

HORN V. THORATEC CORP.,
A “HEARTLESS” DECISION:
WHY PRE-MARKET APPROVAL DOES NOT
PREEMPT ALL STATE TORT CLAIMS
AGAINST MEDICAL DEVICE
MANUFACTURERS

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INTRODUCTION

Imagine that you urgently need a life-saving medical device. What questions would you ask your physician? Would you want to know what your available options are? Would you ask if the model that your doctor selected has ever been reported to fail? Would you ask how thoroughly the Food and Drug Administration (“FDA”) investigated the selected device before approving it for sale in the United States? Most Americans are unaware of the importance of asking any or all of these questions.¹ Most of us would simply trust the choice of our physician, believing that he or she is sufficiently informed about the device’s safety profile to make the best choice.² In addition, most Americans assume that the FDA would not permit a manufacturer to market a device that was unsafe or negligently designed.³ However, like any other administrative agency, the FDA has limited financial and human resources. Sometimes, despite the most thorough evaluation possible, a device poses

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¹ See Roger W. Bivans, *Substantially Equivalent? Federal Preemption of State Common-Law Claims Involving Medical Devices*, 74 TEX. L. REV. 1087, 1087 (1996).

² See *id.*

³ See *United States v. Chatterji*, 46 F.3d 1336, 1344 (4th Cir. 1995) (Murnaghan, J., dissenting) (arguing that the public relies on FDA approval to feel safe when taking medications); Bivans, *supra* note 1, at 1087 (asserting that patients do not question the quality of medical devices given that the federal government tests these products for safety).

risks that were not evident during the FDA approval process.⁴ Tragically, those risks can result in serious injury or even death to the patient.

Imagine further that because of a defect undetected by both the manufacturer and the FDA you have been seriously injured by the very device that was meant to restore your health. Yet, you are told that you have no recourse in the American legal system because the FDA's approval of the device bars your claims against the manufacturer via the legal doctrine of preemption. This is precisely what happened in the recent Third Circuit case, *Horn v. Thoratec Corp.*⁵

In January 1998, Daniel Horn suffered a heart attack.⁶ A week later, a medical device, known as the HeartMate, was implanted into his body to aid blood circulation through his heart.⁷ Because of a defect in the device, air entered the closed system and an air embolus traveled to Mr. Horn's brain, ultimately causing his death.⁸ Mrs. Horn, as executor of Mr. Horn's estate, brought common law tort claims against the manufacturer in the United States District Court for the Middle District of Pennsylvania.⁹ The district court dismissed the case, finding Mrs. Horn's state claims preempted because they would impose requirements on the manufacturer that were different from, or in addition to, the requirements imposed by the FDA's

⁴ See *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 236–37 (6th Cir. 2000) (discussing the plaintiff's potential claim for breach of the manufacturer's duty to warn of risks discovered subsequent to FDA approval of a device); see also *Stupak v. Hoffman-La Roche, Inc.*, 287 F. Supp. 2d 968, 974–75 (E.D. Wis. 2003) (accepting plaintiff's causation argument based on an acne drug manufacturer's failure to warn of risk of suicidal ideation where risk became evident after FDA approval of the drug); *Enlow v. St. Jude Med., Inc.*, 171 F. Supp. 2d 684, 691 (W.D. Ky. 2001) (stating that warnings about risks first identified after the FDA has granted pre-market approval of a medical device still require FDA approval); *Kociemba v. G.D. Searle & Co.*, 683 F. Supp. 1579, 1580 (D. Minn. 1988) (noting that the FDA regulation requiring a warning about the risk of pelvic inflammatory disease associated with defendant manufacturer's medical device was not enacted until after FDA approval of the device).

⁵ 376 F.3d 163 (3d Cir. 2004).

⁶ *Id.* at 165.

⁷ *Id.*

⁸ See *id.*

⁹ See *id.* (stating that the complaint alleged claims for defective design and manufacture of the HeartMate and failure to warn of the device's alleged defects).

approval process.¹⁰ On appeal, the Court of Appeals for the Third Circuit affirmed the district court's ruling.¹¹

This Comment proposes that the Third Circuit was too hasty in finding that Mrs. Horn's state tort claims were preempted by the Medical Device Amendments to the Food, Drug and Cosmetic Act ("MDA"). Part I will explain the background of the MDA and the preemption defense, and will describe the *Horn* decision. Part II will demonstrate that the presumption against preemption, as informed by the legislative intent and the statutory structure of the MDA, supports the conclusion that Mrs. Horn's state tort claims should not have been deemed preempted. Part III will discuss the importance of the FDA's view of preemption and will show that FDA regulations require a court to evaluate a plaintiff's tort claims individually before finding preemption. Part IV will illustrate that the *Horn* court did not adequately evaluate the nature of each of Mrs. Horn's tort claims to determine whether they would impose requirements different from or in addition to those imposed by the FDA. Finally, a more exhaustive analysis of Mrs. Horn's claims will show that some—but not necessarily all—of the claims should have survived preemption.

I. MDA PREEMPTION OF STATE CLAIMS IN *HORN V. THORATEC*

A. *Background of the Preemption Defense and the Medical Device Amendments*

The American tort system has two major functions. First, it is a "vehicle of legal redress" for victims who have been injured at the hands of another.¹² Second, it deters wrongful or negligent conduct with the threat of large damage awards.¹³ Within this system, every manufacturer is under a common law duty to use due care to avoid foreseeable dangers in the products that it sells.¹⁴ However, where the product at issue is federally

¹⁰ *See id.*

¹¹ *Id.* at 164.

¹² VINCENT R. JOHNSON & ALAN GUNN, *STUDIES IN AMERICAN TORT LAW* 3 (3d ed. 2005). There is a strong public interest in providing a means for accident victims to obtain compensation for their injuries from the party responsible for the harm. *See id.* at 9.

¹³ *See DeLoach v. Alfred*, 960 P.2d 628, 632 (Ariz. 1998) (en banc) (stating that tort liability is a powerful tool in deterring future dangerous behavior).

¹⁴ *See Michael Weinberger, Federal Preemption and Product Liability*, N.Y. L.J.,

regulated, manufacturers often argue that state common law tort claims must be preempted by the federal regulation.¹⁵

Preemption is the doctrine under which federal law supersedes state law by operation of the Supremacy Clause of Article VI of the United States Constitution.¹⁶ When a court upholds the preemption defense in a products liability controversy, the injured party is often left with no legal recourse.¹⁷ Therefore, it is imperative that a court evaluate Congress' intended scope of preemption,¹⁸ each of the plaintiff's claims, and the applicable federal requirement before deciding that a conflict exists.

Congress enacted the MDA in 1976 in response to injuries caused by a contraceptive device known as the Dalkon Shield.¹⁹ With new, more complicated devices entering the market, Congress sought to protect the public health by "assur[ing] the reasonable safety and effectiveness of medical devices intended for human use."²⁰ Although Congress also noted its intention to encourage the development of new medical devices by instituting a uniform regulatory scheme, commentators have recognized that

Apr. 18, 1997, at 1 (discussing the general requirement that every manufacturer exercise reasonable care in designing and manufacturing a product); *see also* *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 501 (1996) (describing the general duties of manufacturers).

¹⁵ The defense of preemption asserts that an act of Congress expressly or impliedly preempts any and all requirements that conflict with requirements placed on the product by a federal agency or enactment. *See* *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) ("[I]t has been settled that state law that conflicts with federal law is 'without effect.'" (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981))); *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383 (1992).

¹⁶ *See* KATHLEEN M. SULLIVAN & GERALD GUNTHER, *CONSTITUTIONAL LAW* 324 (15th ed. 2004); *see also* U.S. CONST. art. VI, cl. 2 ("[T]he 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.").

¹⁷ *See* Betsy J. Grey, *Make Congress Speak Clearly: Federal Preemption of State Tort Remedies*, 77 B.U. L. REV. 559, 562 (1997).

¹⁸ *See id.* at 566–69 (explaining that the Supreme Court's preemption analysis requires either a "clear statement" of congressional intent to preempt, or implied preemption due to the impossibility of complying with both state and federal law).

¹⁹ *Id.* at 583. The Dalkon Shield caused many serious injuries during the 1960s and early 1970s, including deaths, infections, infertility, and inadvertent pregnancies. *See Id.*; David C. Vladeck, *Federal Preemption of State Tort Law: the Problem of Medical Drugs and Devices*, 33 PEPP. L. REV. 95, 103 (2005).

²⁰ Grey, *supra* note 17, at 583 (quoting H.R. REP. NO. 94-1090, at 51 (1976) (Conf. Rep.), *as reprinted in* 1976 U.S.C.C.A.N. 1070, 1103).

the chief goal of the MDA was the protection of public health.²¹

Section 360k(a) of the MDA explicitly preempts any requirement established by a state or political subdivision “with respect to” a medical device, “which is different from, or in addition to, any [federal] requirement applicable under [the statute] to the device.”²² Congress’ use of the word “requirement” as it refers to state action has been a source of fierce litigation and debate.²³ The central issue of the debate is whether Congress intended state “requirements” to include only state legislative and administrative enactments or to encompass state common law tort remedies as well.²⁴

In addition, courts have diverged about how specific to a particular device the state and/or federal requirements must be

²¹ See Anne-Marie Dega, *The Battle over Medical Device Regulation: Do the Federal Medical Device Amendments Preempt State Tort Law Claims?*, 27 LOY. U. CHI. L.J. 615, 624–25 (1996).

²² 21 U.S.C. § 360k(a)(1) (2000).

²³ A split remains among the United States circuit courts over whether the MDA preempts state tort claims. Before the Third Circuit decision in *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004), the Tenth Circuit in *Oja v. Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997), held that the plaintiff’s tort claims were not preempted by the MDA because they would not impose device-specific state requirements on the device in issue. *Id.* at 789. Similarly, in *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999), the Eleventh Circuit held that the FDA’s pre-market approval of the defendant’s medical device imposed no device-specific federal requirement and preemption did not apply. *Id.* at 1382. Following the *Horn* decision, the Sixth and Seventh Circuits joined the Third Circuit’s rationale and held the plaintiffs’ state tort claims preempted by the pre-market approval of the defendant’s medical devices. *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 490 (7th Cir. 2005); *Cupek v. Medtronic, Inc.*, 405 F.3d 421, 425 (6th Cir. 2005). Notably, the Supreme Court denied petitions for certiorari in both *McMullen* and *Cupek*; thus, the split remains. *McMullen v. Medtronic, Inc.*, 126 S. Ct. 1464, 1464 (2006) (denying certiorari); *Knisley v. Medtronic, Inc.*, 126 S. Ct. 420, 420 (2005) (denying certiorari).

