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PATIENTS BEWARE: PREEMPTION OF COMMON LAW CLAIMS UNDER THE MEDICAL DEVICE AMENDMENTS

MICHAEL P. DINATALE*

I. INTRODUCTION

“According to the Rand Corporation, the current cost to the United States from injuries on the job, negligent health care, and defective products total \$176 billion each year.”¹

Products are useful creations but can cause suffering as well. Medical devices are designed to protect and lengthen the lives of humans, but those same devices can quickly end a life if the product fails to work properly.

In order to foster the creation of safe medical devices, Congress, in 1976, passed the Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act of 1938² with two purposes in mind. First, it was intended to protect public health by promoting safe and effective medical devices.³ The second aim of the MDA was to create a uniform regulatory scheme, which would encourage innovation in the field and prevent overregulation.⁴ These aims counterbalance each other, with safety of consumers on one side and the interests of industry on the other.⁵ Congress passed the MDA in

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1. ROGELIO LASSO, PRODUCTS LIABILITY AND SAFETY: AN AMERICAN AND COMPARATIVE APPROACH, 9-10 (2003).

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

3. 21 U.S.C. §§ 360c(a)(1)(A)(i), 360c(a)(1)(B), 360e(d)(2) (1976). Theresa J. Pulley Radwan, *Meeting the Objectives of the MDA: Implied Preemption of State Tort Claims by the Medical Device Amendments*, 10 J.L. & HEALTH 343, 349-50 (1995/96).

4. 21 U.S.C. §§ 360j(g)(1), 360k(a) (1976). In 1999, a bill was proposed in both houses of Congress that would have limited the ability of Congress and government agencies to preempt state and local laws. Federalism Accountability Act of 1999, S. 1214, 106th Cong. (1999). Big business opposed the legislation and the bill was dropped. Cindy Skrzycki, *The Chamber Reached a Sticking Point*, WASH. POST, Sept. 17, 1999, at E1.

5. See Pulley Radwan, *supra* note 3, at 349-50. Radwan quoted the House of Representatives:

Those involved in the development, promotion, and application of medical devices generally agree that the public deserves more protection against unsafe, unproven, ineffective, and experimental medical devices. But this belief is counterbalanced by an equally strong conviction that excessive or ill-conceived Federal device

response to a number of injuries and deaths caused by interuterine birth control devices.⁶ When Congress enacted the MDA, the legislation included an express preemption clause prohibiting states from enacting or enforcing any requirement that is different from, or in addition to, the Food and Drug Administration (FDA) requirements.⁷

Despite Congress's efforts, federal courts continue to disagree about whether the preemption clause prevents injured people from bringing state tort claims against the manufacturers. A majority of federal courts have ruled that FDA certification of a medical device preempts state law claims.⁸ However, other federal courts of appeal have held that state claims are not preempted.⁹

regulation would stifle progress in this field.
H.R. REP. NO. 94-853 (1976).

Similar arguments were offered by the Senate during debates over the 1990 amendments to the MDA: "[S]imply put, the [MDA] sought to avoid overregulation, [the elimination of any] unnecessary resource costs to industry and the government, foster incentives to encourage innovation in a relatively youthful industry and, most importantly, provide the public reasonable assurances of safe and effective devices." *Id.* at 349-50 (quoting S. REP. NO. 101-513 (1990)).

6. Laura K. Jortberg, *Who Should Bear the Burden of Experimental Medical Device Testing: The Preemptive Scope of the Medical Device Amendments under Slater v. Optical Radiation Corp.*, 43 DEPAUL L. REV. 963, 978 (1994). See also *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996) (explaining that the Dalkon Shield was an intrauterine prophylactic device that caused a large number of pregnancies, infections, and some deaths).

7. 21 U.S.C. § 360k(a). FDA regulations provide in part:

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

21 C.F.R. § 808.1(d) (2005).

FDA regulations also state that the Uniform Commercial Code's warranty of fitness is not preempted. 21 C.F.R. § 808.1(d)(1). State statutes prohibiting the manufacturing of adulterated or misbranded devices will usually not be preempted. 21 C.F.R. § 808.1(d)(6)(ii). It should be noted that claims such as express warranty claims will likely not be preempted nor will claims that the manufacturer did not comply with FDA requirements. Michael E. Nast, *Medical Device Preemption—A Plaintiff's Perspective*, 12 WIDENER L.J. 87, 99-100 (2003).

8. See generally *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004) (ruling that 21 U.S.C. § 360k(a) expressly preempted state common law claims of defective design and manufacture and failure to warn); *Brooks v. Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001) (*en banc*) (holding that 21 U.S.C. § 360k preempts plaintiff's claim of failure to warn); *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001) (declaring that the FDA's pre-market approval procedure preempts common law product liability tort claims); *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000) (holding that the Medical Device Amendments of 1976 preempt common law and statutory product liability tort claims); *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997) (finding that the plaintiffs' claims were preempted).

9. See generally *In re: St. Jude Med., Inc., No. 01—1396*, 2004 U.S. Dist. LEXIS 148 (D. Minn. Jan. 5, 2004) (refusing to allow FDA approval to preempt state claims of strict liability for failure to warn); *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir.

Part II of this Comment will discuss the classification of medical devices under the MDA, the process manufacturers go through to obtain FDA approval of a device, and the principles of preemption. Part III will analyze the case law applying those principles. Lastly, part IV will propose a possible solution to the problem.

II. BACKGROUND

A. Device Classification

The MDA placed medical devices into one of three categories,¹⁰ which determines how much scrutiny that device will receive before being approved for use.¹¹ Class I devices are those that are not used to support human life and do not pose an unreasonable risk of injury.¹² Examples of Class I devices include: elastic bandages and tongue depressors. Class II devices are those that cannot be classified as Class I and may pose an unreasonable risk of injury or that could be used to support human life.¹³ Some home pregnancy kits and powered wheelchairs are examples of Class II devices. Class III devices are the most regulated because they present a “potential unreasonable risk of illness or injury.”¹⁴ Class III devices are also meant to be used to support or sustain human life.¹⁵ Pacemakers, intraocular lenses, and artificial hips fall into the Class III category.

