

Is the Preemption Defense for PMA-Approved Medical Devices in Jeopardy?

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MOST jurisdictions have held that § 360k(a) of the Medical Device Amendments preempts conflicting state common-law claims arising from the design, manufacture, and labeling of a medical device that received pre-market approval.¹ However, the preemption defense may be in further jeopardy. Pending before the United States Supreme Court, and argued on December 4, 2007, is a challenge of the Second Circuit's holding in *Riegel v. Medtronic, Inc.*² The Supreme Court has taken up the following issue:

Does the express preemption provision of the Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a), preempt state law claims seeking damages for injuries caused by medical devices that received premarket approval from the Food and Drug Administration?³

Background

On May 10, 1996, Charles Riegel underwent an angioplasty, during which his surgeon attempted to dilate Mr. Riegel's

¹ *Horn v. Thoratec Corp.*, 376 F.3d 163 (3rd Cir. 2004); *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001); *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000); *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997); *Brooks v. Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001); *Worthy v. Collagen Corp.*, 967 S.W.2d 360, 376 (Tex. 1998); *Fry v. Allergan Med. Optics*, 695 A.2d 511, 516 (R.I. 1997); *Green v. Dolsky*, 685 A.2d 110, 117 (Pa. 1996).

² 451 F.3d 104 (2nd Cir. 2006).

³ See Petition for a Writ of Certiorari in *Riegel v. Medtronic, Inc.*, ___ U.S. ___, 127 S.Ct. 3000, ___ L.Ed.2d ___ (2007); 06-179 *Riegel v. Medtronic, Inc.* Questions Presented, Cert. Granted 6/25/2007.



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right coronary artery.⁴ During the angioplasty, Mr. Riegel's right coronary artery was found to be "diffusely diseased" and "heavily calcified."⁵ After his surgeon attempted to remove the calcium deposits and unsuccessfully inserted several balloon catheters, the surgeon was finally able to successfully insert the Evergreen Balloon Catheter.⁶ During the final inflation, the

⁴ *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 107 (2nd Cir. 2006).

⁵ *Id.*

⁶ The Evergreen Balloon Catheter label stated that its use is contraindicated for patients who have "diffuse or calcified stenosis." Even though the label specified that it should not be inflated beyond the "rated burst pressure" of eight atmospheres, the surgeon inflated it to ten atmospheres. *Id.*

Evergreen Balloon Catheter burst. Mr. Riegel lost consciousness, was intubated, and placed on advanced life support. He was immediately taken to have an emergency coronary bypass surgery. Mr. Riegel survived the procedure.

In 1999, Mr. Riegel and his wife filed suit against Medtronic, Inc., the manufacturer of the Evergreen Balloon Catheter, in the Northern District of New York alleging five state common-law causes of action: (1) negligence in the design, testing, inspection, manufacture, distribution, labeling, marketing, and sale of the Evergreen Balloon Catheter; (2) strict liability; (3) breach of express warranty; (4) breach of implied warranty; and (5) loss of consortium.⁷

Medtronic moved for summary judgment based on the affirmative defense of federal preemption pursuant to 21 U.S.C. § 360k(a). The FDA approved Medtronic's premarket approval ("PMA") application for the Evergreen Balloon Catheter on August 30, 1994. It subsequently approved two PMA supplements on April 27, 1995 and April 18, 1996, which requested approval for revised labeling of the catheter. Because of this PMA approval, on March 14, 2002, the district court ruled that all of the Riegels' negligence claims (except for the negligent manufacturing claim), the strict liability claim, and breach of implied warranty claim were preempted. Subsequently, Medtronic moved for summary judgment on other grounds on the two remaining claims, negligent manufacturing and breach of express warranty. The district court dismissed both of these claims because they were without factual basis. The Riegels appealed to the Second Circuit challenging both summary judgment rulings; however, they did not challenge the summary judgment dismissal of their breach of express warranty claim.⁸

The Second Circuit Court of Appeals' Decision

The Second Circuit Court of Appeals began its analysis with a discussion of the regulatory structure. In 1976, Congress enacted the Medical Device Amendments ("MDA") which established a regulatory structure to regulate medical devices.⁹ The MDA divides medical devices into three classes, depending on the level of risk that the medical device poses. The strictest FDA regulation is reserved for Class III devices, defined as those which (1) are to be used for supporting or sustaining human life or that are of substantial importance in preventing impairment of public health; or (2) present a potential unreasonable risk of illness injury.¹⁰

Because the Class III device poses the greatest risk, it must undergo premarket approval ("PMA") prior to making the device to provide "reasonable assurance of its safety and effectiveness."¹¹ The PMA process is lengthy and rigorous. The manufacturer must submit a detailed PMA application that includes, "full reports of all investigations of the safety and effectiveness of the device; a full statement of the components, ingredients, properties, and principles of operation of the device; a full description of the methods used in manufacture and processing of the device; information about performance standards of the device; samples of the device; specimens of the proposed labeling for the device; and any other relevant information."¹² The FDA spends an average of 1,200 hours on each PMA submission.¹³ After the application is filed, the FDA has authority to approve, deny, or request modification.¹⁴ As a condition of PMA approval, the FDA may impose other

⁹ *Id.*

¹⁰ *Id.* at 109 (citing 21 U.S.C. § 360c(a)(1)(C)).

¹¹ *Id.* (citing 21 U.S.C. § 360c(a)(1)(C)).

¹² *Id.* (citing 21 U.S.C. § 360e(c)).

¹³ *Id.* (referring to Lohr, 518 U.S. at 477).

¹⁴ *Id.* at 110 (referring to 21 C.F.R. § 814.44(e) and 21 C.F.R. § 814.44(f)).