²⁴ See Suzanne Darrow Kleinhaus, *Medtronic v. Lohr: For Want of a Word, the Patient Was Almost Lost—Fixing the Mischief Caused in Cipollone by Dividing the Preemption Stream*, 53 FOOD & DRUG L.J. 297, 298 (1998) (commenting on the “mischief” created by the interpretation of the word “requirement”). Notably, the word “requirement” is used in section 360k and other sections of the MDA to refer only to positive statutory and regulatory enactments. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 489–90 (1996) (plurality opinion).

[S]ubsections (a)(2) and (b) of [section 360k] also refer to “requirements”—but those “requirements” refer only to statutory and regulatory law that exists pursuant to the MDA itself, suggesting that the pre-empted “requirements” established or continued by States also refer primarily to positive enactments of state law Of the limited number of “exemptions” from pre-emption that the FDA has granted, none even remotely resemble common-law claims.

Id.

in order for preemption to apply.²⁵ This is the concept of device specificity. Some courts have found preemption limited to situations where both the state and federal requirements are developed “with respect to” a particular medical device, while other courts have found preemption in any case where the federal requirement was specific to the device, regardless of the state claim’s device specificity.²⁶

The federal requirements established by the FDA are derived from the structure of the statute itself. The MDA divides medical devices into three classes based upon the risk of injury posed by each device.²⁷ Class I encompasses simple devices, which are subject only to the general controls necessary to provide the FDA with “reasonable assurance of the safety and effectiveness of the device.”²⁸ Class II devices are subject to special controls because general controls are insufficient to provide reasonable assurance of the safety and effectiveness of the devices.²⁹ Class III devices are those that are used to support or sustain human life, or present a potential risk of illness or injury, such as pacemakers, cardiac catheters, and heart valves.³⁰

²⁵ Compare *Oja*, 111 F.3d at 788 (explaining that a court engaged in a preemption analysis must consider the specificity of the state requirement in relation to the particular device, as well as the device specificity of the federal requirement), with *Papike v. Tambrands, Inc.*, 107 F.3d 737, 742 (9th Cir. 1997) (describing the focus of the preemption inquiry under *Lohr* as being on the device specificity of the federal requirement).

²⁶ See *supra* note 25. Courts that have focused solely on the specificity of the federal requirement have even found preemption of state tort claims of general applicability in direct derogation of the Code of Federal Regulations, which states that “[section 360k] does not preempt State or local requirements of general applicability.” 21 C.F.R. § 808.1(d)(1) (2005); see also *Mitchell v. Collagen Corp.*, 126 F.3d 902, 911–13 (7th Cir. 1997) (reaffirming an earlier holding that general claims, such as strict liability and breach of implied warranty of merchantability, would impose burdens on the manufacturer that were different from or in addition to those imposed by the FDA).

²⁷ See 21 U.S.C. § 360c(a).

²⁸ *Id.* § 360c(a)(1)(A). Crutches and tongue depressors are examples of Class I devices. *Bivans*, *supra* note 1, at 1090.

²⁹ See 21 U.S.C. § 360c(a)(1)(B). Tampons and oxygen masks are examples of Class II devices. *Bivans*, *supra* note 1, at 1091.

³⁰ See 21 U.S.C. § 360c(a)(1)(C); see also *Bivans*, *supra* note 1, at 1091.

The MDA requires manufacturers of Class III devices to receive pre-market approval (“PMA”) from the FDA before the device can be commercially manufactured and sold.³¹ PMA applications must contain sufficient information to provide the FDA with reasonable assurance of the device’s safety and efficacy.³² In some instances, a manufacturer can bypass the PMA process by showing its device to be substantially equivalent to a device that was commercially distributed prior to the 1976 effective date of the MDA, unless a separate regulation is promulgated requiring an application for PMA.³³ In such a case, the manufacturer may continue to market the device pursuant to section 510(k) of the Food Drug and Cosmetic Act unless and until the FDA orders the manufacturer to submit an application for full PMA approval.³⁴ This latter clearance method was employed by the defendant manufacturer in the seminal medical device products liability case, *Medtronic, Inc. v. Lohr*.³⁵

In *Lohr*, the United States Supreme Court took up the issue of tort claim preemption under the MDA. The case concerned the recipient of a defective pacemaker who brought claims of strict liability and negligence against the manufacturer of the device.³⁶ The device in question did not undergo the full PMA approval process, but instead received FDA clearance under the

³¹ See 21 U.S.C. § 360c(a)(1)(C).

³² See *id.* The application includes reports concerning the safety and effectiveness of the device, a statement of the components, ingredients, and principles of operation, a full description of the methods of manufacture and processing, references to any performance standards that would have been required of the device if it were in Class II, samples of the device and the labeling, and other relevant information. See *id.* § 360e(c)(1)(A)–(G). The FDA must respond to the application within 180 days of its submission by either issuing an order of approval or denial. *Id.* § 360e(d)(1)(A).

The FDA must approve the application within 180 days unless (1) there is a failure to establish a reasonable assurance that the device is safe or effective under the recommended conditions of use, (2) the manufacturing methods do not conform to the requirements for good manufacturing practices, (3) the proposed labeling is false or misleading, or (4) the device does not conform to an applicable performance standard.

Bivans, *supra* note 1, at 1091.

³³ See 21 U.S.C. § 360e(a)–(b).

³⁴ See Bivans, *supra* note 1, at 1091–92. In addition, a medical-device manufacturer may obtain an Investigational Device Exemption in order to enter into clinical human studies of an experimental device prior to full PMA approval. *Id.* at 1092.

³⁵ 518 U.S. 470 (1996).

³⁶ *Id.* at 481.

substantial equivalency provision of section 510(k).³⁷ The Lohrs' negligence claims alleged breach of the manufacturer's "duty to use reasonable care in the design, manufacture, assembly, and sale" of the product, as well as failure to warn or properly instruct the patient or her physician of the attendant risks.³⁸

The case resulted in a fractured Court opinion, with Justice Stevens writing for the plurality.³⁹ Justice Breyer's vote created a majority as to all but two parts of the plurality opinion.⁴⁰ The Court essentially found that section 510(k) "substantial equivalence" approval focused on equivalence rather than safety and did not require the device in question to be formally reviewed by the FDA.⁴¹ The Court stated that the FDA's clearance of the pacemaker did not require the device to "take any particular form for any particular reason."⁴² Therefore, the Court concluded that the substantial equivalence clearance of the pacemaker did not establish any specific federal requirements for the device and did not conflict with or preempt the plaintiff's claims.⁴³

Although the Court's decision ultimately turned on the lack of a device-specific federal requirement, parts of the opinion also suggested that the plaintiff's claims did not seek to impose a specific state requirement and were too general to be preempted. Furthermore, the Court stated that although it was not holding that a general state requirement could never be preempted, there was an "overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest."⁴⁴ A majority of the Court agreed that for preemption to apply, a state claim must reach a minimum level of device specificity;⁴⁵ however, a majority did not agree on what the requisite level of specificity was and did not discuss how a court faced with the question should make such a determination.⁴⁶ Importantly, the Court concluded that any

³⁷ See *id.* at 492–94.

³⁸ *Id.* at 481 (citation omitted).

³⁹ See *id.* at 473.

⁴⁰ See *id.*

⁴¹ See *id.* at 493.

⁴² *Id.*

⁴³ See *id.* at 493–94.

⁴⁴ *Id.* at 500.

⁴⁵ See *id.* (maintaining that "[s]tate requirements must be 'with respect to' medical devices and 'different from, or in addition to,' federal requirements").

⁴⁶ See *id.* at 501–02; *id.* at 502–03 (plurality opinion). The plurality asserted that the state common law claims were not device-specific requirements as

state requirements created by the Lohrs' tort claims for negligent manufacture and failure to warn were far too general to be "with respect" to the device, and this generality left them outside the ambit of section 360k(a).⁴⁷

The *Lohr* opinion also underscored the importance of deferring to congressional intent in cases where a federal statute expressly preempts a state law, but the exact scope of preemption is unclear.⁴⁸ The Court stated that Congress' purpose in passing the MDA preemption provision, as well as the purpose of the underlying statute, is the "ultimate touchstone" in determining the scope of preemption.⁴⁹ Furthermore, the plurality opinion argued that because the use of the word "requirement" in the preemption provision of the MDA was ambiguous, the Court had to look at both legislative history and statutory purpose to determine Congress' intended scope of preemption.⁵⁰ The plurality stated that because Congress enacted the MDA to place more stringent controls on medical device manufacturers, it would be "perverse" to use the statute to absolve reflexively the entire industry from liability for the injuries it causes.⁵¹

Justice Breyer concurred separately, stating that he did not agree with the plurality's view that incidents of MDA preemption of common law claims by the MDA would be "few" or "rare."⁵² He agreed, however, with the plurality's finding that the Lohrs' tort claims were not preempted because they did not conflict with any specific federal requirements.⁵³

The *Lohr* decision left unanswered the question of whether a device approved under the more stringent PMA process, rather than the section 510(k) substantial equivalence process, would

contemplated by section 360k:

[G]iven the critical importance of device specificity in our . . . construction of § 360k, it is apparent that few, if any, common-law duties have been preempted by this statute. It will be rare indeed for a court hearing a common law cause of action to issue a decree that has 'the effect of establishing a substantive requirement for a specific device.'

Id. (quoting 21 C.F.R. § 808.1(d)(6)(ii) (1995)). Justice Breyer, however, did not join in this part of the opinion.

⁴⁷ *Id.* at 502 (majority opinion).

⁴⁸ *See id.* at 484–86.

⁴⁹ *Id.* at 485–86.

⁵⁰ *See id.* at 487–91 (plurality opinion).

⁵¹ *Id.* at 487.

⁵² *Id.* at 508 (Breyer, J., concurring).