In order to bring a new Class III device into the marketplace, the manufacturer must undergo an FDA pre-market approval process to “provide reasonable assurance of [the device’s] safety and effectiveness.”¹⁶ To further ensure safety, the FDA can impose regulations on the manufacturing processes that must be followed when making the devices.¹⁷

1999)(finding that the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act do not preempt state claims).

10. 21 U.S.C. § 360c.

11. See Pulley Radwan, *supra* note 3, at 345-46 (offering an excellent description of the three categories).

12. 21 U.S.C. § 360c(a)(1)(A)(ii)(II).

13. 21 U.S.C. § 360c(a)(1)(B). State law claims are generally the only remedy for those injured by Class I and II devices and are not preempted because the FDA has no control over the design of those devices. *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1419 (1993).

14. 21 U.S.C. § 360c(a)(1)(C)(ii)(II). Class III devices include heart valves, heart pumps, and pacemakers.

15. 21 U.S.C. § 360c(a)(1)(C)(ii)(I).

16. 21 U.S.C. § 360(a)(1)(C)(i)(B).

17. 21 U.S.C. § 360j(f) (2000). The FDA has authority to enact regulations governing “the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packing, storage, and installation . . .” of devices. This authority extends to all devices regardless of classification. *Id.*

B. The Pre-Market Approval Process

On average, the pre-market approval process (PMA) requires 1200 hours to conduct.¹⁸ The process begins with the manufacturer or a representative of the manufacturer filing an application. The application contains information ranging from the name of the applicant to the results of clinical studies.¹⁹ The information collected includes product specifications, the intended uses of the device, how the device is manufactured, results for clinical studies, and a sample of the device.²⁰

After receiving the completed application, the FDA will begin to review it.²¹ The FDA will either review the application itself or will submit the information to a panel of experts to evaluate.²² The entire PMA process is dependent on the manufacturers supplying the FDA with testing and safety information.²³

Manufacturers can undertake the PMA process in other ways than the traditional method. Manufacturers may also submit a modular PMA, a streamlined PMA, or a Product Development Protocol (PDP).²⁴ The modular PMA process allows manufacturers to submit parts of the

18. *Lohr*, 518 U.S. at 477. In 2002, the average total time of review for PMA applications was 213 days. In 2003, the time of review increased to 221 days. OFFICE OF DEVICE EVALUATION AND OFFICE OF IN VITRO DIAGNOSTIC DEVICE EVALUATION AND SAFETY ANNUAL REPORT, pt. 7, tbl.3 (2003), available at <http://www.fda.gov/cdrh/annual/fy2003/ode/part7.html> (last visited Oct. 4, 2005) [hereinafter ODE REPORT]. An example often cited by critics of the PMA process is that of an artificial heart that had been used in Europe for ten years before it was finally approved in the United States. Pulley Radwan, *supra* note 3, at 347.

19. See 21 C.F.R. § 814.20 (2005) (laying out in detail the exact information that must be present in the PMA application). See also U.S. Food and Drug Admin., Device Advice, PMA Application Contents, <http://www.fda.gov/cdrh/devadvice/pma/index.html> (last visited Oct. 4, 2005) [hereinafter FDA, Device Advice, Application Contents] (explaining that manufacturers are “encouraged” to provide information about what countries the device has been distributed in and “encouraged” to provide summaries of reported adverse effects of the device).

20. 21 U.S.C. § 360e(c)(1) (2000); 21 C.F.R. § 814.20; FDA, Device Advice, Application Contents, *supra* note 19. See also Gregory J. Scandaglia & Therese L. Tully, *Express Preemption and Premarket Approval Under the Medical Device Amendments*, 59 FOOD DRUG L.J. 245, 249-50 (2004) (giving an in-depth explanation of the information that must be submitted in the application and adding that if supplying a sample of the device is impracticable, then the manufacturer must provide time for the FDA to examine it).

21. See 21 C.F.R. § 814.44 (2005) (explaining the approval process once the completed application is received).

22. 21 U.S.C. § 360c(e)(2000).

23. Michael E. Petrella, *License to Maim: Federal Pre-emption and the Medical Devices Amendments of 1976*, 6 HEALTH MATRIX 349, 369 (1996). Allegations have been made that those at the FDA charged with reviewing medical devices are required to maintain a ninety-eight percent approval rate on devices. *Id.*

24. U.S. Food and Drug Admin., Device Advice, PMA Application Methods, available at http://www.fda.gov/cdrh/devadvice/pma/app_methods.html#traditional (last visited Oct. 5, 2005) [hereinafter FDA, Device Advice, PMA Application Methods]. See also Scandaglia & Tully, *supra* note 20, at 249 (offering a more detailed overview of the different applications’ processes).

application at different times.²⁵ The FDA recommends this approval method for devices that are just beginning clinical studies because the manufacturer can then supply the study results as they are acquired.²⁶ In order to begin the modular process, the manufacturer must develop a “PMA shell,” which outlines the schedule for submitting different modules to the FDA.²⁷ As each module is submitted, the FDA begins the review process.²⁸ This method can actually expedite the approval process because the manufacturer gets feedback throughout the process, so when it files the last modules, the FDA has already completed most of the review.²⁹

Another method of approval, currently available only as a pilot program, is the streamlined PMA.³⁰ This method is only offered for devices or technologies that are already familiar to the FDA.³¹ The final method is the product development protocol (PDP). The PDP allows the manufacturer and the FDA to agree on the criteria for determining whether a device is safe and effective.³² If the FDA accepts the PDP proposed by the manufacturer, it is the equivalent of an approved PMA application.³³

Although there are a number of exceptions to the rule that new Class III devices must go through the pre-market approval process, there are three commonly used exceptions.³⁴ First, a device that was in the market prior to the passing of the MDA does not have to undergo the pre-market approval process.³⁵ A second exception is the “substantial equivalence” or the “section 510(k) process.”³⁶ This process allows a manufacturer to get a device approved quickly if it is “substantially equivalent” to a product that

25. FDA, Device Advice, PMA Application Methods, *supra* note 24.

26. *Id.* Generally this method is not recommended if a manufacturer can almost complete a full PMA application or if the device is going to undergo design changes. *Id.*

