anna Edney, *High Court Ruling Spurs New Debate on FDA Approvals*, Congress Daily PM, Feb. 22, 2008; Inside Washington Publishers, *Michigan Governor Calls for Reversal of Tough Preemption Law*, FDA Week, Feb. 1, 2008; Press Release, Public Citizen, Congress Must Pass Medical Device Safety Act, Restore Patient Access to Courts (Mar. 5, 2009), http://www.citizen.org/hot_issues/issue.cfm?ID=2180; Bill Swindell, *Trial Lawyers Lay Out Agenda for ‘09, Press Pre-Emption*, Congress Daily PM, Jan. 12, 2009.

¹⁹² Marisa McQuilken, *House Hears Testimony on Medical Device Bill that Would Reverse Supreme Court Ruling*, National Law Journal, May 14, 2009.

¹⁹³ *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 337 (2008) (Ginsburg, J. dissenting).

¹⁹⁴ *Id.* at 326. Justice Scalia did note that “[c]ontrary to Justice Stevens’ contention ... we do not ‘advance’ this argument [that the text of the statute is the only indication of congressional intent]. We merely suggest that if one were to speculate upon congressional purposes, the best evidence for that would be found in the statute.” *Id.* at 326, n. 5.

program or bring a tort action against an airline or any other party, but could not do both, except to sue “any person who is a knowing participant in any conspiracy to hijack an aircraft or commit any terrorist act.”¹⁹⁵

Future Legislation Referencing a State’s “Requirements” and State Common Law

The *Riegel* Court held that “[a]bsent other indication, reference to a State’s ‘requirements’ includes its common law duties.”¹⁹⁶ It appears that the Supreme Court arrived at this conclusion based on previous Supreme Court decisions addressing the term “requirements” in the state common law context, without relying on congressional intent, the FDA’s own regulation,¹⁹⁷ or the agency’s change in its position regarding preemption, which could be a motivation for congressional legislative action. Senator Kennedy and Representative Waxman argued in their *amicus* brief that the use of the term “requirement” in one statute—the Public Health Cigarette Smoking Act of 1969, which was at issue in the 1992 Supreme Court case *Cipollone v. Liggett Group, Inc.*, and was interpreted by the Supreme Court to include common law tort claims—“does not mandate a conclusion that use of the same term in a very different statute with different goals means the same thing,”¹⁹⁸ as the MDA “was enacted by a different Congress at a different time.”¹⁹⁹

Based on this statement by the *Riegel* Court however, it appears that Congress and its legislative counsel should be aware of the use of the term “requirements” in existing statutes and proposed legislation.²⁰⁰ This would appear to hold true regardless of congressional intent or when the statute was enacted, as the MDA was enacted approximately 16 years prior to the Court’s analysis of the term “requirements” in *Cipollone*. It appears that Congress may have already recognized post-*Cipollone* that the use of the term “requirement” in a preemption provision could preempt product liability claims.²⁰¹ Thus, if Congress does not want to preempt state common law claims,

¹⁹⁵ See CRS Report 95-797, *Federal Tort Reform Legislation: Constitutionality and Summaries of Selected Statutes*, by (name redacted); see also CRS Report RL33927, *Selected Federal Compensation Programs for Physical Injury or Death*, coordinated by (name redacted) and (name redacted) (describing federal programs that “compensate or assist individuals who have suffered physical or psychological harm as a consequence of specific events (including the actions of others), or who have suffered specific types of physical or psychological harm”).

¹⁹⁶ *Riegel*, 552 U.S. at 324.

¹⁹⁷ *Id.* at 327-29. “Even assuming that this regulation could play a role in defining the MDA’s preemptive scope, it does not provide unambiguous support for the Riegels’ position.” *Id.* at 328. “All in all, we think that §808.1(d)(1) can add nothing to our analysis but confusion. Neither accepting nor rejecting the proposition that this regulation can properly be consulted to determine the statute’s meaning; and neither accepting nor rejecting the FDA’s distinction between general requirements that directly regulate and those that regulate only incidentally; the regulation fails to alter our interpretation of the text insofar as the outcome of this case is concerned.” *Id.* at 329. In contrast, the *Riegel* Court recognized that “[i]n *Lohr*, a majority of this Court interpreted the MDA’s pre-emption provision in a manner ‘substantially informed’ by the FDA regulation set forth at 21 CFR §808.1(d).” *Id.* at 322.

¹⁹⁸ Brief for Amici Curiae Senator Kennedy and Congressman Waxman, *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); 2007 U.S. S. Ct. Briefs LEXIS 644, at *7-*8.

¹⁹⁹ *Id.* at *15.

²⁰⁰ See Linda Greenhouse, *Supreme Court Hears Medical Device Case*, N.Y. Times, Dec. 5, 2007, at C3.

²⁰¹ Brief for Amici Curiae Senator Kennedy and Congressman Waxman, *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); 2007 U.S. S. Ct. Briefs LEXIS 644, at *17 (noting that post-*Cipollone*, “Congress began explicitly stating in statutes that the term ‘requirement’ in preemption provisions did not preempt product liability actions. In two amendments to the FFDCFA since 1992, in which Congress preempted state ‘requirements,’ Congress explicitly stated that product liability cases were not preempted.”).

it may be advisable to provide a specific exemption for such claims when it uses the term “requirements” in the preemption context. Congress could consider inserting savings clauses to preserve state common law claims, such as those discussed in *Geier v. American Honda Motor Co.*²⁰² and *Sprietsma v. Mercury Marine*.²⁰³

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²⁰² 529 U.S. 861 (2000). In *Geier*, the Supreme Court held that a federal motor vehicle safety standard preempted a state common law action against a manufacturer for negligence for failure to equip a vehicle with a driver’s side airbag. According to the Court, the express preemption provision of the National Traffic and Motor Vehicle Safety Act, which prohibits states from applying “any safety standard” different from an applicable federal standard, did not by itself preempt the state tort action. *Id.* at 865, 867. Preemption by statute was inconsistent with the statute’s “saving clause,” which provides that “compliance with” a federal safety standard “does not exempt any person from any liability under common law.” *Id.* at 868. This saving clause, however, did not foreclose or limit the operation of ordinary preemption principles governing override of state laws—including common law tort rules—that conflict with federal statutes or regulations. Rather, the Court held, application of the tort rule would actually conflict with the vehicle safety standard because it would operate to frustrate the objectives of the federal regulation.

²⁰³ Unlike the decision in *Geier*, however, the Court’s pronouncement on federal preemption of a state tort law claim in *Sprietsma v. Mercury Marine* upheld the common law action in the face of a preemption challenge. 537 U.S. 51 (2002). In *Sprietsma*, the Court held that the Federal Boat Safety Act of 1971 does not preempt a state common law tort action for damages from the manufacturer of an outboard motor not equipped with a propeller guard. The statute contained an express preemption clause prohibiting states from adopting or enforcing “a law or regulation ... not identical to a regulation prescribed under [the Act].” *Id.* at 59. No federal regulation requires propeller guards on outboard motors; the Coast Guard studied the matter and decided not to issue a regulation. Using basic principles of statutory construction, the Court concluded that the statute’s preemption language did not encompass common law claims. The Court found that the statute’s saving clause, providing that compliance with the federal standards or regulations “does not relieve a person from liability at common law,” supported this conclusion. *Id.*

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