⁷ *Id.*

⁸ *Id.* at 108.

requirements on manufacturers.¹⁵ Once the PMA is approved, the manufacturer must comply with the standards in the PMA approval order.¹⁶ A PMA supplement must be submitted for approval for any changes that the manufacturer believes may affect the safety or effectiveness of the device.¹⁷ Continued approval of the PMA requires the manufacturer to submit detailed post approval reports annually.¹⁸ A manufacturer must also timely submit an “Adverse Reaction Report” or “Device Defect Reporting.”¹⁹

The Court noted, however, that the majority of Class III devices do not go through the PMA process. Instead, devices that are “substantially equivalent” to medical devices in existence prior to 1976 can be marketed and sold without PMA approval.²⁰ This is known as premarket notification or “§ 510(k)” process.²¹ According to the United States Supreme Court in *Lohr*, the § 510(k) process is, “by no means comparable to the PMA process.”²² “Unlike the PMA process which requires reasonable assurance that the new device is itself safe and effective, and ultimately results in the FDA’s ‘approval’ of the device, the § 510(k) process simply requires a manufacturer to show that the device is substantially equivalent...to a legally marketed device that did not go through the PMA process.”²³ A § 510(k) device is not considered to be FDA approved.²⁴ Although the PMA process is estimated to take the FDA 1,200 hours to complete, the § 510(k) process is completed

in an average of 20 hours.²⁵ Moreover, a § 510(k) device only needs a supplemental submission filed if the device “is about to be significantly changed or modified in design, components, method of manufacturer, or intended use.”²⁶

The express preemption provision applies to devices that enter the market through both the PMA and § 510(k) processes:²⁷

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

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which related to the safety and effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.²⁸

The Second Circuit Court of Appeals next reviewed the U.S. Supreme Court decision in *Medtronic, Inc. v. Lohr*. In that case, the Lohrs filed suit seeking damages from an allegedly defective Class III § 510(k) cleared pacemaker.²⁹ The *Lohr* Court held that none of the Lohrs’ claims based on defective design, defective manufacture and failure to warn were preempted by the MDA.³⁰

The *Riegel* Court interpreted *Lohr* as providing a two step analysis for determining whether a claim is preempted by the MDA. “First, on the federal side of the analysis, courts must consider whether there are any device-specific federal requirements with respect to the device at hand. If so, courts must then turn to the

¹⁵ *Id.* at 111 (citing 21 C.F.R. § 814.82(a)).

¹⁶ *Id.* at 110 (citing 21 C.F.R. § 814.80).

¹⁷ *Id.* (citing 21 C.F.R. § 814.39(a)).

¹⁸ *Id.* (referring to www.fda.gov/devadvice/pma).

¹⁹ *Id.* at 111 (referring to www.fda.gov/devadvice/pma).

²⁰ Another exception to obtaining a PMA is the investigational device exemption, which is not at issue. 21 C.F.R. § 812.1.

²¹ *Riegel*, 451 F.3d at 111.

²² *Id.* at 112 (citing *Lohr*, 518 U.S. at 478-79).

²³ *Id.*

²⁴ *Id.* (referring to 21 C.F.R. § 807.97).

²⁵ *Id.* (citing *Lohr*, 518 U.S. at 478-79).

²⁶ *Id.* at 112-13 (citing 21 C.F.R. § 807.81(a)(3)).

²⁷ *Id.* at 113.

²⁸ 21 U.S.C. § 360k(a).

²⁹ *Lohr*, 518 U.S. 470 (1996).

³⁰ *Id.* at 502.

state side to determine whether there would be a conflict between that device-specific federal requirement and any of the liability-creating premises of the plaintiffs' state law tort suit.³¹ The Court noted that the majority of circuits have applied this two step analysis and concluded that common-law tort actions as to PMA-approved devices are preempted by the MDA. The Court noted that only the Eleventh Circuit has held the opposite and found that the PMA process does not constitute a federal device-specific requirement and therefore, claims are not preempted.³²

The Court applied its own two step process for determining if the Riegels' claims are preempted and issued a 2-1 opinion. It first analyzed whether the Evergreen Balloon Catheter is subject to federal device-specific requirements. The Court compared the § 510(k) process with the PMA process. First, clearance through the § 510(k) process does not equate to a review of the device's safety and effectiveness; in contrast, the PMA process requires reasonable assurance of a device's safety and effectiveness.³³ Second, a § 510(k) clearance does not signify that the device has been approved by the FDA; however, PMA clearance does signify FDA approval. Third, the PMA process is a different process, created for devices that were not substantially equivalent to other devices. Finally, the PMA process provides the FDA with the ability to require the device to take a particular form in order to be approved. Also, after a device has received PMA approval, the manufacturer must obtain further FDA approval for any changes that would affect the safety and effectiveness of the device. After considering these differences, the Court concluded that the Evergreen Balloon Catheter was subject to the federal device-

specific requirements set forth in its PMA application.³⁴

The Court rejected the Riegels' position that their failure to warn claim is not subject to a federal device-specific requirement. The Riegels argued that the only federal regulation governing the substance of the catheter's label was the same provision that was at issue in *Lohr*, which the *Lohr* Court found too general to be considered a device-specific requirement. They also argued that manufacturers of PMA-approved devices can make labeling changes to add or strengthen a contraindication or instruction and delete misleading, false, or unsupported information changes without FDA approval. The Court found the arguments unpersuasive because in the case of the Evergreen Balloon Catheter, unlike in *Lohr*, the FDA explicitly approved the labeling during the PMA process.³⁵

Since the Court held that the Evergreen Balloon Catheter was subject to federal device-specific requirements, the Court then focused on the second step of the analysis, to determine whether the Riegels' claims, if successful, would result in different state device-specific requirements. The Court began by analyzing Supreme Court precedent and ascertained that the Supreme Court view has consistently been that common-law actions, which are based on the alleged violation of a legal duty, do impose state requirements.³⁶ Similarly, the Court held that the Riegels' claims alleging liability, despite a PMA-approved device's adherence to those standards (*e.g.*, Riegels' negligent design, testing, inspection, distribution, labeling, marketing, sale, strict liability, and breach of implied warranty) were preempted.³⁷ The Court reasoned that

³¹ Riegel, 451 F.3d at 116.