27. *Id.*

28. *Id.*

29. *Id.*

30. *Id.*

31. *Id.*

32. *Id.* This method has the potential to save time and money because the FDA and the manufacturers are communicating early in the process. *Id.*

33. *Id.*

34. There are three other exceptions, but they are not commonly used: 1) humanitarian devices, 21 U.S.C. § 360j(m); 2) custom devices, 21 U.S.C. § 360j(b); and 3) emergency devices. The emergency devices exception does not arise from language of the statute. Rather, it arises from the ability of the FDA to use discretion in enforcing its authority:

The [FDA] recognizes that emergencies arise where an unapproved device may offer the only possible life-saving alternative, but an IDE [Investigation Device Exemption] for the device does not exist, or the proposed use is not approved under an existing IDE, or the physician or institution is not approved under the IDE. Using its enforcement discretion, FDA has not objected if a physician chooses to use an unapproved device in such an emergency, provided that the physician later justifies to FDA that an emergency actually existed.

U.S. Food and Drug Admin., Guidance for Institutional Review Boards and Clinical Investigators, Emergency Use of Unapproved Medical Devices (1998), available at <http://www.fda.gov/oc/ohrt/irbs/devices.html> (last visited Oct. 6, 2005).

35. 21 U.S.C. § 360e(b)(1)(A).

36. 21 U.S.C. § 360c(i)(1)(A)-(C).

was in the market prior to 1976.³⁷ Since approval under this standard is much easier and faster, it appeals more to manufacturers.³⁸ The final exception is the investigational device exemption (IDE).³⁹ The IDE permits medical devices to be used while compiling the necessary information for a PMA.⁴⁰

C. Post Approval Requirements

After a device receives PMA approval, the FDA may impose obligations on the manufacturer in order to maintain that approval.⁴¹ The manufacturer must submit FDA post approval reports each year after the initial date of approval notifying the FDA of modifications such as changes in design or device usage.⁴² Manufacturers are required to perform post approval surveillance of the devices they put onto the market and must have their surveillance plan approved by the FDA.⁴³

D. General Preemption Principles

The Supremacy Clause states: "The Laws of the United States. . . shall

37. Nast, *supra* note 7, at 92.

38. See *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 348 (2001) (finding that the § 510(k) process lacks the rigor of the PMA). The § 510(k) process has an average review time of only eighty days while the average for PMA is 12.5 months. CTR. FOR DEVICES AND RADIOLOGICAL HEALTH, U.S. FOOD AND DRUG ADMIN., DEVICE CENTER'S FY 1999 PERFORMANCE (1999), available at <http://www.fda.gov/bbs/topics/ANSWERS/ANS00998attachments/cdrh.html> (last visited Oct. 7, 2005). See also ODE REPORT, *supra* note 18, pt. 7, tbl.3 (citing that, in 2002, forty-nine PMA applications were filed with the FDA as compared to 4320 applications under the substantial equivalence process.)

39. 21 U.S.C. § 360j(g) (2000).

40. 21 U.S.C. § 360j(g)(1) (2000).

41. U.S. Food and Drug Admin., Device Advice, Postapproval Requirements, <http://www.fda.gov/cdrh/devadvice/pma/postapproval.html#general> (last visited Oct. 7, 2005) [hereinafter FDA, Device Advice, PMA Postapproval]. See also Scandaglia & Tully, *supra* note 20, at 252-53 (giving a very detailed explanation of the various postapproval requirements with which a manufacturer may have to comply). See also Pulley Radwan, *supra* note 3, at 349 (explaining that amendments to the MDA in 1990 required postapproval surveillance of all devices first introduced after Jan. 1, 1991, if the device fit into the Class III designation). Other 1990 amendments increased the FDA's power to stop distribution of devices, to inform hospitals of potentially dangerous devices, to subpoena evidence to aid in evaluating PMA applications, and to fine violations of FDA provisions. *Id.*

42. FDA, Device Advice, PMA Postapproval, *supra* note 41. The reports must list at least any changes to the device that could effect its safety or effectiveness due to: 1) new uses, 2) any labeling changes, 3) changes in manufacturing location or practices, 4) changes in design or performance characteristics, or 5) changes in packaging. The reports must also include any updated clinical studies even if unpublished. Scandaglia & Tully, *supra* note 20, at 252-53.

43. 21 C.F.R. §§ 822.8-822.14. The submitted documents must contain: 1) name and address of the manufacturer, 2) name of the device (generic and trade name), 3) contact person for the submission, 4) the PMA numbers of the device, 5) table of contents, 6) description of the device, 7) products codes and all relevant model numbers, 8) a list of uses for the device, and 9) the actual surveillance plan that will be used. 21 C.F.R. § 822.9.

be the supreme Law of the Land.”⁴⁴ A plain statement like this would seem to leave no ambiguity as to the supremacy of federal law. However, the reservation to the states of powers not granted to the federal government leaves room for disagreement over exactly what federal laws are supreme.⁴⁵

A federal statute may preempt state law either expressly or implicitly. To determine if a statute expressly preempts state law, all that needs to be examined is the precise wording of the statute.⁴⁶ Implied preemption is determined by looking at the language of the statute and ascertaining the intent of Congress.⁴⁷

There are two types of implied preemption.⁴⁸ The first is field conflict. Field conflict occurs when federal legislation is intended to dominate a

44. U.S. CONST. art. VI, cl. 2 states that:

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority 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.

When considering the Supremacy Clause there is an assumption that Congress did not have the intent of displacing state laws. *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981). See also Viet D. Dinh, *Reassessing the Law of Preemption*, 88 GEO. L.J. 2085, 2088 (2000) (“[I]t is critically important to note [that] the Supremacy Clause itself does not authorize Congress to preempt state laws.”); Stephen A. Gardbaum, *The Nature of Preemption*, 79 CORNELL L. REV. 767, 768 (1994) (“In the American context, the most common and consequential error is the belief that Congress’s power of preemption is closely and essentially connected to the Supremacy Clause of the Constitution.”). Some authors propose that Congress’ power to preempt state law does not come from the Supremacy Clause, but rather, from the Commerce Clause. Betsy J. Grey, *Make Congress Speak Clearly: Federal Preemption of State Tort Remedies*, 77 B.U.L. REV. 559, 607 (1997). Others propose that congressional power comes from the Necessary and Proper Clause. Stephen A. Gardbaum, *The Nature of Preemption*, 79 CORNELL L. REV. 767, 782(1994)

45. “[T]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.” U.S. CONST. amend. X. Historically, the power to regulate health and safety and the power to compensate persons injured by defective products has rested with the states under the police power. *Hillsborough County, Fla. v. Automated Med. Lab., Inc.*, 471 U.S. 707, 719 (1994).