⁵³ *See id.*

impose specific federal requirements sufficient to preempt tort claims. If it did, a court would be required next to determine whether state tort claims were device-specific. These issues were addressed by the United States Court of Appeals for the Third Circuit in *Horn v. Thoratec Corp.*⁵⁴

B. Horn v. Thoratec Corp.

In *Horn*, the Third Circuit faced the question of whether the federal requirements imposed on a device that received full PMA approval, rather than merely section 510(k) clearance, preempted the claimant's Pennsylvania common law tort claims for defective design, defective manufacture, and failure to warn.⁵⁵ On January 17, 1998, Daniel Horn suffered a heart attack and his doctors determined that he needed a heart transplant.⁵⁶ Before a donor heart became available, Mr. Horn's condition deteriorated, and on January 22, 1998, a HeartMate pump, manufactured by defendant Thoratec, was implanted to provide circulatory assistance between the ventricle and aorta of Mr. Horn's heart.⁵⁷

In early May of the same year, "Mr. Horn began bleeding from the spot where the HeartMate tube exited his body."⁵⁸ Exploratory surgery revealed that the suture covering the screw ring connection of the device had worn off and the screw ring had disconnected.⁵⁹ The surgeon conducting the operation determined that the suture had worn through from rubbing against the patient's sternum.⁶⁰ The disconnection allowed an air embolus to travel to Mr. Horn's brain, rendering him brain

⁵⁴ 376 F.3d 163 (3d Cir. 2004).

⁵⁵ *See id.* at 165.

⁵⁶ *Id.*

⁵⁷ *Horn v. Thermo Cardiosystems, Inc.*, 229 F. Supp. 2d 381, 384 (M.D. Pa. 2002), *aff'd sub nom. Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004). The HeartMate consisted of a "pump body" and two conduit assemblies. *Id.* On one side of the pump, a conduit was attached to the aorta; this was the outlet side because blood flowed from the device into the aorta and then out to the patient's body. *Id.* Between the pump body and the outlet was a small tube connection, otherwise known as the "elbow." *Id.* The elbow was attached by screw into the pump housing with a screw ring tightened over it. *Id.* To prevent the screw ring from rotating, a suture was tied over the screw ring and attached to the adaptor conduit. *Id.* The device was fully assembled during manufacture and required no manipulation from the implanting surgeon. *Id.*

⁵⁸ *Horn*, 376 F.3d at 165.

⁵⁹ *See id.*

⁶⁰ *See Thermo Cardiosystems*, 229 F. Supp. 2d at 384.

dead.⁶¹ On May 8, 1998, Mr. Horn's doctors discontinued life support and his viable organs were donated for transplantation.⁶²

Subsequently, Mrs. Horn filed a complaint in the United States District Court for the Middle District of Pennsylvania against the manufacturer Thoratec, primarily claiming that the HeartMate was defectively designed.⁶³ In addition, her complaint alleged negligence for "(1) failure to test and study adequately the HeartMate; (2) failure to provide adequate warnings regarding the possibility that the screw ring may disconnect; (3) failure to provide adequate instructions to physicians; and (4) failure to use proper suture material."⁶⁴ Furthermore, Mrs. Horn claimed strict liability against Thoratec for "(1) failure to use 'good manufacturing practices'; and (2) failure to provide adequate warnings."⁶⁵

The district court granted Thoratec's motion for summary judgment using the familiar two-prong preemption test previously endorsed by the Sixth and Eleventh Circuits.⁶⁶ The test required a device-specific federal requirement and a device-specific state requirement that was different from, or in addition to, the federal requirement.⁶⁷ The district court found that "the HeartMate's PMA approval process imposed a specific federal requirement applicable to the HeartMate," and if Mrs. Horn prevailed, "any [state] judgment that the HeartMate was unsafe or otherwise substandard would be in direct conflict [with] . . . the FDA's determination that the product was suitable

⁶¹ *Horn*, 376 F.3d at 165.

⁶² *See id.*

⁶³ *See id.* Specifically, the complaint asserted that "[h]ad the screw ring been of an appropriate and feasible design . . . the disconnection which ultimately caused Mr. Horn's death would never have occurred." *Thermo Cardiosystems*, 229 F. Supp. 2d at 384–85.

⁶⁴ *Id.* at 385.

⁶⁵ *Id.*

⁶⁶ *See Horn*, 376 F.3d at 165.

⁶⁷ *See Kemp v. Medtronic, Inc.*, 231 F.3d 216, 224–25 (6th Cir. 2000); *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1372 (11th Cir. 1999).

for use.”⁶⁸ On appeal, the Third Circuit Court of Appeals affirmed the district court’s decision by a two-judge majority.⁶⁹

The Third Circuit adopted the two-prong test used by the district court.⁷⁰ First, the court addressed whether the PMA approval process placed specific federal requirements on the HeartMate.⁷¹ The court held that when the FDA grants approval by the exhaustive PMA mechanism, it imposes extensive device-specific federal requirements sufficient to give rise to preemption under section 360k(a) of the MDA.⁷² The court distinguished the instant matter from the *Lohr* case by pointing out that the product at issue in *Lohr* had undergone the far less stringent section 510(k) approval process.⁷³ The court emphasized that the *Lohr* Court found that the section 510(k) clearance process did not impose any federal requirement specific to the device, but rather imposed only the generic requirements that the device be safe and substantially equivalent to predecessor devices.⁷⁴ In contrast, the PMA approval process employed for the HeartMate included the FDA’s review of the device’s manufacturing, packaging, storage, labeling, distribution, and advertising.⁷⁵ In addition, the court found that years of mandatory submissions—including live animal and human cadaver studies, clinical trials, and design alterations—unquestionably imposed specific federal requirements on the HeartMate’s design, testing, intended use, and performance standards.⁷⁶ Therefore, the court held that the *Lohr* decision did not control the first prong of the preemption test here and there were sufficiently specific federal standards applicable to the HeartMate.⁷⁷

The Third Circuit then turned to the second prong of the preemption analysis and examined the state requirements imposed by Mrs. Horn’s common law tort claims.⁷⁸ Mrs. Horn argued that her state common law claims did not seek to

⁶⁸ *Horn*, 376 F.3d at 165.

⁶⁹ *See id.* at 163–64.

⁷⁰ *See id.* at 169–73.

⁷¹ *See id.* at 169.

⁷² *See id.* at 170.

⁷³ *See id.* at 168.

⁷⁴ *See id.*

⁷⁵ *See id.* at 170.

⁷⁶ *See id.* at 169–70.

⁷⁷ *See id.* at 169.

⁷⁸ *See id.* at 173.

establish device-specific state requirements because they were founded on the general duties to use due care in manufacturing and to warn users of attendant risks.⁷⁹ The court rejected this argument. The court began by acknowledging that Mrs. Horn was not asserting claims specific to the device or alleging protection under any statute of the Commonwealth of Pennsylvania.⁸⁰ In fact, the court characterized Mrs. Horn's claims as general, common law claims, "which [were] not *specific 'with respect to'* the HeartMate."⁸¹ The court determined that the only remaining question was whether Mrs. Horn's general claims could constitute requirements different from or in addition to the federal requirements promulgated by Congress in section 360k(a).⁸²

To answer that question, the court took note of the *Lohr* Court's holding that the common law claims for negligent manufacture and failure to warn were too general to be "with respect to" the particular device.⁸³ The court recognized that the state claims Mrs. Horn brought against Thoratec were "essentially the same" as the claims asserted in *Lohr*,⁸⁴ but that did not end the inquiry. The Third Circuit stated that it would follow Justice Breyer's *Lohr* concurrence under the Court's "'narrowest ground' approach."⁸⁵ The court interpreted Justice Breyer's concurrence to mean that when considering preemption, a court should carefully examine each of the state common law claims to determine whether the "claim would *impose* a

⁷⁹ *Id.* at 166.

⁸⁰ *Id.* at 173. Concededly, if the Commonwealth of Pennsylvania had established requirements with respect to the HeartMate, they would be preempted as positive enactments imposing specific state requirements different from or in addition to federal requirements, and Mrs. Horn would be unable to seek compensation under them. *See* 21 U.S.C § 360k(a) (2000).

⁸¹ *Horn*, 376 F.3d at 174.

⁸² *Id.* at 173–74.

⁸³ *See id.* at 174.

⁸⁴ *Id.*

⁸⁵ *See id.* at 175. Although Justice Stevens' plurality opinion in *Lohr* determined that section 360k did not preempt most common law duties, Justice Breyer concluded that it would preempt a common law duty that was similar to the state requirements contained in statutes, rules, or regulations that were preempted by the FDA. *See id.* Therefore, the Third Circuit decided to follow Justice Breyer's concurrence given that his rationale was narrower than the plurality. *See id.*

substantive requirement that conflicts with, or adds a greater burden to, a specific federal requirement.”⁸⁶

Although the Third Circuit claimed to adopt a careful and systematic approach to the preemption analysis, the court gave only a bundled and cursory examination to Mrs. Horn's claims. Without much scrutiny, the court decided that Mrs. Horn's general state law claims would impose substantive requirements on the HeartMate that would conflict with or add to those imposed by the FDA.⁸⁷ The court found Mrs. Horn's claim that the screw ring was negligently designed would force Thoratec to alter the FDA-approved design by changing either the screw-ring feature or the suture used to hold it in place.⁸⁸ In addition, without an in-depth explanation, the court found that Mrs. Horn's failure-to-warn claim would require Thoratec to provide warnings and instructions different from those approved by the FDA.⁸⁹ Thus, the court found that all of Mrs. Horn's claims were preempted.

In dissent, Judge Julio Fuentes stated that for state tort claims to be preempted, they had to impose specific requirements on the manufacturer that would conflict with the requirements imposed by the federal standards or otherwise frustrate congressional intent.⁹⁰ He contended that requirements of general applicability are not preempted and a common law claim must impose some exacting requirement upon the specific device for preemption to apply.⁹¹ Judge Fuentes asserted that the claims here were far too general for preemption, and even though the majority gave lip service to the device specificity requirement, it failed to employ that standard fully.⁹²

⁸⁶ *Id.* at 174. Although the court announced this as the proper analysis for preemption under the MDA, it failed to engage in a full independent examination of each state tort claim alleged in the complaint. *See infra* notes 87–89 and accompanying text.

⁸⁷ *See Horn*, 376 F.3d at 176.

⁸⁸ *See id.*

⁸⁹ *Id.*

⁹⁰ *See id.* at 180–82, 184–85 (Fuentes, J., dissenting).

⁹¹ *See id.* at 182. In fact, Judge Fuentes argued that the FDA's reference to the specificity of the state requirements would have been superfluous if the specificity of the federal device requirements was all that mattered to the preemption analysis. *See id.*

⁹² *See id.* at 181.