³² *Id.* at 117 (referring to *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1376-77 (11th Cir. 1999)).

³³ *Id.* at 118.

³⁴ *Id.* at 119.

³⁵ *Id.* at 120.

³⁶ *Id.* at 122 (referring to *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), *Lohr*, 518 U.S. at 470 and *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005)).

³⁷ *Id.* at 121. The Second Circuit Court of Appeals' ruling as to the other summary judgment motion on the negligent manufacturing and express warranty

the liability-creating premise of such claims is that the Evergreen Balloon Catheter in its present PMA approved form is defective.³⁸ A verdict based on such a finding would clearly differ from the FDA's PMA-approval of the Evergreen Balloon Catheter. The Court made it clear that its ruling does not preempt all common-law causes of action. For instance, a claim based on a manufacturer's deviation from the PMA application, such as the Riegels' negligent manufacturing claim, would not be preempted.³⁹

U.S. Supreme Court

In August 2006, the Riegels filed a Petition for a Writ of Certiorari in the United States Supreme Court requesting that the Court answer the following question, "[w]hether the express preemption provision of the Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a), preempts state-law claims seeking damages for injuries caused by medical devices that received premarket approval from the Food and Drug Administration."⁴⁰ The U.S. Supreme Court granted certiorari on June 25, 2007 and heard oral argument on December 4, 2007.⁴¹

The Riegels Overcame a Hurdle in the Supreme Court's Review

On August 1, 2007, Donna Riegel filed a Suggestion of Death and Motion for Substitution.⁴² Mr. Riegel passed away in

claims are not discussed in this article as they are not at issue before the U.S. Supreme Court.

³⁸ *Id.* at 122.

³⁹ *Id.* at 123.

⁴⁰ See Petition for a Writ of Certiorari in Riegel v. Medtronic, Inc., __ U.S. __, 127 S. Ct. 3000, __ L.Ed.2d __ (2007).

⁴¹ Riegel v. Medtronic, Inc., __ U.S. __, 127 S. Ct. 3000, __ L.Ed.2d __ (2007).

⁴² See Donna Riegel's Suggestion of Death and Motion for Substitution in Riegel v. Medtronic, Inc., __ U.S. __, 127 S. Ct. 3000, __ L.Ed.2d __ (2007).

December, 2004, well before the Petition for Writ of Certiorari was filed. Medtronic filed a Response to the Motion for Substitution and requested that the Court deny the motion as untimely, deem Mr. Riegel's claims as having abated and dismiss the writ as improvidently granted.⁴³ On October 1, 2007, the Supreme Court granted the Riegels' Motion for Substitution.⁴⁴ Donna Riegel now proceeds as the Administrator of the Estate of Charles R. Riegel.

Briefs Filed Opposing Preemption

Other amicus briefs, including briefs from Senator Edward M. Kennedy and Representative Henry A. Waxman and a number of other states, were filed asserting the position that state law damages claims stemming from injuries due to a PMA approved device are not preempted. In asserting this position, those briefs rely on one or more of the following arguments: (1) Congress did not intend to preempt damages claims; (2) *Lohr* is similar to this case and therefore, the Supreme Court should follow *Lohr* and not preempt the defective design, defective manufacture, or failure to warn claims; (3) Even assuming that there are federal requirements applicable to the Evergreen Balloon Catheter, the design defect and inadequate warning claims are based on duties equivalent to federal standards, and thus should not be preempted; and (4) PMA approved devices injure many people and if the Supreme Court preempts claims, the injured will be left without a remedy. In addition, the States contend that the

⁴³ See Medtronic's Response to Motion for Substitution in Riegel v. Medtronic, Inc., __ U.S. __, 127 S. Ct. 3000, __ L.Ed.2d __ (2007).

⁴⁴ See Order of the Supreme Court dated October 1, 2007 in Riegel v. Medtronic, Inc., __ U.S. __, __ S. Ct. __, __ L.Ed.2d __, (2007) WL 2819701 (Mem) (U.S.); The Chief Justice and Justice Scalia denied the motion because it was filed more than six months after Mr. Riegel's death. *Id.*

Supreme Court should give no weight to the United States' position.

1. Congress Did Not Intend to Preempt Damages Claims

The primary argument is that Congress did not intend to preempt state tort suits. The legislative record reflects that the preemption provision was enacted to protect manufacturers from state regulatory programs, such as those that were in existence in California, which could subject the manufacturers to separate state requirements, in addition to federal requirements.⁴⁵ At the time of the enactment in the MDA, the Kennedy Brief states that Congress was aware of tort lawsuits involving medical devices.⁴⁶ The Kennedy Brief maintains that there is no suggestion anywhere in the legislative history to suggest that Congress considered preempting these state tort suits. Moreover, he argues, if Congress intended to preempt state lawsuits, Congress would have expressly done so. In fact, at the time the preemption provision was enacted, the Kennedy Brief maintains that the terminology used in the provision was understood by Congress not to include product liability litigation.⁴⁷

Indeed, the Riegels take the position that it would have been unprecedented for Congress to have preempted damages claims in 1976 without providing an alternate remedy. "The glaring absence in the legislative record of any suggestion that consumers would lose their only means of obtaining compensation for injuries caused by poorly designed or inadequately labeled PMA devices counsels against a finding of

preemption."⁴⁸ The States, in their amicus briefs, also take a similar position claiming that Congress' silence "takes on added significance in light of Congress' failure to provide any federal remedy for injuries, including deaths, caused by unsafe medical devices, the very danger that prompted the MDA's enactment."⁴⁹

Further, the Riegel's and Kennedy's briefs analyze § 360k(b) and contend that the word "requirement" in § 360k(b) should have the same meaning as in § 360k(a).⁵⁰ Section 360k(b) permits states to obtain an exemption from § 360k(a) for a state "requirement."⁵¹ Therefore, the Riegels state that it is implausible that "requirement" in section (b) would include state common-law damages claims.⁵² Moreover, the Riegel Brief points out that the FDA has previously interpreted the word "requirement" in § 360k(b) to apply to a "statute, rule, regulation or ordinance."⁵³ The Kennedy Brief makes this same argument, that it is not practical under § 360k(b) for a state to seek an exemption for a lawsuit.⁵⁴ Arguing statutory construction, the Kennedy Brief urges that Congress did not contemplate that the general preemption rule would apply to state tort lawsuits.⁵⁵ Therefore, the argument continues that since "requirement" in § 360k(b) must be limited to statutes and regulations, that same term

⁴⁸ Riegels' Brief at 19.