46. See Trent Kirk, *Fraud on the FDA & Buckman—The Evolving Law of Federal Preemption in Products Liability Litigation*, 53 S.C. L. REV. 673, 675 (2002) (offering a short concise definition of express and implied preemption). See also *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (requiring Congress to provide a clear indication that it intends to preempt state law); *Nationsbank of N.C., N.A. v. Variable Annuity Life Ins. Co.*, 513 U.S. 251, 257 (1995) (explaining that if a statute contains an express preemption clause the court will start by looking at the language of the clause); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 518 (1992) (stating that when it is not clear if Congress had the intent to preempt state law the court will rule against preemption).

47. Kirk, *supra* note 46, at 675. The Supreme Court developed a three part test for determining preemption: 1) “[did] the Act’s express pre-emption provision pre-empt this lawsuit?”; 2) “[did] ordinary pre-emption principles nonetheless apply?”; and 3) “[did] this lawsuit actually conflict with the act itself?” *Id.* at 678 (discussing *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000)).

48. *Id.* at 675.

particular field.⁴⁹ In general, courts will find field preemption in those areas where the federal government has exclusive authority, such as immigration and foreign policy, where Congress intended to eliminate dual federal and state legislation, or where there is a comprehensive regulatory scheme.⁵⁰ The second type of implied preemption is conflict preemption, which arises when a state law conflicts with, or is contrary to, a federal law, in which case the federal law prevails.⁵¹

E. The MDA's Preemption Clause

The MDA's preemption clause states that:

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

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

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.⁵²

Even though Congress passed the statute in 1976, courts and commentators continue to debate over the definition of the word "requirement" as it is used in the statute.

This dispute, however, did not receive much attention until 1992 when manufacturers began to widely use the MDA's preemption clause as an affirmative defense against common law tort claims.⁵³ Then, in 1996, the United States Supreme Court ruled on the MDA's preemption clause in *Medtronic, Inc. v. Lohr*.⁵⁴ In that case, a heart patient alleged injury by a

49. 2 DAVID G. OWEN ET AL., MADDEN & OWEN ON PRODUCTS LIABILITY §28.2, at 885 (3d ed. 2000).

50. ERWIN CHERMERINSKY, CONSTITUTIONAL LAW: PRINCIPLES AND POLICIES 385-90 (2d ed. 2002).

51. See *Cipollone*, 505 U.S. at 516 ("In the absence of an express Congressional command, state law is pre-empted if that law actually conflicts with federal law or if federal law, so thoroughly occupies a legislative field as to make reasonable inference that Congress left no room for the States to supplement it.") (citations and internal quotes omitted). Some examples of conflict preemption are: *McDermott v. Wisconsin*, 228 U.S. 115 (1913) (holding that the federal labeling requirements preempted the Wisconsin statute); *Mich. Canners & Freezers Ass'n v. Agric. Mktg. & Bargaining Bd.*, 467 U.S. 461 (1984) (holding that the Agricultural Fair Practices Act of 1967 preempted a Michigan statute that was an obstacle to the accomplishment of the federal act's goals). See Richard C. Ausness, *Preemption of State Tort Law By Federal Safety Statutes: Supreme Court Preemption Jurisprudence Since Cipollone*, 92 KY. L. J. 913, 922-23 (2003-2004) (discussing conflict preemption in more detail).

52. 21 U.S.C. § 360k(a) (emphases added).

53. See, e.g., *Cipollone*, 505 U.S. 504. The plaintiffs in *Cipollone* brought a wrongful death claim against cigarette manufacturers. The court held that the failure-to-warn claims were preempted because the Public Health Cigarette Smoking Act of 1969 contained certain warnings that had to be placed on cigarette packages and state law could not require different warnings.

54. *Lohr*, 518 U.S. 470.

defective pacemaker manufactured by Medtronic.⁵⁵ The pacemaker in question had been approved pursuant to the § 510(k) process.⁵⁶ The Court, although divided in parts of the decision, did agree on a few issues. The Court held: First, the MDA's preemption clause did not expressly preempt all common law causes of action;⁵⁷ second, if a common law cause of action is a mirror image of the federal requirements, then that claim is not barred;⁵⁸ and, finally, based on the fact that the pacemaker in the case underwent the § 510(k) process, the claims were not preempted.⁵⁹

The Supreme Court's decision in *Lohr* never affirmatively defined "requirement," which has allowed the debate to carry on. The plurality found that claims under state common law were not "requirements" as the word is used in the MDA.⁶⁰ However, five other Justices thought that state claims may be "requirements" in some situations.⁶¹ Another Justice, although agreeing that state claims could be "requirements," still found that *Lohr*'s claims were not preempted.⁶²

III. ANALYSIS

The first part of this analysis will discuss the arguments offered by courts in interpreting *Lohr*, holding that the MDA's preemption clause does not preempt common law claims against manufacturers of medical devices.⁶³ *Goodlin v. Medtronic, Inc.*⁶⁴ will be offered as a leading example of the argument against preemption.⁶⁵ The second part of this analysis will discuss the arguments for preemption using the recent case of *Horn v. Thoratec*⁶⁶ as a primary example of the arguments in support of preemption.

A. Arguments Against Preemption

A leading case ruling against preemption is *Goodlin*.⁶⁷ Like *Lohr*,⁶⁸ *Goodlin* involved an allegedly defective pacemaker that Medtronic Inc. had manufactured. After *Goodlin* received her FDA approved Medtronic

55. *Id.*

56. *Id.* at 480-81.

57. *Nast*, *supra* note 7, at 95.