Judge Fuentes acknowledged that a judgment against Thoratec might have the indirect consequence of holding the HeartMate to a higher standard than the FDA required, but he noted that the *Lohr* Court authorized such a result.⁹³ He explained that Congress, through section 360k(a), and the *Lohr* Court were aiming to prevent a manufacturer from facing specific state requirements that were “different from, or in addition to[,]” federal requirements.⁹⁴ Judge Fuentes argued that since Mrs. Horn’s state common law claims merely alleged the breach of a generalized duty of care and not device-specific inadequacies, no conflicting obligations would emerge from a jury award in her favor, and her claims were therefore not preempted.⁹⁵

The majority of federal courts that have addressed the preemption question, where the offending device has received full PMA approval, have held that the FDA’s rigorous level of scrutiny, and the FDA’s continuous ability to withdraw its approval, are sufficient to impose device-specific federal requirements on the manufacturer.⁹⁶ Although it may be argued that PMA approval is not necessarily tantamount to a specific federal requirement,⁹⁷ this Comment does not dispute that the PMA approval process imposed specific federal requirements on the HeartMate. Therefore, the remainder of this Comment will

⁹³ *See id.* at 184.

⁹⁴ *See id.* at 180–82.

⁹⁵ *See id.* at 184.

⁹⁶ *See, e.g.,* *Martin v. Medtronic, Inc.*, 254 F.3d 573, 583–84 (5th Cir. 2001); *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 226–28 (6th Cir. 2000); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 913 (7th Cir. 1997). *But see* *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1375 (11th Cir. 1999) (holding that the PMA approval process does not impose federal device-specific requirements). The *Goodlin* court found that although the FDA requires a showing that a device is safe and effective prior to submission to the market, the FDA’s review, supporting information, and actual approval do not impose any ascertainable requirements on the device. *See id.* The court stated that at no point during review or upon approval does the FDA issue a “regulation, order, or any other statement of its substantive benchmark.” *Id.* The court held that approval was merely a determination by the FDA that the manufacturer furnished reasonable assurances of safety and effectiveness without indication of what substantive requirements the agency applied to reach its result. *See id.* Furthermore, the *Goodlin* court found that the “Conditions of Approval” document accompanying the FDA’s notice of approval was merely a list of rules and regulations generally applicable to all devices approved through the PMA process, such as the obligation to report adverse events. *See id.* at 1377. Finally, the court stated that permission to market the device is not “implied validation of the safety of [the] device and every step of its manufacture.” *Id.* at 1375–76.

⁹⁷ *See supra* note 96.

analyze only the state requirements that would have allegedly been imposed by Mrs. Horn's tort claims. Because the preemptive scope of section 360k is ambiguous, the *Horn* court should have looked to the legislative history and purpose of the MDA before concluding that Mrs. Horn's tort claims were preempted. Furthermore, the regulations promulgated by the FDA support a thorough examination of the potential requirements arising from each state tort claim and an evaluation of whether those requirements would conflict with the requirements imposed by the FDA. The *Horn* court did neither. If it had engaged in a more thorough analysis of Mrs. Horn's claims, at least some would have survived preemption.

II. LEGISLATIVE HISTORY, PURPOSE, AND STRUCTURE OF THE MEDICAL DEVICE AMENDMENTS

"[P]roblems arise when . . . federal legislation does not clearly disclose its intended impact on state laws. . . . [P]reemption rulings often turn on a determination of congressional intent in the setting of the particular text, history[,] and purposes of the federal legislation involved."⁹⁸ As there is no clear statement from Congress that state tort claims are always preempted under section 360k, the *Horn* court should have looked to the legislative history, purpose, and structure of the MDA to discern congressional intent regarding the scope of preemption. Such an examination suggests that Congress did not intend to preempt state tort claims in all situations.

Part III of the *Lohr* opinion—part of the majority holding—directs a court considering the preemption question to view section 360k(a) as informed by two statutory presumptions. First, federalism requires that the traditional police powers of the states are not to be "superseded by the Federal Act unless that was the *clear* and *manifest* purpose of Congress."⁹⁹ Second, courts must view congressional purpose as "the ultimate touchstone" when analyzing the scope of a statute's express preemption provision.¹⁰⁰ By looking for a clear statement from Congress, the *Lohr* Court implied that statutory preemption should apply to state tort claims only where Congress has faced

⁹⁸ SULLIVAN & GUNTHER, *supra* note 16, at 324.

⁹⁹ *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (emphasis added) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

¹⁰⁰ *Id.* (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963)).

and intentionally brought into issue the preemption of such claims.¹⁰¹ Where there is no clear statement and congressional intent is unclear, however, a presumption against preemption arises, and courts should be reluctant to preempt state tort claims.¹⁰² This presumption is even stronger where, as here, the federal statute does not afford the injured party an alternative remedy.¹⁰³

In addition to the absence of a clear congressional statement, there is no indication anywhere in the MDA or its legislative history that Congress intended to include state tort claims in the express preemption provision.¹⁰⁴ Instead, there is evidence suggesting that Congress included the express preemption provision in the MDA as a direct response to individual states enacting their own regulatory approval procedures for medical devices sold within their borders.¹⁰⁵ Thus, the legislative history

¹⁰¹ See Grey, *supra* note 17, at 609–10 (quoting Astoria Fed. Sav. & Loan Ass'n v. Solimino, 501 U.S. 104, 109 (1991)).

¹⁰² See *id.* at 565. The presumption against preemption arises from federalism concerns and the traditional power of the states to regulate the health and safety of their citizens. *Id.* at 585. “Few values are more central to federalism than the right of states to provide a compensatory remedy for their injured citizens.” *Id.* at 565; see also Bivans, *supra* note 1, at 1122 (describing certain common law claims as historically in the province of states and demanding that Congress clearly indicate its intention to preempt them).

¹⁰³ See Grey, *supra* note 17, at 563, 571. Where the preemption defense is upheld, the injured parties have to carry the entire burden of their injury. See Chase Garwood, III, Mitchell v. Collagen Corp. *A Trend in Defensive Use of MDA Preemption*, 5 J. PHARMACY & L. 191, 198 (1996). There is no provision for compensation of injuries or expenses resulting from medical device malfunction in the MDA. See *id.* at 198–99; see also 21 U.S.C. § 360h(b)(2) (2000). The statute only requires the manufacturer of a malfunctioning device to repair or to replace the device or to refund the purchase price. 21 U.S.C. § 360h(b)(2). In addition, congressional silence with respect to state tort claims is particularly significant where there is a failure to provide a federal remedy for injured persons. See Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 251 (1984) (holding that the Atomic Energy Act did not preempt the plaintiff's tort claims because there was no indication that Congress had considered precluding state remedies for injuries in nuclear plants).

¹⁰⁴ See Garwood, *supra* note 103, at 197; Grey, *supra* note 17, at 606 (indicating that the impact of the MDA on state tort claims was not discussed in legislative history); see also S. REP. NO. 94-33, at 1–50 (1976), as reprinted in 1976 U.S.C.C.A.N. 1070, 1070–103; H.R. REP. NO. 94-1090, at 51–66 (1976) (Conf. Rep.), as reprinted in 1976 U.S.C.C.A.N. 1103, 1103–18; H.R. REP. NO. 94-853 (1976); 121 CONG. REC. 10687–710 (1975).

¹⁰⁵ See Vladeck, *supra* note 19, at 104–05 (noting that before Congress enacted the MDA, California had passed procedures for pre-market approval of intrauterine devices, while other states regulated hearing aides).

shows that “Congress crafted a preemption provision that permitted state regulatory programs to remain in place until the FDA implemented specific counterpart regulations. Thereafter, . . . FDA regulations would preempt conflicting state . . . regulatory measures.”¹⁰⁶

Moreover, in *Lohr*, Justice Stevens wrote that it is “‘difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by [improper] conduct.’”¹⁰⁷ He maintained that it would take much clearer language than that of section 360k in order to convince him that Congress intended such a result.¹⁰⁸ Yet, the legislative history reveals no discussion or debate about the inclusion of state tort remedies in the term “requirement.”¹⁰⁹ It is unlikely that Congress would remove all remedy without intense discussion, debate, and review.¹¹⁰

¹⁰⁶ *Id.*

¹⁰⁷ *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 487 (1996) (plurality opinion) (quoting *Silkwood*, 464 U.S. at 251).

¹⁰⁸ *Id.*

¹⁰⁹ See Robert J. Katerberg, *Patching the “Crazy Quilt” of Cipollone: A Divided Court Rethinks Federal Preemption of Products Liability in Medtronic, Inc. v. Lohr*, 75 N.C. L. REV. 1440, 1463–64 (1997). The legislative history contains statements from both Houses such as, “[t]he legislation is written so that the benefit of the doubt is always given to the consumer.” *Id.* at 1464 (quoting 121 CONG. REC. 10688 (1975) (statement of Sen. Kennedy)). Yet, conspicuously absent from the legislative materials is any mention of state tort claims. See *id.*; see also Dega, *supra* note 21, at 655 (“[T]he MDA’s legislative history does ‘not [contain] one word of debate or commentary address[ing] state tort law remedies.’” (quoting Reply Brief for Appellant at 17, *Talbott v. C.R. Bard, Inc.*, 63 F.3d 25 (1st Cir. 1995) (No. 94-1951))).

¹¹⁰ See Dega, *supra* note 21, at 655; see also *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 541–42 (1992) (Blackmun, J., concurring in part, dissenting in part). *Cipollone* involved common law claims alleging that cigarette manufacturers breached express warranties contained in their advertisements, failed to warn of the hazards of smoking, fraudulently misrepresented those hazards, and conspired to deprive the public of information about smoking. *Id.* at 508 (majority opinion). The Federal Cigarette Labeling and Advertising Act of 1965 and the Public Health Cigarette Smoking Act of 1969 each contained express preemption provisions. See *id.* at 514–15. The 1965 Act stated that “[n]o statement relating to smoking and health shall be required in the advertising of any cigarettes the packages of which are labeled in conformity with the provisions of [the] Act.” *Id.* at 514 (quoting Federal Cigarette Labeling and Advertising Act of 1965, Pub. L. No. 89-92, 79 Stat. 282 (codified at 15 U.S.C. §§ 1331–1341 (2000))). The 1969 Act contained different language, stating that “[n]o requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of [the] Act.” *Id.* at 515 (quoting Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87 (1970) (codified at 15 USC §§ 1331–1341 (2000))) (emphasis added). The issue for the Court was whether either one or both of these provisions