⁴⁹ Brief for the States of New York, Arizona, Arkansas, Connecticut, Delaware, Florida, Hawaii, Idaho, Illinois, Iowa, Kansas, Maryland, Massachusetts, Minnesota, Mississippi, Missouri, Montana, Nevada, New Mexico, North Dakota, Ohio, Oregon, South Carolina, Tennessee, Utah, Vermont, Washington, West Virginia, Wisconsin, Wyoming, and the District of Columbia in *Riegel v. Medtronic, Inc.*, ___ U.S. ___, 127 S. Ct. 3000, ___ L.Ed.2d ___ (2007) ("States' Brief") at 5 (citing *Silkwood v. Kerr-McGee corp.*, 464 U.S. 238, 251 (1984)).

⁵⁰ Kennedy Brief at 14-15; Riegels' Brief at 19.

⁵¹ Kennedy Brief at 12-13.

⁵² Riegels' Brief at 19.

⁵³ *Id.* at 19-20 (referring to 21 C.F.R. § 808.20(c)).

⁵⁴ Kennedy Brief at 9.

⁵⁵ *Id.* at 14-15.

⁴⁵ Brief for Petitioners in *Riegel v. Medtronic, Inc.*, ___ U.S. ___, 127 S. Ct. 3000, ___ L.Ed.2d ___ (2007) ("Riegels' Brief") at 16 (citing H.R. Rep. No. 94-853, at 45).

⁴⁶ Brief of Senator Edward M. Kennedy and Representative Henry A. Waxman in *Riegel v. Medtronic, Inc.*, ___ U.S. ___, 127 S. Ct. 3000, ___ L.Ed.2d ___ (2007) ("Kennedy Brief") at 15.

⁴⁷ *Id.* at 3.

in § 360k(a) must be limited in the same way.⁵⁶

It is also argued that there is a well-established presumption against preemption.⁵⁷ Respect for the States' role as "independent sovereigns in our federal system" gives rise to this presumption.⁵⁸ Health and safety traditionally fall within state power.⁵⁹ The "police powers" of the states are not superseded by federal law unless Congress' clear intent is evident.⁶⁰ The Riegels acknowledge in their brief that although the Court has held that the word "requirements" may include state common-law damages claims, there is no clear intent that Congress intended for the word "requirements" to include these claims.⁶¹

2. *Lohr* is Similar to *Riegels*

Although *Lohr* involved a § 510k-approved device, and the Evergreen Balloon Catheter is a PMA-approved device, the Riegels contend that the interpretation of § 360k(a) produces the same result and therefore, the damages claims should not be preempted.⁶² Even though both the § 510k and PMA processes apply to Class III medical devices, neither specifies how a Class III medical device should be designed, labeled, or manufactured. The Riegels and the States both assert that the FDA does not mandate specific federal "requirements" for the design or labeling of a device. Instead, a medical device manufacturer is able to select any design and labeling features, so long as they satisfy the "general minimum standards" of the

federal regulations.⁶³ It is acknowledged that a PMA may have a preemptive effect, but only if there is an additional, different state PMA requirement for the same device.⁶⁴

A device manufacturer may obtain permission from the FDA, through a PMA supplement, to alter the device's design.⁶⁵ In fact, the Riegels point out that Medtronic filed two PMA supplements to make design changes and market new models, and the FDA approved both.⁶⁶ Therefore, the Riegels argue that it is evident that the FDA did not impose specific "requirements" for the design of the Evergreen Balloon Catheter. Accordingly, similar to *Lohr*, the design defect claim should not be preempted because the FDA has not issued any specific design requirements for the Evergreen Balloon Catheter.⁶⁷

Similarly, a device manufacturer may obtain permission from the FDA, through a PMA supplement, to alter a device's label. Labeling changes that would enhance the safety of a device can be made prior to receiving FDA approval. Medtronic filed two PMA supplements requesting permission to alter its label, and the FDA approved both.⁶⁸ The Riegels maintain that PMA did not impose specific labeling "requirements." Instead, the FDA regulation governing the content of the label is 21 C.F.R. § 801.09, the same regulation the Riegels point out was found too general to warrant preemption of the failure to warn claim in *Lohr*.⁶⁹

Further, the existence of a precondition, such as PMA supplemental approval, to change a device is not, in the States' opinion, tantamount to a "requirement."⁷⁰ The States argue that since it is the device manufacturer who makes the decision

⁵⁶ *Id.*

⁵⁷ Riegels' Brief at 21 (citing *Lohr*, 518 U.S. at 485).

⁵⁸ States' Brief at 2 (citing *Lohr*, 518 U.S. at 485-86).

⁵⁹ *Id.* (referring to *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 715 (1985)).

⁶⁰ Riegels' Brief at 21 (citing *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 814 n. 8 (1997)).

⁶¹ *Id.* at 22 (citing *Bates*, 544 U.S. at 443).

⁶² *Id.* at 23.

⁶³ *Id.* at 4-5; States' Brief at 13-15.

⁶⁴ Riegels' Brief at 25.