58. *Id.*

59. *Id.* It is significant that the Court in *Lohr* did not deal with a device approved under the PMA process. The court held that claims against devices that did not undergo PMA would not be preempted but did not go as far as saying that those devices that did undergo PMA would be shielded.

60. *Lohr*, 518 U.S. at 487-89.

61. *Id.* at 512 (O'Connor, J., concurring in part, dissenting in part).

62. *Id.* at 503-04 (Breyer, J., concurring).

63. *Id.* at 508.

64. 167 F.3d 1367, 1368 (11th Cir. 1999).

65. *Id.*

66. *Horn v. Thoratec Corp.*, 376 F.3d 163, 164.

67. *Goodlin*, 167 F.3d at 1367. *See also* *Weiland v. Telectronics Pacing Sys., Inc.* 721 N.E.2d 1149 (Ill. 1999); *Sowell v. Bausch & Lomb, Inc.*, 656 N.Y.S.2d 16 (N.Y. App. Div. 1997); *Mears v. Marshall*, 944 P.2d 984 (Or. Ct. App. 1997) (holding, in various state courts, that the PMA does not preempt common law claims).

68. *Goodlin*, 167 F.3d at 1367.

pacemaker, the FDA discovered that there was a risk that the pacemaker could fail due to wiring insulation failure.⁶⁹ As a result, Goodlin underwent open-heart surgery to replace the faulty wiring.⁷⁰ Goodlin then brought suit asserting claims of negligent design and strict product liability.⁷¹ The *Goodlin* decision represents the minority view. Courts following the *Goodlin* reasoning would find that the PMA process does not impose specific requirements,⁷² preemption would be inconsistent with the purpose of the MDA,⁷³ and preemption would leave injured parties without judicial recourse.⁷⁴

1. *The PMA Process Does Not Impose Device-Specific Requirements*

As discussed earlier, the PMA process requires a substantial amount of time to complete. Although that process seems grueling, it is mostly administrative; as long as the manufacturer supplies the FDA with all requested information and convinces the FDA the device is reasonably safe, the product will be approved.⁷⁵ Once the FDA issues approval for a device, the manufacturer may start to sell that device. The FDA approval does not cite any requirements that were used in the approval process.⁷⁶

The PMA process, although specific to the particular device being approved and more stringent than the § 510(k) process, does not involve any particular requirements that must be met in order to gain approval.⁷⁷ Therefore, the MDA's preemption clause is not satisfied. If the PMA process itself is the federal requirement, then § 360k(a) would essentially preempt all claims, leaving manufacturers immune from tort actions.⁷⁸ An

69. *Id.* The wire that could fail was the 4004/M lead, which is the wire that provides the electrical pulse from the pacemaker to the heart. *Id.*

70. *Id.* at 1369.

71. *Id.* At the district court level, Medtronic motioned for summary judgment based on preemption and the district court granted its motion. *Id.*

72. *Id.* at 1375.

73. *Id.* at 1378.

74. *Id.* at 1379 ("There is no explicit private cause of action against manufacturers contained in the MDA, and no suggestion that the Act created an implied private right of action") (quoting *Lohr*, 518 U.S. at 487).

75. *Id.* See also *Horn*, 376 F.3d at 186 (Fuentes, J., dissenting) (stating that the proper way to resolve the issue between the FDA approving a device as safe and a state claim saying it is unsafe is to view the PMA process as a "'floor' of minimum standards for Class III devices, but not a 'ceiling.'").

76. *Goodlin*, 167 F.3d at 1375.

77. *Id.* at 1376 ("[W]hile a PMA review is considerably more rigorous and detailed than the premarket notification [510k] process at issue in [*Lohr v. Medtronic*], it is, in fact, no more 'specific' a requirement.") (quoting *Sowell v. Bausch & Lomb, Inc.*, 656 N.Y.S.2d 16, 20 (N.Y. App. Div. 1997)).

78. *In re St. Jude Med.*, 2004 U.S. Dist. LEXIS 148, at *33. It should be noted that one goal of products liability law is to allocate the cost of loss/injury to those who are most capable of absorbing that cost. See Lasso, *supra* note 1, at 12-18 (discussing the objectives of product liability law). As a point of reference, Thoratec Corp., which manufactured the faulty HeartMate in *Horn*, had a net profit of \$1,294,000 and paid \$133,000 in legal settlements for the first quarter of 2004. Thoratec Corp., Quarterly Report (10-Q Filing), at 4-5 (May 13, 2004), available at <http://www.sec.gov/Archives/>

example of a requirement that would invoke § 360k(a) preemption protection for manufacturers would be if the FDA stated that all pacemakers must be made with ceramic insulation and if, subsequently, those ceramic insulators failed.⁷⁹

The *Lohr* Court interpreted the MDA's preemption clause to apply preemption only to device-specific requirements.⁸⁰ The Court looked to the FDA's interpretive regulations, which state that § 360k(a)(1) only applies when there is a specific requirement "applicable to a particular device."⁸¹ It must be remembered that all the FDA requires of a manufacturer is to provide a "reasonable assurance" of the safety and effectiveness of the device.⁸² This reliance on manufacturers' cooperation has led to allegations of the FDA "pandering to the medical device industry" and that the FDA has not properly enforced its own provisions when manufacturers have not complied.⁸³ Simply because the FDA requires manufacturers to submit specific information and follow specific procedures does not automatically make the PMA process a specific requirement that would allow manufacturers to invoke preemption to remain immune from lawsuits.⁸⁴

2. Preemption Would Be Inconsistent With the Purpose Of the MDA

Congress enacted the MDA for the purpose of "providing for the safety and effectiveness of medical devices intended for public use" ⁸⁵ The legislative history of the MDA discusses the FDA's failed attempts to stop dangerous devices from entering the marketplace.⁸⁶ Neither the MDA itself,

edgar/data/350907/000095013404007440/f98986e10vq.htm#105 (last visited Sep. 22, 2005).

79. *Weiland*, 721 N.E.2d at 1153. See also *Lohr*, 518 U.S. at 504 (Breyer, J., concurring in part) (offering hypothetical FDA regulation requiring a two-inch wire for a certain component of hearing aids would preempt state common law claim that premises liability on the manufacturer's failure to use a one-inch wire).