Furthermore, congressional activity since the enactment of the MDA is inconsistent with a finding that Congress intended to include state tort claims under the express preemption provision. For example, to encourage the reporting of medical device failure, Congress promulgated the Safe Medical Devices Act of 1990 (“SMDA”).¹¹¹ By not allowing those reports to be entered into evidence in civil litigation against device manufacturers, the SMDA preserved the confidentiality of persons making them.¹¹² Congress’ explicit reference to civil litigation demonstrates that it indeed anticipated lawsuits against manufacturers and thus never intended to eliminate such cases.¹¹³ Also, the legislative history of the SMDA indicates that Congress viewed products liability law as a mechanism for holding device manufacturers accountable for consumers’ injuries and enhancing device safety.¹¹⁴ Additionally, in 1995, the House of Representatives passed a bill that would have all but eliminated punitive damages in products liability actions against medical device manufacturers.¹¹⁵ Although the bill was ultimately vetoed by the

included the preemption of state common law claims. *Id.* at 517. In a plurality opinion authored by Justice Stevens, the Court held that the 1969 Act, but not the 1965 Act, preempted some of the plaintiff’s common law claims. *See id.* at 530–31 (plurality opinion). Justice Stevens was convinced that in the 1969 Act, Congress intended to include common law actions in the phrase “requirement or prohibition.” *See id.* at 522. In addition, Justice Stevens reasoned that although there was no reference to common law actions in the 1969 Act’s legislative history, the “obviously broader language of the 1969 version extended that section’s pre-emptive reach.” *Id.* at 521, 523. Furthermore, the version of the 1969 Act passed by the Senate preempted “any State *statute or regulation*”; this language was later replaced in the bill (and ultimately passed and signed) with the words “State *law*.” *Id.* at 523 (quoting 15 U.S.C. § 1334(b) (1970); S. REP. NO. 91-566, at 16 (1969)). Justice Stevens found that this modification was a clear indication of Congress’ intent to include some common law tort actions in the preemption provision. *Id.* Notably, the Court’s decision in *Cipollone* prompted defendants to start asserting the defense of preemption in medical device liability cases. *See Katerberg, supra* note 109, at 1469.

¹¹¹ *See* H.R. REP. No. 101-808, at 21 (1990).

¹¹² *See id.* (“The reports may not be admitted into evidence or otherwise used in any civil actions involving private parties. However, there is no prohibition on civil litigation about the events that are the subject of the report.”).

¹¹³ *See* Bivans, *supra* note 1, at 1105.

¹¹⁴ *See id.* at 1119 (“Explicitly recognized in the legislative history of the SMDA was the role of products liability law in holding the industry accountable for defective medical devices.”).

¹¹⁵ *See* Common Sense Product Liability and Legal Reform Act of 1995, H.R. 956, 104th Cong. § 201(f) (1995), as reprinted in 141 CONG. REC. H2941–48 (daily ed. Mar. 9, 1995); *see also* Katerberg, *supra* note 109, at 1464 n.175 (summarizing progression of bill).

President, its mere proposal demonstrates that Congress did not believe that state common law tort claims were entirely preempted by the MDA.¹¹⁶

Further, the legislative purpose behind the MDA suggests that Congress did not intend to include state tort claims in the express preemption provision. The purpose of the MDA is to protect the health and safety of device users.¹¹⁷ One sponsor of the bill stated: “[W]ithout [the Act,] the American people will continue to be subjected to indefensible risk of illness, injury and even death After all it is the consumer who pays with his health and his life for medical device malfunctions.”¹¹⁸ Congress therefore enacted the MDA primarily to promote the safety and effectiveness of medical devices, not to insulate manufacturers from liability.¹¹⁹

In *Lohr*, the plurality reasoned that because there was no private right of action contained in the MDA, complete tort preemption would have the “perverse effect” of giving immunity to an industry that Congress believed was in need of increased regulatory control.¹²⁰ This result remains the same whether the device was approved by the section 510(k) process or by the PMA process. It is unlikely that Congress would intentionally allow compensation for persons injured by devices that reached the market through the section 510(k) approval process, but would eliminate it entirely for consumers equally harmed by a device approved under the PMA process. If Congress intended this disparate result, there would be at least *some* evidence of that

¹¹⁶ Cf. Bob Herbert, *A Gift for Drug Makers*, N.Y. TIMES, Jan. 14, 2005, at A23 (discussing President Bush's support for a similar prohibition on punitive damages, demonstrating that members of both the executive and legislative branches believe that not all tort claims against device manufacturers are automatically preempted by the MDA).

¹¹⁷ See Grey, *supra* note 17, at 583.

¹¹⁸ 121 CONG. REC. 10688 (1975) (statement of Sen. Kennedy).

¹¹⁹ See Grey, *supra* note 17, at 583.

¹²⁰ See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 487 (1996) (plurality opinion).

intention in the legislative history or in the text of the preemption provision itself—yet no such evidence exists.¹²¹

Finally, the structure of the MDA supports the conclusion that Congress did not intend to preempt state tort remedies. Specifically, section 360h(d) contains a savings clause which provides:

Compliance with an order issued under this section shall not relieve any person from *liability* under Federal or *State* law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.¹²²

This clause indicates that even after taking required remedial actions, a manufacturer will not be insulated from all liability. Congress' recognition of the possibility of litigation against device manufacturers thus strongly suggests that it did not intend to preempt all state tort claims under the statute's express preemption provision.¹²³

Moreover, Congress' undefined use of the word "requirement" in the text of the preemption provision does not make "clear and manifest" what constitutes a state "requirement." Notably, the only time the Supreme Court attempted to discern Congress' intended meaning, it found that the state tort claim escaped preemption.¹²⁴ In fact, in *Lohr*, Justice Stevens remarked that if Congress intended to include state tort claims in the term "requirement," "it chose a singularly odd word with which to do it."¹²⁵ Justice Stevens argued that "requirement" applied only to positive state enactments, such as legislation or administrative rules. He stated that Congress could have made clear its intent to preempt tort claims by simply

¹²¹ See *Bivans*, *supra* note 1, at 1113–14; *Dega*, *supra* note 21, at 654–56 ("The absence of a clear statement by Congress remains a significant consideration in weighing against preemption.").

¹²² 21 U.S.C. § 360h(d) (emphasis added).

¹²³ See *Bivans*, *supra* note 1, at 1094 (indicating that such a conclusion is logical even though the savings clause is not included in the same section as the preemption provision).

¹²⁴ See *Lohr*, 518 U.S. at 486–87 (plurality opinion) ("[The defendant] suggests that any common-law cause of action is a 'requirement' which alters incentives and imposes duties This] argument is not only unpersuasive, it is implausible."); see also *id.* at 503 (majority opinion).

¹²⁵ *Id.* at 487 (plurality opinion).

substituting or adding the word “remedy.”¹²⁶ Indeed, Congress’ use of “requirement” in other areas of the statute refers only to enactments by state legislatures and administrative bodies, indicating that its use in the preemption provision refers only to positive enactments and not to state tort awards.¹²⁷

Because it is unclear whether Congress intended to preempt state tort claims by using the word “requirement” in section 360k, a court trying to determine congressional intent should look to legislative history, purpose, and structure to inform its decision. Here, the legislative history of the MDA reveals that Congress did not bring state tort awards into issue and deliberately choose to preempt them. The purpose of the MDA, furthermore, is to protect the consumer from injury, not to protect the manufacturers from paying damages. Finally, within the text of the MDA itself, Congress acknowledged deficiencies in the device approval process and specifically stated that manufacturers remain open to liability. If, after analyzing the statute under this traditional interpretative framework, the *Horn* court remained unconvinced that state tort claims survive section 360k preemption, it should have gone on to examine the regulations promulgated by the FDA before reflexively holding Mrs. Horn’s tort claims to be preempted.

III. THE ROLE AND THE WORD OF THE FDA

The regulations promulgated by the FDA to execute the provisions of the MDA demonstrate that a court should not automatically find preemption simply because the injuring device received full PMA approval. Instead, the tenor of the FDA regulations suggests that a court should examine each claim

¹²⁶ See *id.* Justice Stevens admitted that in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), the Court found the term “requirement” in the Public Health Cigarette Smoking Act of 1969 to include state common law remedies. See *Lohr*, 518 U.S. at 488 (plurality opinion). He stated, however, that because the statute was limited to the health effects of smoking, and the preemption provision applied only to the advertisement or promotion of cigarettes, the preemption provision at issue in *Cipollone* had a far narrower effect on available damages than what Medtronic proposed for the MDA. See *id.* As such, Justice Stevens noted, the plaintiff in *Cipollone* was permitted to maintain theories of damage that “did not run afoul” of the preemption provision. *Id.* In contrast, the broad interpretation proposed by Medtronic of section 360k would result in wiping out all remedies available to the plaintiff. *Id.* at 488–89.

¹²⁷ See *supra* note 24 and accompanying text (discussing disagreement as to the meaning of “requirement”).

individually to decide if it imposes requirements that conflict with those the FDA imposed on the device. Here, the FDA has a particularly important role in determining the scope of section 360k, because Congress specifically granted it the authority to implement the provisions of the MDA.¹²⁸ The *Lohr* Court agreed that, in the absence of a clear guiding statement from Congress, courts must give substantial deference to the regulations of the relevant administrative agency.¹²⁹

Horn, in attempting to resolve the preemptive scope of the MDA, failed to take note of two important FDA regulations. First, the FDA regulation codified at 21 C.F.R. § 808.1(d) states that “[section 360k] does not preempt State or local requirements of *general applicability* where the purpose of the requirement relates . . . to other products in addition to devices.”¹³⁰ The regulation gives examples of requirements that would not be preempted, such as “general electrical codes, and the Uniform Commercial Code (warranty of fitness), or . . . unfair trade practices in which the requirements are not limited to devices.”¹³¹

The *Restatement (Second) of Torts* section 402A derives from the common law the notion that “[o]ne who sells *any* product in a defective condition unreasonably dangerous to the user or

¹²⁸ See *Lohr*, 518 U.S. at 495–96. The MDA is enabling legislation with which Congress gave the FDA complete control to determine what requirements should be placed on medical devices. Compare this to other authority-delegating statutes where Congress has kept that power for itself and prescribed the exact manufacturing requirements within the text of the statute, leaving the agency only the ability to enforce the statutory provisions. For example, the Federal Insecticide, Fungicide and Rodenticide Act (“FIFRA”) gives the Environmental Protection Agency (“EPA”) the authority to register an insecticide if it meets the safety standards outlined in the Act itself. The EPA, however, does not have the authority to define the safety requirements themselves. See Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. § 136a(c)(5) (2000); see also Grey, *supra* note 17, at 589 (noting that a pesticide will not be registered by the EPA unless it meets FIFRA’s requirements). Under the MDA, a manufacturer cannot even raise the defense of preemption unless the FDA, acting under its statutory authority, has set forth specific device requirements. See *Lohr*, 518 U.S. at 496. Because Congress has empowered the FDA both to enforce and to interpret the MDA, a court should give deference to the FDA’s interpretation of the preemption clause. Cf. Katerberg, *supra* note 109, at 1483 (writing that broader congressional delegation of authority in MDA to FDA “laid the foundation for the high deference that Justice Stevens granted to the FDA’s interpretation of preemption”); Kleinhaus, *supra* note 24, at 316 (emphasizing that *Lohr* “affirm[ed] the role and authority of [the] FDA”).