⁶⁵ *Id.* at 29 (citing 21 C.F.R. § 814.39).

⁶⁶ *Id.*

⁶⁷ *Id.* at 13.

⁶⁸ *Id.* at 31.

⁶⁹ *Id.* at 30 (citing *Lohr*, 518 U.S. at 497-501).

⁷⁰ States' Brief at 15.

whether to seek PMA supplemental approval, “it would create perverse incentives against device improvement to allow a manufacturer to rest on its initial FDA approval in any future state law tort suit, on the theory that federal law ‘required’ the manufacturer to maintain the approved design and labeling.”⁷¹

Since the federal law’s lack of device specificity as to Evergreen Balloon Catheter is dispositive under *Lohr*, and therefore, there are no federal device specific requirements, the Riegels contend that the Court should not reach the question of whether the state law claims fall within the scope of § 360k(a).⁷² However, if the Court were to analyze whether the state law claims fall within § 360k(a), the Riegels assert that the claims would not impose state law “requirements” under § 360k(a).⁷³ The Riegels rely on the *Lohr* majority who held that state laws of general applicability (e.g., general duties to warn users of potential risks and to use due care in manufacturing a product), as opposed to laws specifically applicable to medical devices, are not preempted by the MDA.⁷⁴

3. Design Defect and Inadequate Warning Claims Have Equivalent Standards

The Court in *Lohr* held that § 360k(a) does not preempt state law claims that parallel federal requirements.⁷⁵ The Riegels make this same argument in their brief.

The Riegels maintain that a design defect claim under New York law (the controlling substantive law for the *Riegel* case) and federal law are similarly premised.⁷⁶ They both prohibit marketing a device in which the design is unreasonably

dangerous.⁷⁷ Although the remedies under New York law and federal law for marketing an unreasonably dangerous product are different, the Riegels’ position is that a difference in remedies does not equate to imposing different or additional requirements within the meaning of § 360k(a).⁷⁸ The Riegels suggest that a state verdict based on a finding that a device is not reasonably safe is consistent with federal law.⁷⁹

Similarly, the Riegels assert that their inadequate warning claim seeks to enforce parallel duties under New York law and under the MDA’s general labeling rules. They both command instructions and warnings that adequately provide for the safe use of a device. It is the Riegels’ position that a state verdict that holds Medtronic liable for failing to revise the label once it became aware that the label was inadequate would not impose an additional requirement within the meaning of § 360k(a) on Medtronic.⁸⁰

The States’ brief further argued that the FDA does not prescribe mandatory standards for a medical device by approving its PMA application.⁸¹ Moreover, FDA approval does not signify that federal law disfavors changing the medical device’s design or label.

4. If the Court Preempts Claims, the Injured Will Be Left without a Remedy

A PMA is required for life-sustaining devices and those that present the greatest risk of causing injury.⁸² The Riegels assert that those devices cause many injuries which result in multiple lawsuits. The Riegels’ brief recounts several examples of PMA devices that have caused injuries.

⁷¹ *Id.*

⁷² Riegels’ Brief at 34.

⁷³ *Id.*

⁷⁴ *Id.* at 35 (citing *Lohr*, 518 U.S. at 501-02).

⁷⁵ *Id.* at 39 (citing *Lohr*, 518 U.S. at 495).

⁷⁶ *Id.* at 40 (comparing *Voss v. Black & Decker Mfg. Co.*, 450 N.E.2d 204, 207 (N.Y. 1983) with 21 U.S.C. § 360e(d)(2)(A), (B)).

⁷⁷ *Id.*

⁷⁸ *Id.* at 41 (citing *Lohr*, 518 U.S. at 513).

⁷⁹ *Id.* at 40.

⁸⁰ *Id.* at 42-43.

⁸¹ States’ Brief at 14.

⁸² Riegels’ Brief at 43 (citing 21 U.S.C. § 360a(a)(1)(C)).

They point out that neither the MDA or any other federal law provides any means for the injured to recover from these devices. They state, “[w]here the federal regulatory scheme does not provide a damages remedy, the Court has ascribed preemptive intent to Congress only in the most compelling circumstances.”⁸³ According to the Riegels, no compelling circumstances exist with respect to PMA devices. Moreover, the States’ maintain that the threat of product liability suits creates a continuing incentive for the device manufacturers to improve the safety of their device, even after receiving a PMA.⁸⁴

5. The Supreme Court Should Give No Weight to the United States’ Position

The States contend that the Supreme Court should give no weight to the position of the United States (“U.S.”).⁸⁵ The U.S., in its amicus brief, asserts that FDA approval displaces all state product liability claims, except claims that allege a device manufacturer failed to adhere to the specifications in its application. First, the States point out that the Supreme Court has generally not granted deference to an agency’s position on the preemptive scope of a federal statute. Second, the U.S.’s current view of preemption was developed and asserted during the scope of litigation. It was not developed through notice-and-comment procedures which would have afforded Members of Congress, the States and other interested parties an opportunity to provide their opinions. Further, the U.S. has not voiced the same opinion in the past. Until 2004, it was the U.S.’s position that the FDA did not preempt state product liability suits for injuries caused by a device.⁸⁶ Yet another reason the States

provide for giving no weight to the U.S.’s position is that it is based on an anachronism.⁸⁷ In 1994, when the FDA approved the Evergreen Balloon Catheter, the FDA was approving that the Evergreen Balloon Catheter was minimally safe and that state product liability suits would operate to provide incentive for Medtronic to continue to improve the device. According to the States, the FDA did not intend, as its position is today, that the approval of the Evergreen Balloon Catheter established specific device requirements that provided both a floor and a ceiling as to its safety and effectiveness.⁸⁸

Briefs Filed Supporting Preemption

The U.S. filed its brief in response to the Supreme Court’s Order inviting the solicitor general to file a brief expressing the views of the United States.⁸⁹ The U.S. requested that the Supreme Court deny certiorari.⁹⁰ The U.S.’s position is that the Second Circuit Court of Appeals correctly decided that § 360(k) preempts state common-law claims regarding PMA-approved devices.⁹¹ The U.S. emphasizes the previously accepted public policy that “the FDA’s views on preemption questions under 21 U.S.C. 360k are entitled to ‘substantial weight.’”⁹²

The arguments in support of preemption, bolstered by the U.S.’s position, include (1) FDA premarket approval of a Class III device imposes federal “requirements;” (2) *Lohr* can be differentiated because the devices underwent different FDA review processes; (3) the majority of cases involving Class III devices are not preempted; and (4) there is a

⁸³ *Id.* at 46 (referring to *English v. General Elec. Co.*, 496 U.S. 72, 87-90 (1990)).