80. *Lohr*, 518 U.S. at 498.

81. 21 C.F.R. § 808.1(d), *quoted in Lohr*, 518 U.S. at 498.

82. 21 U.S.C. § 360c(a)(1). See also Michael D. Green & William B. Schultz, *Tort Law Deference to FDA Regulations of Medical Devices*, 88 GEO. L.J. 2119, 2139-40 (2000) (noting that the scientific evidence that provides reasonable assurance of device safety is not as demanding as that required for new drugs). A new drug generally requires two controlled clinical studies as opposed to medical devices that only require one clinical study and also which may not require any controls. *Id.* at 2136. New drugs require a manufacturer to provide "substantial evidence" of the drugs safety. 21 U.S.C. § 355(d) (2000).

83. *Petrella*, *supra* note 23, at 364. A 1992 report of the House of Representatives found that manufacturers often follow deceptive practices to avoid disclosing adverse effects of their products and the FDA does not take adequate action against those parties. *Id.*

84. See *Lakie v. SmithKline Beecham*, 965 F.Supp. 49, 54 (D.D.C. 1997) (stating that simply having to comply with certain procedures and regulations does not rise to the level of a specific requirement).

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

86. See S.REP. NO. 94-33 at 2-7 (1976), *reprinted in* 1976 U.S.C.C.A.N. 1070, 1071-76. *Goodlin*, 167 F.3d at 1378 (offering the Dalkon Shield intrauterine device as an

nor the FDA's interpretive regulations, directly address the question of liability arising in connection with defective medical devices.⁸⁷ It is important that Congress did not "clearly and manifestly" state that its intention was to preempt all common law tort claims because Congress will not usurp the traditional police powers of the states without making that purpose clear.⁸⁸

In *Lohr*, Justice Stevens wrote convincingly that preemption would be contrary to the purpose of the MDA.⁸⁹ Finding that the MDA preempts all common law claims would leave the injured consumer, whom the MDA was meant to protect, with no legal relief from a company's negligent design or manufacturing.⁹⁰ Justice Stevens went on to add that it would be difficult to believe that Congress would take away all means of legal recourse from injured consumers without making that intention incredibly clear.⁹¹ Justice Stevens also reasoned that reading § 360k in favor of preemption would have the effect of granting immunity to the industry whose dangerous products the MDA were specifically passed to regulate.⁹²

Another issue bringing Congress' intent into question was the "savings clause" it included in the MDA, namely, that complying with orders under the MDA does not relieve a party from federal or state liability.⁹³ The language of the savings clause supports a finding that Congress had not intended to immunize manufacturers of medical devices from civil liability.⁹⁴ In *Sprietsma v. Mercury Marine*, the Court stated that a savings clause is an important indication that Congress recognized the "important remedial role [of state law] in compensating accident victims."⁹⁵ The Court further reasoned that the goal of product uniformity was less important than the

example).

87. *Lohr*, 518 U.S. at 491.

88. *Lohr*, 518 U.S. at 485. See also *Woods v. Gliatech Inc.*, 218 F. Supp. 2d 802, 810 (2002) (rejecting the defendant's claim that Congress' intent to have § 360k(a) preempt common law claims when manufacturer had only received a conditional approval from the FDA.); *Grey*, *supra* note 44, at 610 (stating that the Court should follow the "clear statement" rule, which requires that before preemption will occur, the intent of Congress must be perfectly clear and unambiguous).

89. *Lohr*, 518 U.S. at 487. See also *supra* note 85 and accompanying text (stating the purpose of the MDA).

90. *Lohr*, 518 U.S. at 487. See also *Woods*, 218 F.Supp. 2d at 810 (quoting Justice Stevens's reasoning in *Lohr*).

91. *Lohr*, 518 U.S. at 487.

92. *Id.*

93. 21 U.S.C. § 360h(d) (1994) ("Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law.").

94. *Goodlin*, 167 F.3d at 1378-79 (stating that inclusion of a savings clause expresses congressional intent not to preempt state common law claims, which would leave injured consumers with no legal recourse). See *Kirk*, *supra* note 46, at 692 (2002) (discussing principles of savings clauses); See also *Roberts S. Adler & Richard A. Mann, Preemption and Medical Devices: The Courts Run Amok*, 59 MO. L. REV. 895, 929 (1994) ("[The savings clause] explicitly indicates that a company's compliance with an FDA recall order will not bar tort claims against it.").

95. 537 U.S. 51 (2002). In *Sprietsma*, the Court balanced an express preemption clause with the savings clause within the Federal Boat Safety Act of 1971.

objective of safety.⁹⁶ Some commentators argue that courts should give the words used in a statute their ordinary meaning and if a savings clause states, “compliance with a federal safety standard does not exempt any person from any liability under common law,” the court should rule against preemption.⁹⁷

B. Arguments for Preemption

Recently, the Third Circuit joined the majority of courts finding preemption with its decision in *Horn v. Thoratec Corp.*⁹⁸ In *Horn*, the wife of a man killed when his “HeartMate”⁹⁹ separated from his body causing an air embolus¹⁰⁰ to travel to his brain, filed suit against the manufacturer.¹⁰¹ Five months after receiving the HeartMate, Horn began bleeding where the HeartMate tube exited his body. An exploratory surgery was then performed on Horn and the surgeon found that the suture connecting the pump to the output side had become worn, allowing a disconnection.¹⁰² The HeartMate underwent the PMA process¹⁰³ and the FDA approved it.¹⁰⁴

The manufacturer moved for summary judgment, arguing that the MDA’s preemption clause expressly preempted Mrs. Horn’s claims.¹⁰⁵ The District Court ruled in favor of the manufacturer after applying a two-pronged test, which states a claim is preempted if: “1) the FDA has established specific federal requirements that are applicable to that particular device, and 2) the state claim is different from, or in addition to, the specific federal requirements.”¹⁰⁶

96. *Id.* at 69-70. See also Jean Macchiaroli Eggen, *Shedding Light on the Preemption Doctrine in Product Liability Actions: Defining the Scope of Buckman and Sprietsma*, 6 DEL. L. REV. 143, 172 (2003) (discussing in more depth the Court’s reasoning in *Sprietsma*).