¹²⁹ See *Lohr*, 518 U.S. at 505–06 (Breyer, J., concurring).

¹³⁰ 21 C.F.R. § 808.1(d)(1) (2005) (emphasis added).

¹³¹ *Id.*

consumer . . . is subject to liability for physical harm thereby caused”¹³² Likewise, many common law duties—such as those relied upon by Mrs. Horn and the plaintiff in *Lohr*—are generally applicable to all products, not just medical devices.¹³³ *Lohr*, for instance, found that the common law duties at issue were not sufficiently specific to be preempted.¹³⁴ The Court reasoned that the general duties to use due care to avoid foreseeable dangers and to inform users of the risks involved with potentially dangerous items were applicable to all products and were too broad to impede the implementation and enforcement of federal safety requirements.¹³⁵ Like the Uniform Commercial Code and general trade practices excluded from preemption by the FDA, the Court held that these common law duties were “no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations[,] . . . or to use due care in the training and supervision of a work force.”¹³⁶ The *Horn* court expressly acknowledged that Mrs. Horn’s claims were general, not device-specific, and essentially the same as those in *Lohr*.¹³⁷ Thus, because most of Mrs. Horn’s claims were general in nature and would not impede the implementation of federal requirements, they too should have escaped preemption.

A second provision of the FDA regulations also implies that Congress did not intend to include state tort claims in section 360k. Section 808.1(c) codifies the procedure by which the Commissioner of the FDA may grant an exemption from preemption and thereby allow a state or political subdivision to impose a substantive state requirement on a device.¹³⁸ Because

¹³² JOHNSON & GUNN, *supra* note 12, at 707 (emphasis added) (quoting RESTATEMENT (SECOND) OF TORTS § 402A(1) (1965)). A product is in a defective condition if at the time it leaves the hands of the seller, it is “in a condition not contemplated by the ultimate consumer which will be unreasonably dangerous to him.” *Id.* at 708. This applies even if the seller has exercised all possible care in the preparation of the product. *Id.* at 707. In addition, holding the seller to strict liability “does not preclude liability based upon the alternative ground of negligence.” *Id.*

¹³³ *See Lohr*, 518 U.S. at 501.

¹³⁴ *See id.* (“[T]he general state common-law requirements in this suit were not specifically developed ‘with respect to’ medical devices.”).

¹³⁵ *See id.*

¹³⁶ *Id.* at 501–02.

¹³⁷ *See supra* note 81 and accompanying text.

¹³⁸ 21 C.F.R. § 808.1(c) (2005). Section 360k(b) of the MDA provides that a state or political subdivision may petition for an exemption where it seeks to impose a requirement that is more stringent than the federal requirements, and the

it is not the proper province of the courts to petition the Commissioner of the FDA for an exemption for the purposes of a tort remedy,¹³⁹ Congress was likely contemplating only legislative and administrative enactments when it provided for this exemption mechanism.¹⁴⁰ It is therefore equally likely that Congress was, similarly, only contemplating state legislative and administrative enactments in the express preemption language of section 360k. Quite simply, a court should not read state tort claims into statutory provisions where Congress has left them out.¹⁴¹

Overall, the FDA regulations pertaining to the MDA tend to show that the duties implicated by Mrs. Horn's state tort claims would not create a substantive requirement for the HeartMate. The regulations are too general to interfere with the agency's ability to implement the necessary federal standards. Moreover,

requirement is necessary because of compelling local conditions. *See* 21 U.S.C. § 360k(b) (2000). The regulation promulgated by the FDA codifies the procedure by which such an exemption could be granted. *See* 21 C.F.R. § 808.1.

¹³⁹ *See* Michael J. Diamondstein, Comment, *Illinois: An Oasis in the Middle of a Judicial Desert*, Haudrich v. Howmedica, Inc., 2 WIDENER L. SYMP. J. 331, 354 (1997) (arguing that courts could never apply for exemptions to a governmental entity, such as the Secretary of Health, Education and Welfare).

¹⁴⁰ *See* Haudrich v. Howmedica, Inc., 642 N.E.2d 206, 209–11 (Ill. App. Ct. 1994), *aff'd*, 662 N.E.2d 1248 (Ill. 1996). In *Haudrich*, the court pointed out that section 360k(a) provides that “no State or political subdivision . . . may establish . . . any requirement . . .” *Id.* at 209 (quoting 21 U.S.C. § 360k(a)) (omission in original) (emphasis omitted). The exemption allowance in section 360k(b) states that, “[u]pon application of a State or a political subdivision thereof, the Secretary may . . . exempt . . . a requirement . . .” *Id.* at 209 (quoting 21 U.S.C. § 360k(b)) (omission in original). The Court found that because courts cannot apply for an exemption from the preemption provision, they were likely not included in the meaning of “State or political subdivision” as the term was used in section 360k(b). *See id.* at 209–10. Because a term is considered to carry the same meaning throughout a statute, courts were also likely not included in section 360k(a). *See id.* Thus, the court held that courts “cannot be the source of ‘requirements’ that are preempted,” because they are not state or political subdivisions. *Id.* at 210. In addition, the *Haudrich* court analyzed the FDA regulation by referencing the exemption language from § 808.20(a) of the Code of Federal Regulations: “An exemption may only be granted for a requirement that has been *enacted, promulgated, or issued* in final form by the authorized body or official of the State or political subdivision . . .” *Id.* at 212 (quoting 21 C.F.R. § 808.20(a)). The court held that “issued” referred to legislative or regulatory action because the words “enacted” and “promulgated” “clearly refer to legislative and/or regulatory methods,” and when two or more analogous words are used in succession in a statute, they are understood to express the same meaning. *See id.* (citing *People v. Goldman*, 287 N.E.2d 177, 179 (Ill. App. Ct. 1972)).

¹⁴¹ *See* Dega, *supra* note 21, at 648–49 (“[I]f the statute says ‘anything’ about preemption, it should say ‘everything.’”).

because the FDA has explicitly stated that generally applicable claims will not be preempted, the claims here should have survived preemption.

It must be noted that in its most recent opinion, the FDA indicated that it now believes that the MDA preempts state tort claims.¹⁴² Because of the great weight to be accorded the FDA's

¹⁴² The FDA submitted an amicus curiae brief to the *Horn* court stating that it was changing its previous opinion and now believed that state common-law claims regarding PMA-approved devices are preempted. See *Horn v. Thoratec Corp.*, 376 F.3d 163, 177 (3d Cir. 2004) (noting the FDA's view that PMA approval in this case required preemption); *Thoratec: New FDA Position on Device Preemption Should Be Given Deference*, 9–11 MEALEY'S EMERGING DRUGS & DEVICES, June 3, 2004, at 9 (noting the change in the FDA's position). The significance of this opinion letter, however, is unclear because it contradicts the FDA's former position of non-preemption, its argument made before the Supreme Court in *Lohr*, and parts of the FDA regulations codified at 21 C.F.R. § 808 (2004). See *FDA's New Position on Device Preemption Seen as Contradicting Regulation*, 9–12 MEALEY'S EMERGING DRUGS & DEVICES, June 17, 2004, at 5 [hereinafter *FDA's New Position*]. "The FDA has never questioned the continued viability of these regulations . . ." *Id.* (quoting petitioner Barbara Horn). Yet the FDA's letter brief does not explain how its new view is consistent with the regulations. *Plaintiff, Device Maker Differ on Significance of Government's New Stand on Preemption*, PRODUCT SAFETY & LIABILITY REP., June 21, 2004, available at <http://litigationcenter.bna.com/pic2/lit.nsf/id/BNAP-622PLR> [hereinafter *Plaintiff, Device Maker Differ*].

In addition, these statements conflict with previous FDA opinions. For example, in one letter, the FDA Associate Commissioner for Regulatory Affairs wrote in response to a request for an advisory opinion: "There is no indication in the legislative history of [section 360k] that Congress intended . . . [to] preempt . . . available legal remedies, or State or local statutes that only incidentally apply to devices." Katerberg, *supra* note 109, at 1467 n.190 (quoting Letter from Joseph P. Hile, Associate Commissioner for Regulatory Affairs, FDA, to Robert E. Manchester, National Women's Health Network (Mar. 8, 1984), in Brief for Cross-Petitioners Lora Lohr and Michael Lohr at 13a, *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) (Nos. 95-754 and 95-886)). In a letter to a Washington attorney, Joseph Sheehan, Chief of the FDA Regulations Staff, stated that the "FDA believes that [section 360k] does not preempt general product liability requirements." *Id.* (quoting Letter from Joseph Sheehan, Chief, Regulations Staff, FDA, to Cindy Whaley, Attorney (Feb. 2, 1987), in Brief for Cross-Petitioners Lora Lohr and Michael Lohr at 14a, *Medtronic*, 518 U.S. 470 (Nos. 95-754 and 95-886)). Finally, Richard Cooper, former Chief Counsel to the FDA has written: "[The] FDA has no expertise or authority for managing systems of redress for private injuries. The value judgments necessary for such management—how the scales for plaintiffs and defendants should be set up—are best left to legislatures and the courts." *Id.* at 1467–68 (quoting Richard M. Cooper, *Drug Labeling and Products Liability: The Role of the Food and Drug Administration*, 41 FOOD DRUG COSM. L.J. 233, 233 (1986)).