⁸⁴ States’ Brief at 21.

⁸⁵ *Id.* at 22.

⁸⁶ *Id.* at 24 (referring to Brief for United States as Amicus Curiae in Opposition to Certiorari, Kernats (No. 96-1405)).

⁸⁷ *Id.* at 25.

⁸⁸ *Id.*

⁸⁹ Brief for the United States as Amicus Curiae in Opposition to Petition for a Writ of Certiorari filed in *Riegel v. Medtronic, Inc.*, __ U.S. __, 127 S.Ct. 3000, __ L.Ed.2d __ (2007) (“U.S. Brief”) at 1.

⁹⁰ *Id.* at 20.

⁹¹ *Id.* at 1.

⁹² *Id.* at 10.

need for national uniformity in overall public health; otherwise, device manufacturers will be subject to varying standards which will cause chaos and uncertainty in the design and manufacture of devices.⁹³

1. FDA Premarket Approval of a Class III Device Imposes Federal “Requirements”

The U. S. confirms that the FDA’s premarket approval of a Class III medical device imposes federal “requirements” applicable to a particular device that precludes the imposition of additional state-law requirements based on tort liability.⁹⁴ The Brief filed by the United States explains that the rigorous FDA approval process is subject to the “most stringent regulatory controls,” including an average of 1,200 hours of agency review time compared to the § 510(k) that averages about twenty hours of review.⁹⁵ More importantly, in addition to the lengthier time for review, this approval is premised on the agency’s finding that there is reasonable assurance that the device is safe and effective under the conditions of use prescribed in the labeling.⁹⁶ Once approved, the manufacturer cannot lawfully implement any changes that would affect the safety or efficacy of the device without submitting a supplemental application to the FDA.⁹⁷ Therefore, an approval of a Class III device under the FDA’s rigorous PMA review process imposes federal requirements that should be given preemptive effect.⁹⁸

⁹³ Medtronic Brief Opposing Certiorari filed in *Riegel v. Medtronic, Inc.*, ___ U.S. ___, 127 S. Ct. 3000, ___ L.Ed.2d __ (2007) (“Medtronic Brief”) at 2.

⁹⁴ U. S. Brief at 10.

⁹⁵ *Id.* at 8 (referring to *Lohr*, 518 U.S. at 478-79).

⁹⁶ *Id.* at 10. *See also* Letter Brief of the United States, *Horn v. Thoratec*, 2004 WL 1143720 at 8.

⁹⁷ *Id.* at 11.

⁹⁸ *Id.* at 19; Medtronic Brief filed in *Riegel v. Medtronic, Inc.*, 451 F.3d 104 (2d Cir 2006) (Medtronic 2nd Cir. Brief) at 10-11.

Medtronic argues that the Evergreen Balloon Catheter, approved through this comprehensive PMA process, was approved for the specific design, labeling, and manufacturing process in its PMA application.⁹⁹ Further, in doing so, the FDA imposed strict federal requirements that Medtronic comply with the approved specifications coupled with the prohibition against modifying them. Medtronic urges that every aspect of the design, labeling, and manufacturing process of the device became a specific federal requirement that should be given preemptive effect.

The U.S. advised the Court of its opinion that judgments in state lawsuits could impose a state requirement different from the federal requirements that the FDA imposed and, therefore, are preempted.¹⁰⁰ The majority of Justices in *Lohr* acknowledged that “state tort law judgments can impose a requirement for purposes of preemption under the MDA when a common law action would impose a requirement different from or in addition to, that applicable under the FDCA.¹⁰¹ Specifically, Justice Breyer in his concurring opinion stated that “[one] can reasonably read the word ‘requirement’ as including the legal requirements that grow out of the application, in particular circumstances, of a State’s tort law.”¹⁰²

As additional argument, Medtronic argues that the legislative history of the MDA establishes that Congress intended extensive preemption of state tort lawsuits under § 360k. Medtronic explains that the House Committee Report for the MDA establishes that the preemption provision was intended to be a “general prohibition on non-Federal regulation.”¹⁰³ Allowing the

⁹⁹ *Id.* at 6.

¹⁰⁰ U.S. Brief at 19; U.S. Brief in *Horn*, 2004 WL at *11 and *13.

¹⁰¹ *Lohr*, 518 U.S. at 488, 509 (Justice O’Connor with whom the Chief Justice, Justice Scalia, and Justice Thomas join).

¹⁰² *Id.* at 504.

¹⁰³ Medtronic 2nd Cir. Brief at 18 (citing H.R. Rep. No. 853, 94th Cong. 2nd Sess. 45 (1976)).