97. Ausness, *supra* note 51, at 974. See also Dinh, *supra* note 44, at 2113 (“Both are words in the same statute and thus each should be given full meaning under ordinary interpretative principles.”).

98. *Horn*, 376 F.3d 163.

99. The HeartMate pumps blood between the heart’s ventricle and the aorta. The inlet side is attached to the ventricle and it carries blood to the pump. The outlet side takes blood from the pump to the aorta where it is then dispersed throughout the body. A tube attached to the pump exits the body and connects to a console that powers the HeartMate with compressed air. *Horn*, 376 F.3d at 164.

100. “Air Embolus: an abnormal particle (as an air bubble) circulating in the blood.” MERRIAM WEBSTER ON-LINE DICTIONARY, <http://www.m-w.com/cgi-bin/dictionary?book=Dictionary&va=embolus&x=16&y=13> (last visited Nov. 1, 2004).

101. Ms. Horn’s complaint alleged “defective design and manufacture of the HeartMate and failure to warn of the alleged defects; it was based on Horn’s claim that the HeartMate’s output side elbow was defectively designed.” *Horn*, 376 F.3d at 165.

102. *Id.*

103. 21 U.S.C. § 360e(c).

104. *Horn*, 376 F.3d at 164-65.

105. *Id.* at 165. 21 U.S.C. § 360k(a).

106. *Horn*, 376 F.3d at 165. See also Kemp, 231 F.3d at 224-25 (applying this test and finding preemption); *Goodlin*, 167 F.3d at 1382 (applying this test and finding that plaintiff’s claims were not preempted).

1. *The PMA Process Establishes Specific Federal Requirements That Are Applicable to That Particular Device*

The *Horn* majority held that “the requirements imposed by the FDA upon the HeartMate when it was granted PMA approval are precisely ‘the sort of concerns regarding a specific device’ which the Supreme Court intimated would give rise to preemption under § 360k(a).”¹⁰⁷ Another major reason given for finding preemption is the apparent rigors of the PMA process.¹⁰⁸ The court found specific requirements existed because the manufacturer had spent so much time and effort working with the FDA to get the HeartMate approved and had made modifications to the device at the FDA’s request.¹⁰⁹ Despite Mrs. Horn’s argument that the FDA had previously argued the opposite conclusion,¹¹⁰ the majority was also greatly influenced by the FDA’s assertion that PMA approval is a specific requirement that imposes preemption.¹¹¹

107. *Horn*, 376 F.3d at 169. (quoting *Lohr*, 518 U.S. at 501).

108. See, e.g., *Martin*, 254 F.3d at 584-85 (finding MDA preemption); *Mitchell*, 126 F.3d at 911-12 (finding preemption based on PMA requirements; *Buckman*, 531 U.S. at 348 (“[T]he §510(k) process lacks the PMA review’s rigor: The former requires only a showing of substantial equivalence to a predicate device, while the latter involves a time-consuming inquiry into the risks and efficacy of each device.”)).

109. *Horn*, 376 F.3d at 170. The court notes that there was correspondence between the manufacturer and the FDA discussing a leak from the screw ring of the HeartMate and that the FDA approved design changes. *Id.* It is important for the reader to note that the court only says that the FDA approved a design change and that the FDA did not tell the manufacturer what change to make. *Id.* It is also important to note that a leak from the screw ring is what led to the death of Mr. Horn. *Id.* at 165.

110. This author finds it curious that in 1998 the FDA filed an *amicus curiae* brief with the Supreme Court espousing the opposite view. *Smiths Indus. Med. Sys., Inc. v. Kernats*, 520 U.S. 1208 (1997). It is also interesting that in 1997 the FDA proposed a rule to aid in “clarify[ing] and codify[ing] the agency’s *longstanding* position that available legal remedies, including State common law tort claims, generally are not preempted under the Federal Food, Drug, and Cosmetic Act” for medical devices. *Medical Devices; Preemption of State Product Liability Claims* 62 Fed. Reg. 65384 (Dec. 12, 1997) (emphasis added). The FDA withdrew this proposal the following year. 63 Fed. Reg. 39789 (July, 24 1998). The fact that the agency in charge of interpreting its own provisions would take the opposite stance in cases only separated by six years seems odd, but it may be helpful to remember that in those six years there has been a pro-tort reform political climate. It has been argued that “[t]hose who are limited by a legal restriction should not be permitted to determine the nature of the limitation, or to decide its scope,” rather the scope of the limitation should be determined by an entity other than the agency to be restricted. Cass R. Sunstein, *Interpreting Statutes in the Regulatory State*, 103 HARV. L. REV. 405, 446 (1989). Sunstein’s argument is even stronger “when an unelected agency is seeking to diminish the historic police powers of the states.” Ausness, *supra* note 51, at 975-76.

111. *Id.* at 171-72. The FDA filed an *amicus curiae* Letter Brief in which it stated:

The FDA can impose requirements by rule or order, regardless of whether or not the requirements were initially suggested to the agency by an outside party. . . . Although the PMA approval order does not itself expressly reiterate all of the specific features the device’s design . . . must have, *it specifically approves as a matter of law those features set forth in the application and binds the manufacturer to produce and market the product in compliance with the specifications as approved by the FDA.*

2. *The State Claim is Different From, or in Addition to, the Specific Federal Requirements*

The second step courts have taken when dealing with preemption is to compare the federal and state requirement and decide if the state claim is different from, or in addition to, the specific federal requirement.¹¹² Courts that find common law claims are preempted often start with the premise that it has been clearly established that under § 360k(a), a requirement can include legal requirements that are the result of court decisions when common law claims are brought.¹¹³ Operating on this premise, these courts then go on to determine if the particular claim being brought is preempted.¹¹⁴ If the common law claim imposes a requirement that is different from, or in addition to, an identified specific federal requirement, then the claim is preempted.¹¹⁵

One major reason courts offer for finding preemption is that if a state jury comes to a different result than the FDA, manufacturers will be subjected to many different standards.¹¹⁶

In *Horn*, Mrs. Horn's design defect and failure to warn claims were preempted because a jury finding a design defect would require the manufacturer to use a new design in this jurisdiction, but would allow the manufacturer to continue selling its device, as is, in other jurisdictions.¹¹⁷ In line with this argument is the slippery slope argument that some

Brief for FDA as *Amicus Curiae*, at 23-24; *Horn*, 376 F.3d 163 (No. 02-04597).