In January 2006, the FDA included a preemption analysis in the comments to its final rule regarding prescription drug labeling. In the comments, the FDA reinforced its position that "FDA approval of labeling . . . preempts conflicting or contrary State law." FDA Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3,922, 3,934 (Jan. 24, 2006)

position on this issue, its new position is likely the strongest point in favor of preemption.¹⁴³ However, even if the FDA has changed its position, it has neither altered its official regulations nor indicated that the courts should no longer heed those regulations.¹⁴⁴ At a minimum, the confusion resulting from contradictory FDA opinions—along with the legislative history, purpose, and structure of the MDA—supports the assertion that the *Horn* court should not have rushed to find Mrs. Horn's claims preempted. Instead, the court should have reviewed each of the claims more extensively to determine whether they would directly conflict with the FDA requirements.¹⁴⁵

IV. THE STATE REQUIREMENT

As discussed above, because Congress did not explicitly indicate whether it intended to include state common law tort claims in section 360k, a court should look to the statutory history, purpose, and structure of the MDA to discern congressional intent. The legislative history shows that Congress did not raise the issue of preemption of tort claims. Because the legislative purpose of the MDA is to enhance the health and safety of patients requiring medical devices, it is unlikely that Congress would remove all redress for injured persons without some discussion and debate. In addition, in other sections of the MDA, Congress expressly noted that manufacturers were vulnerable to liability. As these items suggest that Congress did not intend to preempt all tort claims, it is proper for a court to examine the regulations implemented by the FDA. In this case, such regulations expressly state that general requirements, those applicable to products, in addition to medical devices, will not be preempted.

To determine if a plaintiff's claims are device-specific rather than applicable to all products in general, a court must examine each claim individually and determine if that claim would impose

(to be codified at 21 C.F.R. pts. 201, 314, 601). In its statement, the FDA includes, as an example of a preempted claim, failure to warn arising from omission of information on drug labels. Lisa Brennan, *FDA Move May Aid Defense*, LEGAL TIMES, Feb. 6, 2006, at 10. In as much as the FDA seeks to treat medical devices in the same manner as prescription drugs, the statement tends to show that the FDA is moving toward a position more strongly in favor of preemption.

¹⁴³ See *supra*, notes 128–29 and accompanying text.

¹⁴⁴ Cf. *FDA's New Position*, *supra* note 142 at 5.

¹⁴⁵ See *infra* notes 146–48 and accompanying text.

requirements different from, or in addition to, the requirements established by the FDA.¹⁴⁶ In fact, the *Lohr* Court instructed that “[t]he statute and regulations . . . require a *careful comparison* between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement”¹⁴⁷ Further, *Horn* recognized that “[t]he more logical reading of Justice Breyer’s concurring opinion [in *Lohr*] is that a court should *carefully examine* the state common law claim in order to determine whether that claim would *impose* a substantive requirement”¹⁴⁸

The *Horn* court, however, failed to conduct such an examination. It merely stated that it was “satisfied” that Mrs. Horn’s general state law claims would impose conflicting substantive requirements.¹⁴⁹ The court gave brief examples of why some of the claims would conflict,¹⁵⁰ but it never separately examined the nature and effects of each of the claims.¹⁵¹ A more thorough analysis of the claims would have shown that some—

¹⁴⁶ See, e.g., *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 523 (1992) (plurality opinion) (stating that, in light of the presumption against preemption, narrow construction of the preemption provision at issue was proper and that each of the plaintiffs’ common law claims had to be examined to determine whether it constituted a “requirement”); *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 228–37 (6th Cir. 2000) (reviewing plaintiffs’ claims individually); *Martin v. Telectronics Pacing Sys., Inc.*, 105 F.3d 1090, 1098–100 (6th Cir. 1997) (analyzing each of plaintiffs’ common law tort claims for manufacturing defect, design defect, and failure to warn).

¹⁴⁷ *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 500 (1996) (emphasis added).

¹⁴⁸ *Horn v. Thoratec Corp.*, 376 F.3d 163, 174 (3d Cir. 2004) (first emphasis added).

¹⁴⁹ See *id.* at 176.

¹⁵⁰ See *id.* at 176–77. The court stated that Mrs. Horn’s claim that the screw ring was defectively designed would force the manufacturer to alter the design that had previously been approved by the FDA and would result in the need for additional FDA approval. *Id.* at 176. In addition, it found that Mrs. Horn’s failure to warn claims would require the manufacturer to provide warnings and instructions different from those approved by the FDA. *Id.*

¹⁵¹ Part V of the *Lohr* opinion, joined by Justice Breyer, systematically evaluated all of the plaintiff’s claims, discussing the nature of each and its potential effect on the manufacturer. See *Lohr*, 518 U.S. at 492–502. The *Horn* court only focused on distinguishing the two cases and failed to give adequate deference to the rule of the Supreme Court for evaluating state requirements. For example, in *Lohr*, the Court individually examined the design defect and manufacturing and labeling claims. See *id.* at 492–94, 497–502. It determined that, in each circumstance, the federal requirements were not sufficiently specific to have a preemptive effect. See *id.* at 493–94, 501. Although never expressly stated, *Lohr*’s method of carefully comparing each federal and state requirement should have been considered binding on lower courts in subsequent cases.

although not all—should have survived preemption.

Mrs. Horn's claims sounded in both strict liability and negligence. The Pennsylvania Supreme Court has adopted the strict liability standard of the *Restatement (Second) of Torts* section 402A.¹⁵² In order to prevail under this standard, Mrs. Horn needed to show that the device was unsafe for its intended user.¹⁵³ To succeed on her negligence-based claims, she had to establish that the manufacturer had a duty or obligation to conform to a certain standard of conduct, failed to conform to that standard, and caused the injury that resulted in actual damage or loss.¹⁵⁴ Holding Thoratec liable based on these tort theories would not have imposed device-specific requirements on the HeartMate because Mrs. Horn's claims were general in nature and not drawn specifically with respect to the Heartmate.¹⁵⁵

¹⁵² See *Azzarello v. Black Bros. Co., Inc.*, 391 A.2d 1020, 1024 (Pa. 1978). A federal court sitting in diversity must employ the substantive law of the forum state. See *Klaxon Co. v. Stentor Elec. Mfg. Co., Inc.*, 313 U.S. 487, 496 (1941).

¹⁵³ See *Phillips v. Cricket Lighters*, 841 A.2d 1000, 1007 (Pa. 2003).

¹⁵⁴ See *Macina v. McAdams*, 421 A.2d 432, 434 (Pa. Super. Ct. 1980) (quoting WILLIAM L. PROSSER, *LAW OF TORTS* § 30, at 143 (4th ed. 1971)). To determine if a defendant in a negligence action had a duty of care, the Pennsylvania courts balance the following five factors: "(1) the relationship between the parties; (2) the social utility of the [defendant's] conduct; (3) the nature of the risk imposed and foreseeability of the harm incurred; (4) the consequences of imposing a duty upon the [defendant]; and (5) the overall public interest in the proposed solution." *Phillips*, 841 A.2d at 1008–09 (quoting *Althaus v. Cohen*, 756 A.2d 1166, 1169 (Pa. 2000)).

¹⁵⁵ In addition to defective design and failure to warn, Mrs. Horn also asserted that Thoratec failed to use good manufacturing practices. *Thermo Cardiosystems*, 229 F. Supp. 2d at 385. She made no claim, however, that Thoratec ever deviated from the manufacturing process requirements imposed by the FDA. She claimed that although the manufacturer followed the precise FDA manufacturing guidelines for the HeartMate, the device as manufactured was still unsafe. See *id.* at 390. Because such a finding would mean that something specific was wrong with the FDA-approved manufacturing process, her claim would impose requirements different from, or in addition to, specific federal manufacturing requirements. If Horn asserted, however, that Thoratec's manufacturing process deviated from the requirements of the FDA, the claim would not be preempted because it would be parallel to, rather than opposed to, the federal requirement. See *Martin v. Medtronic, Inc.*, 254 F.3d 573, 585 (5th Cir. 2001) (stating that claims alleging that device manufacturer did not comply with the PMA process were not preempted because they were not "different from, or in addition to," federal requirements). Here, the heavy burden imposed on the device by the exacting federal manufacturing requirements increases the likelihood of conflict with the state standard resulting from a tort award. Therefore, the court correctly held that Mrs. Horn's manufacturing defect claim was preempted.

A. Defective Design Claim

Mrs. Horn's defective design claims were based in negligence. Specifically, she claimed negligent failure to test and study the HeartMate adequately and failure to use proper suture material.¹⁵⁶ Simply because her claims mentioned the HeartMate by name did not mean that they were sufficiently device-specific to impose substantive requirements on the manufacturer. To be the proper subject of preemption, state claims must be both developed "with respect to" medical devices and impose a duty "different from, or in addition to," federal requirements.¹⁵⁷ Thus, an understanding of what is "different from, or in addition to," federal standards becomes particularly important.

It is submitted that the phrase "different from, or in addition to," should be limited to those state requirements that would directly prevent a manufacturer from complying with federal requirements.¹⁵⁸ In *Lohr*, Justice Breyer did not share the plurality's belief that state common law claims are rarely, if ever, preempted by section 360k.¹⁵⁹ His concurrence is, therefore, the narrowest holding of the Court on this point, and is controlling. Nevertheless, even under Justice Breyer's more expansive view of preemption, Mrs. Horn's defective design claims would survive. Justice Breyer was not concerned with the safety requirements imposed by general tort duties; he was troubled with the prospect of a manufacturer facing two conflicting obligations—one federal and one state—and the manufacturer's inability to satisfy both.¹⁶⁰ To illustrate his point, Justice Breyer gave the example of a federal FDA regulation that required a two-inch wire in a hearing aid and a state regulation requiring a one-inch wire.¹⁶¹ Because both requirements are impossible to satisfy, the state

¹⁵⁶ *Horn v. Thermo Cardiosystems, Inc.*, 229 F. Supp. 2d 381, 385 (M.D. Pa. 2002), *aff'd sub nom. Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004).

¹⁵⁷ *Lohr*, 518 U.S. at 500.

¹⁵⁸ See Vladeck, *supra* note 19, at 119 (arguing that preemption makes sense where compliance with both the federal and state requirements would be implausible, but in the case of tort claims, the manufacturer always retains the option of doing nothing).

¹⁵⁹ *Id.* at 508 (Breyer, J., concurring).

¹⁶⁰ See *id.* at 507 (writing that preemption occurs if "the state requirement actually conflicts with the federal requirement . . . [such that] compliance with both is impossible").

¹⁶¹ *Id.* at 504.

agency's regulation is preempted. Justice Breyer argued that if such was the case, a state tort action finding that it was negligent to use a wire greater than one inch would have the same substantive effect as the regulation and, as a result, would also be preempted.¹⁶² Thus, Justice Breyer believed that only claims imposing specific conflicting requirements were preempted and not negligence claims of general applicability, which do not cause a manufacturer to face opposing design requirements.¹⁶³

Here, Mrs. Horn's negligent design claims simply asserted that the HeartMate was not safe for its intended use. Her claims did not allege negligence for failure to adopt a particular alternative design.¹⁶⁴ For example, she did not state what kind of suture material should have been used or what component should have been substituted for the screw ring. A verdict in her favor would not result in the manufacturer having to choose between two diametrically opposed requirements and thus would not fall within the purview of Justice Breyer's conflicting-

¹⁶² *Id.*

¹⁶³ See Vladeck, *supra* note 19, at 119.