Medtronic medical device to be subjected to state law tort claims would impose state law requirements on Medtronic that would conflict with the federal requirements already applicable to the device.¹⁰⁴

2. *Lohr* Can be Differentiated Because the Devices Underwent Different FDA Clearances

An argument is also made that even though the Court did not preempt the claims in *Lohr*, the Court should preempt the claims in this case because the medical devices at issue in both cases underwent different FDA review processes. The facts in *Riegel* are differentiated because *Riegel* involves a PMA-approved device while the device in *Lohr* went through the § 510(k) notification process only.¹⁰⁵

The Supreme Court described the manufacturer's defense in *Lohr* as being one which "exaggerates the importance of the [substantial equivalence] process," as the device at issue was never formally reviewed by the FDA under the MDA for safety or efficacy.¹⁰⁶ The U.S. also notes the majority's reliance on the FDA's own admonition that its substantial-equivalence determination "should not be construed as an endorsement of the device's safety."¹⁰⁷ According to the majority opinion in *Lohr*, the § 510(k) process was intended only to maintain the status quo which included the possibility that a device manufacturer would have to defend against state law claims.¹⁰⁸

In contrast to *Lohr*, the device in *Riegel* was approved through the more rigorous PMA review.¹⁰⁹ Medtronic points out that this approach is consistent with the analysis in *Lohr*, where the majority took some time to differentiate the two FDA processes. This PMA approval process includes

specific requirements, which, in this case, preempts state law.

3. Riegels' Assertion that the Injured are Left Without a Remedy is Without Merit

Medtronic points out that the Riegels raise a red herring when they assert that the injured will be left without a remedy.¹¹⁰ The Second Circuit Court of Appeals noted the relatively small subset of PMA-approved devices in contrast to the much larger population of § 510(k) cleared devices.¹¹¹ Medtronic further notes that the Second Circuit Court's decision did not apply "to the vast majority of Class III devices, 99% of which enter the market via the less-exacting 510(k) process."¹¹² Moreover, the Second Circuit held that not all state tort claims as to PMA-approved devices are preempted.¹¹³ Therefore, the vast majority of claims are not preempted.

Moreover, Medtronic argues, the preemptive effect of the PMA process enhances the safety of medical devices and acts as an incentive to manufacturers to subject their products to the rigorous PMA process rather than the substantially more relaxed § 510(k) notification process.¹¹⁴ If PMA-approved devices become subject to numerous state law products liability claims, there would be substantially less motivation for manufacturers to undergo the rigorous, time-consuming, and costly PMA process for devices that could be cleared pursuant to the § 510(k) review.¹¹⁵

4. Need for National Uniformity

The U.S. further argues that the FDA is the "expert agency" charged by Congress

¹⁰⁴ *Id.* at 29.

¹⁰⁵ U.S. Brief at 8-9.

¹⁰⁶ U.S. Brief at 9.

¹⁰⁷ *Id.* at 8-9 (citing *Lohr*, 518 U.S. at 492-93).

¹⁰⁸ *Lohr* 518 U.S. at 494.

¹⁰⁹ *Id.* at 496.

¹¹⁰ Medtronic Brief at 28.

¹¹¹ *Riegel*, 451 F. 3d at 118.

¹¹² Medtronic Brief at 28.

¹¹³ *Id.* (referring to *Riegel*, 451 F.3d at 118).

¹¹⁴ Medtronic Merits Brief filed in *Riegel* v.

Medtronic, Inc., __ U.S. __, 127 S. Ct. 3000, __ L.Ed. 2d __ (2007) ("Medtronic Merits Brief").

¹¹⁵ *Id.*

with balancing the risks and benefits of medical devices under the FDCA.¹¹⁶ The FDA employs such experts to conduct an in-depth evaluation of the safety and efficacy of Class III PMA-approved devices.¹¹⁷ Moreover, the FDA is vested with centralized authority to promote uniformity of regulations and to decide whether exceptions to preemption of state law should be permitted.¹¹⁸ Medtronic warns that lay juries are ill equipped to evaluate the safety and effectiveness of medical devices.¹¹⁹ Whereas a jury decides a particular case in isolation, the FDA takes a broad public health view and balances the risk and benefits that would be experienced by large classes of patients.¹²⁰ For that reason, Congress gave the FDA exclusive responsibility for making such evaluations.¹²¹

The U.S. thereby advances the argument that the regulatory scheme established by Congress and accomplishment of its regulatory goals will be undermined if lay judges or juries are permitted to second-guess the scientific judgments the FDA makes in approving a PMA application.¹²² Similarly, Medtronic cautions that allowing plaintiffs' claims to proceed to juries to impose their own ad hoc requirements contrary to those set up by the FDA would "guarantee chaos in the controlling standards, unprincipled second guessing of FDA regulatory enforcement decisions, and a flood of scientifically dubious warnings."¹²³

In supporting its position, Medtronic cites the American Medical Association ("AMA") statement regarding the "pernicious public health consequences" of

imposing state law liability on manufacturers of Class III medical devices.¹²⁴ Medtronic keys in on the AMA's recognition of the profound impact that product liability is having on the development of new medical technologies.¹²⁵ Specifically, according to the AMA, innovative new products are not being developed or are being withheld and certain older technologies are being removed from the market because liability suits have exposed manufacturers to unacceptable financial risks.¹²⁶ As a result, Medtronic argues, imposing state law liability on manufacturers of PMA-approved medical devices could decrease the availability of these life-saving devices to patients dependent on such devices for life-sustaining treatment.¹²⁷

Additionally, notes Medtronic, the Eighth Circuit has recognized that this broad prohibition on regulation through litigation stems from the need for national uniformity in an area where risks and benefits to patients require the FDA's expert judgment, one of the explicit goals of the MDA.¹²⁸ Congress sought to "shield medical devices from the 'undue burden' imposed by differing state regulations to protect innovations in device technologies from being shelved by unnecessary restrictions."¹²⁹ "[I]f 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."¹³⁰ A contrary rule would

¹¹⁶ U.S. Brief at 13.

¹¹⁷ Medtronic 2nd Cir Brief at 8; FDA's amicus letter brief in *Horn v. Thoratec*, 2004 WL 1143720 at *6-*12.

¹¹⁸ U.S. Brief at 16.

¹¹⁹ Medtronic Merits Brief at 44-45.

¹²⁰ *Id.* at 45.