¹⁶⁴ The complaint listed alternatives for the design of the outlet elbow:

Had the screw ring been of an appropriate and feasible design which would not permit the screw ring to become unscrewed as a result of pump movement, or had something more durable than a suture been used to secure the tightened screw ring, or had the threaded sleeve with the eyelet been placed in such a way that the retaining suture did not run across the interior portion of the screw ring directly beneath the underside of the sternum, the disconnection . . . would never have occurred.

Horn v. Thermo Cardiosystems, Inc., 229 F. Supp. 2d 381, 384–85 (M.D. Pa. 2002), *aff'd sub nom.* Horn v. Thoratec Corp., 376 F.3d 163 (3d Cir. 2004) (citation omitted). This list, however, merely illustrated the existence of feasible alternative designs, and a verdict in her favor would not have required Thoratec to adopt any of these alternatives.

obligations argument.¹⁶⁵ Therefore, Mrs. Horn's defective design claims should have survived the preemption defense.

B. Warnings Defect Claims

Mrs. Horn's warnings defect claims included failure to provide adequate warnings that the screw ring could disconnect and failure to give physicians adequate instructions regarding implantation.¹⁶⁶ The court determined that these claims would conflict with the HeartMate's labeling and instructions as approved by the FDA.¹⁶⁷ With very little discussion, it concluded that Mrs. Horn's failure to warn claims "would require [Thoratec] to provide different warnings and instructions from those approved by the FDA."¹⁶⁸ Once again, the court failed to evaluate adequately the specificity of the claims in order to gauge whether they would really impose conflicting duties on the manufacturer. A more complete analysis would have revealed that the state claims do not conflict with the specific federal labeling requirements.

First, Mrs. Horn's failure to warn claims were not sufficiently developed "with respect to" the HeartMate in order to be preempted. She merely asserted that the manufacturer failed to warn of the risks attendant with use of the device. Similar to the design defect claim, the complaint does not specifically state what warnings should have been included in the product's labeling, but only that the warnings supplied were deficient.¹⁶⁹ Where, as here, failure to warn claims are predicated solely upon the general duty of every manufacturer to warn consumers of the risks associated with using a potentially dangerous product, they fall within the general-applicability exception of the FDA

¹⁶⁵ It is possible that when faced with the prospect of having to pay additional tort remedies, the manufacturer would choose to adopt a different design. No specific change, however, would be mandated by Horn's claims and such an effect would be an indirect result of the litigation. One court went so far as to hold that even if a common law recovery imposed an additional obligation on a product manufacturer, this was permissible because the manufacturer may opt between making changes in accordance with a tort verdict or paying compensation to future victorious tort plaintiffs. *See Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1540-43 (D.C. Cir. 1984).

¹⁶⁶ *Thermo Cardiosystems*, 229 F. Supp. 2d at 385.

¹⁶⁷ *See Horn v. Thoratec Corp.*, 376 F.3d 163, 176-77 (3d Cir. 2004) (depicting state claims and federal law as being in "severe tension").

¹⁶⁸ *Id.* at 176 (citation omitted).

¹⁶⁹ *See supra* text accompanying notes 164-65.

regulations¹⁷⁰ and are not sufficiently device-specific to be preempted.¹⁷¹

Furthermore, FDA regulations explicitly permit a manufacturer to initiate labeling alterations—even before receipt of an FDA order approving the changes—if they will add or strengthen a contraindication, warning, precaution, or instruction that is intended to enhance the safe use of the device.¹⁷² The warnings reviewed and approved by the FDA could therefore be viewed as the *minimum* safety requirement, rather than as the only warnings that the manufacturer may include.¹⁷³ Because encouraging the manufacturer to implement such changes is within the spirit of the MDA’s purpose of enhancing safety, it seems unlikely that the FDA would sanction a manufacturer if—upon discovering a safety problem with its device—it unilaterally altered the label to make the warnings stronger.¹⁷⁴

¹⁷⁰ See generally *supra* text accompanying notes 130–37.

¹⁷¹ Cf. *Oja v. Howmedica, Inc.*, 111 F.3d 782, 789 (10th Cir. 1997) (finding negligent failure to warn claim at issue not adequately “device-specific”). In *Oja*, after the manufacturer filed a PMA application for use of an artificial hip without adhesive cement, the FDA permitted approval under the section 510(k) process based on use and approval of the same device requiring cement. See *id.* at 787. In considering the original application, the FDA had carefully reviewed the labeling and warnings of the device, conditioning approval upon deletion of one word from the proposed labeling. See *id.* In 1991, the FDA cited the manufacturer for regulatory violations; as a result, the manufacturer issued a “Dear Doctor” letter, which the FDA approved, instructing physicians on proper surgical techniques for device implantation. See *id.* The court held that the original FDA requirement—that the device could not be labeled or promoted for use without cement—was sufficient to establish a specific federal requirement with respect to labeling, even though the device had received section 510(k) approval. See *id.* at 789. The court also held that the injured plaintiff’s negligent failure to warn claim did not constitute a state requirement developed with respect to a particular device, and that the general duty to warn of foreseeable dangers is “‘not the kind[] of requirement[] that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements.’” *Id.* (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 501 (1995)).

¹⁷² 21 C.F.R. § 814.39(d)(2) (2005).

¹⁷³ However, in its January 2006 statement regarding prescription drug labeling, the FDA said that it views its labeling requirements as both a floor and a ceiling, instead of a mere minimum-safety standard. FDA Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3,922, 3,934–35 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601).

¹⁷⁴ See *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 800 (8th Cir. 2001) (Bye, J., dissenting) (“Section 814.39(d)(2) is not a moth-eaten relic of past regulatory efforts to which we attach little or no importance. The provision is a vital component of the

Moreover, it is for the finder of fact at trial to decide whether a reasonable manufacturer would have foreseen the potential for failure of the device and whether Thoratec was negligent for not warning of possible malfunction.¹⁷⁵ It is therefore possible for a jury to find that the manufacturer was negligent for failing to include such additional warnings without such finding conflicting with the requirements previously established by the FDA.¹⁷⁶ If a jury does not state specifically what warnings should have been included, a general finding that Thoratec negligently failed to give proper instructions for the use and safety of the HeartMate, despite FDA approval of the labeling, would not impose labeling requirements in direct conflict with those imposed by the FDA. Therefore, the court improperly held Mrs. Horn's negligent failure to warn claims preempted at the early summary judgment phase of the litigation.

To be sure, Thoratec would likely alter the HeartMate's labeling in response to an adverse verdict, but subsequent alteration would not mean that a new labeling requirement has been established. Thoratec argued that because it would ultimately need to obtain supplementary PMA approval for all label changes, a finding that the approved labeling was insufficient would impose obligations in direct conflict with the specific label approval of the FDA.¹⁷⁷ Again, however, the federal requirement for safety warnings in this case may be viewed as only a threshold;¹⁷⁸ Thoratec always had the ability to add safety warnings to the product labeling.¹⁷⁹ "For example, nothing in the PMA process forbade Thoratec from warning that the heart

FDA's larger regulatory mission of ensuring that manufacturers amend their warnings and their products in response to safety concerns and scientific advancements.").

¹⁷⁵ Clearly, if the risk is determined to have been unforeseeable, the manufacturer will be relieved of liability for failure to warn. *See Palsgraf v. Long Island R.R. Co.*, 248 N.Y. 339, 342, 162 N.E. 99, 99 (1928) (holding that no negligence exists where the risk would have been unforeseeable to the ordinary vigilant person in the defendant's position).

¹⁷⁶ *See Oja*, 111 F.3d at 789 (writing that general duty to warn of foreseeable dangers does not compel preemption).

¹⁷⁷ *See Horn v. Thoratec Corp.*, 376 F.3d 163, 177 & n.21 (3d Cir. 2004).

¹⁷⁸ *See* RESTATEMENT (SECOND) OF TORTS § 288C (1965) ("Compliance with a legislative enactment or an administrative regulation does not prevent a finding of negligence where a reasonable man would take *additional* precautions.") (emphasis added).

¹⁷⁹ *See* 21 C.F.R. § 814.39(d)(2) (2005). *See also supra* text accompanying notes 172-74.

pump should not be installed if the sutures would face upward, toward the patient's sternum."¹⁸⁰ Therefore, voluntary inclusion of additional warnings following an adverse verdict would not impose safety requirements on Thoratec that did not exist already.

Although the Third Circuit correctly found some of Mrs. Horn's claims preempted, it did not give adequate consideration to the design defect and warnings defect claims. Under Justice Breyer's narrowest holding in *Lohr*, a claim is "different from, or in addition to," the federal requirements if it forces the manufacturer to choose between directly conflicting obligations. Here, a jury's general conclusion that the HeartMate was improperly designed or that the warnings were insufficient would not dictate exactly how the product should have been designed or labeled. Because such claims would not impose directly conflicting standards on Thoratec, they are not "different from, or in addition to," the federal requirements, and should therefore have escaped preemption.

CONCLUSION

The Supremacy Clause of the United States Constitution requires that federal law preempt state law where there is a direct conflict. When the federal law is ambiguous and the state law at issue is a common law tort claim, however, a presiding court must examine several variables before it finds preemption. Congressional intent is of paramount importance, and a court should look for a clear statement of intent to preempt tort claims. Where no clear statement exists, a court should look to legislative history, purpose, and structure of the federal law to decipher congressional intent. Examining the MDA in this light suggests that Congress did not intend to preempt state tort claims but does not provide a definitive answer. Thus, the regulations implemented by the controlling regulatory agency should be given substantial weight. Those promulgated by the FDA state that requirements of general applicability will not be preempted by the MDA. To determine whether claims will impose specific or general requirements, a court should compare each claim to the applicable federal requirement and preempt only those that are in direct conflict.

¹⁸⁰ *Plaintiff, Device Maker Differ*, *supra* note 142.

In the case of *Horn v. Thoratec Corp.*, the Third Circuit failed to engage in the proper analysis when it did not address each of the plaintiff's claims individually. If it had done so, the court would have found that although some claims were properly preempted, the general design and warnings defects claims would not establish requirements for the device in direct conflict with those of federal law. Therefore, Mrs. Horn's design and warnings defect claims would not be "different from, or in addition to," the federal requirements and should have escaped preemption. Thus, this important decision deserved greater analysis than that in which the Third Circuit engaged.