¹²¹ *Id.*

¹²² U. S. Brief at 13.

¹²³ Medtronic 2nd Cir Brief at 14-15.

¹²⁴ Medtronic Merits Brief at 47-48.

¹²⁵ *Id.* At 48 citing Am. Med. Ass'n, Report of Board of Trustees: Impact of Product Liability on the Development of New Medical Technologies 1 (1988).

¹²⁶ *Id.*

¹²⁷ *Id.* at 49.

¹²⁸ Medtronic 2nd Cir. Brief at 14-15.

¹²⁹ Medtronic Brief at 2 (citing *H. R. Rep. No. 94-853* at 12 (1976)).

¹³⁰ *Id.*

undermine overall public health protection and the regulatory scheme authorized.¹³¹

Oral Argument Before the Supreme Court

The December 4, 2007 argument before the United States Supreme Court reveals the need for clarification in this hotly contested area. Chief Justice Roberts launched the first salvo to Allison Zieve, regarding the FDA requirements that the manufacturer alert the FDA to new information if there are problems that come to light only after the device is approved.¹³² He also noted that the FDA can pull back the pre-market approval if the problems required it to do so. Justice Scalia joined in and further interrogated Ms. Zieve regarding the requirement that the manufacturer obtained FDA approval prior to marketing a device in which the manufacturer wants to make an improvement, even if the change is designed to improve safety and effectiveness.¹³³ Emphasizing the difference between the process in *Lohr* and the PMA process in this case, Justice Scalia explained that the FDA in *Lohr* “never made a determination of weighing the risks against the benefits, as they do for the issuance of PMA’s. And so the jury was not replowing the same ground that the FDA had already plowed in *Lohr*.¹³⁴ Also weighing in, in apparent favor of preemption, Justice Kennedy compared the process the jury undertakes in determining its verdict to what the FDA does during the PMA process.¹³⁵ He pointed out that the FDA is specifically charged with weighing the risks against the probable benefits. Chief Justice Roberts also asked Ms. Zieve what would happen under her theory if

there is a better device and the manufacturer does not want to risk tort suits. Do they stop selling the old device that’s been approved, even though there is no defect and wait for the FDA approval “that might take forever or at least a year...”¹³⁶ “What happens to patients in that year? They’ve got no device.”¹³⁷

Evidently taking up the oar opposing preemption, Justice Ginsburg compared preemption for PMA devices with the lack of preemption for new drugs, a process that the FDA looks at very closely.¹³⁸ She further questioned counsel for Medtronic regarding what is the heart of this issue, whether the language in the express preemption provision was meant to do any more than limit the states from enacting requirements that conflict with the FDA requirements.¹³⁹

Summarizing what typically occurs in medical products cases, Justice Breyer commented that “it’s a terrible thing when somebody is hurt in these kinds of accidents. And the lawyers are trying to help. So the lawyers will think, look, there’s a problem here. There must be. My client was seriously hurt... And then they’ll work backward from that and say well if he was hurt, there must be something wrong with the design.” He continued by questioning “...could Congress have intended that kind of thing when what they’re trying to do is have a group of experts really look into this and decide whether it should be marketed or not.”¹⁴⁰

Probably the best policy argument in favor of preemption for PMA-approved devices was voiced by Justice Scalia, when he stated: “What’s going on is simply one jury has decided that in its judgment, there was a safer device that should have been used; and because of the judgment of that one jury, the manufacturer is placed at risk in selling a device that scientists at the FDA

¹³¹ Letter Brief of the United States in *Horn v. Thoratec*, 2004 WL 1143720; U. S. Brief at 13.

¹³² Riegel Oral Argument Transcript at 4. Allison Zieve is counsel for the petitioner and attorney with Public Citizen Group.

¹³³ *Id.* at 5, Justice Scalia.

¹³⁴ *Id.* at 8, Justice Scalia.

¹³⁵ *Id.* at 6, Justice Kennedy.

¹³⁶ *Id.* at 17-18.

¹³⁷ *Id.* at 18.

¹³⁸ *Id.* at 8-9, Justice Ginsburg.

¹³⁹ *Id.* at 42.

¹⁴⁰ *Id.* at 23, Justice Breyer.

have said is okay. I find that extraordinary.”¹⁴¹

The questions and discussion presented by the Justices suggest that the Court will uphold preemption for devices approved under § 360k(a) of the Medical Device Amendments and provide further guidance for the application of the preemption defense. Not surprisingly, however, the argument also indicates it will be a divided Court.

Conclusion

Contrary to the Riegels’ assertion that the lower courts are “deeply divided” on this issue, the overwhelming weight of authority is in line with the Second Circuit’s position.¹⁴² In fact, only the Eleventh Circuit and the Illinois Supreme Court have found that the PMA approval was not preemptive.¹⁴³ The Supreme Court must now decide whether it agrees with Medtronic’s position, the position of the U.S., and the decisions of the Second, Third, Fifth, Sixth, Seventh, and Eighth Circuits, as well as those of Pennsylvania, Rhode Island, and the Texas Supreme Courts.¹⁴⁴ Either way, the decision will significantly impact device litigation.

¹⁴¹ *Id.* at 19.

¹⁴² Medtronic Brief at 12-13.

¹⁴³ *Id.* at 14 (referring to *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999) and *Weiland v. Telectronics Pacing Systems, Inc.*, 721 N.E.2d 1149 (Ill. 1999)).

¹⁴⁴ *Horn v. Thoratec Corp.*, 376 F.3d 163 (3rd Cir. 2004); *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001); *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000); *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997); *Brooks v. Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001); *Green v. Dolsky*, 685 A.2d 110, 117 (Pa. 1996); *Fry v. Allergan Med. Optics*, 695 A.2d 511, 516 (R.I. 1997); *Worthy v. Collagen Corp.*, 967 S.W.2d 360, 376 (Tex. 1998).