112. *Horn*, 376 F.3d at 165.

113. *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 541-42 (3rd Cir. 1994).

114. *Horn*, 376 F.3d at 166.

115. *Mitchell*, 126 F.3d at 911-12; *Kemp*, 231 F.3d at 230; *Martin*, 254 F.3d at 581-83. At least one author has commented that it "is 'possible' to comply with conflicting state and federal requirements as long as at least one is enforced by only civil damages" and that potential tortfeasors do not have to change their behavior if willing to pay damages. Susan Raeker-Jordan, *The Pre-emption Presumption That Never Was: Pre-emption Doctrine Swallows the Rule*, 40 ARIZ. L. REV. 1379, 1444 (1998).

116. *Brooks*, 273 F.3d at 797 ("[I]gnore the need for national uniformity in product regulation, one of the explicit goals of the MDA.") (citing H.R. REP. NO. 853, 45 (1976)). "[I]f a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened." See also *Horn*, 376 F.3d at 176, n.20 (stating that The Product Liability Advisory Council argued, in an amicus curia brief, that "[i]f the PMA process does not preempt state product liability suits [and general common law claims] imposing requirements at odds with the approved PMA, then juries in every state will influence device regulation, in numerous and often conflicting ways"). But see, *supra* note 4 and accompanying text (noting that the second aim of the MDA was to create a uniform regulatory scheme, which would encourage innovation in the field and prevent overregulation). It appears that the MDA was meant to assure safety of devices before they are placed on the market and not to offer blanket immunity to devices certified as reasonably safe by the FDA.

117. *Horn*, 376 F.3d at 176-77. See also *Mitchell*, 126 F.3d at 913-14 ("[T]o the extent that [the Mitchells' mislabeling, misbranding and adulteration] allegations claim that Collagen has incurred liability under state law despite its conformity to the requirements of the PMA, the state law claims must be considered preempted."); *Martin*, 105 F.3d at 1100 ("To allow a state cause of action for inadequate warnings would impose different requirements or requirements in addition to those required by federal regulations.").

commentators offer. They contend that if common law claims are not preempted, then development of medical technologies will completely stop.¹¹⁸

IV. PROPOSAL

A. *Pre-market Approval is Not a Specific Requirement That Triggers Preemption.*

The Eleventh Circuit correctly concluded that § 360k is not, in and of itself, a specific requirement.¹¹⁹ Although the pre-market approval process does require a large amount of time, it consists mostly of the manufacturers supplying the FDA with the results of studies that the manufacturer conducted.¹²⁰ The FDA's reliance on information provided by economically motivated manufacturers casts doubt on the whole process.¹²¹ The *Goodlin* approach is also consistent with the goals of the MDA. The MDA was passed to "provid[e] for the safety and effectiveness of medical devices intended for public use."¹²² The *Goodlin* approach is also correct because it recognizes that the FDA can be wrong in certifying products as safe for human use. The recent Vioxx debacle is a prime example where the FDA approved a pharmaceutical and it was later determined to be unsafe.¹²³

118. "The law has worked sufficiently well during the last 20 years to allow the most dramatic era of medical innovation and advancement in history. Overturning the preemption would be enough to bring this dramatic growth in the medical device industry to a grinding halt." Wayne Barlow, *Medical Devices go to Supreme Court*, SAN ANTONIO EXPRESS—NEWS, May 1, 1996, at 5. Barlow asserts that "[t]he threat of crushing litigation and skyrocketing insurance rates would force [medical device companies] to either pull products from the market or not conduct any business at all." *Id.* Thoratec, Inc. is not going to stop operating a business that profited over one million dollars in the first three months of 2004. Medtronic, Inc. reported net earnings of \$535.7 million for the second quarter of 2004. *Medtronic Reports 13-Percent Increase in Second-Quarter Net Earnings*, BUSINESS WIRE, Nov. 17, 2004, available at <http://www.businesswire.com>.

119. *Goodlin*, 167 F.3d at 1376. "[B]ut because the approval itself neither reveals nor imposes any ascertainable substantive prerequisite for approval that we could compare to a purportedly conflicting state requirement, the approval itself does not fit within section 360(k)(a)(1)'s demand for a specific federal requirement." *Id.* It has been argued that even if conflicting requirements exist, compliance is not impossible if at least one is only enforced through civil liability. This is because, in theory, tortfeasors do not have to alter their behavior as long as they are willing to pay damages to their victims. Raeker-Jordan, *supra* note 115, at 1444.

120. See *supra* notes 82-84 and accompanying text.

121. Petrella, *supra* note 23, at 364. "[T]he accuracy of the FDA's PMA process is largely, if not exclusively, dependent upon testing and safety data provided solely by the manufacturer applicant. Limited FDA financial resources and staffing translate into a PMA regulatory system in which economically motivated profiteers are empowered to skew the approval decision." *Id.* at 362-63.

122. See *supra* note 85 and accompanying text.

123. *Big Trouble for Merck*, THE ECONOMIST NEWSPAPER, Nov. 10, 2004, available at <http://www.economist.com>.

An article in the New England Journal of Medicine on October 21st blasted Merck for putting 'sales over safety' and its regulator, the [FDA], for sitting on its hands as evidence of health risks mounted. (The FDA has since asked the Institute of

B. Congress Should Rewrite the Express Preemption Clause of the MDA

At least one author proposes modifying the language of the MDA's preemption provision.¹²⁴ Congress should not modify the preemption clause; rather, Congress should completely rewrite the clause. Over the course of the last ten years, there has been extensive litigation over the meaning of the clause and no consensus has been reached.¹²⁵

The new preemption clause should explicitly state that it does not immunize manufacturers from state tort law liability simply because their devices were subjected to the pre-market approval process. The MDA contains a savings clause that already states compliance with the FDA does not immunize a party from civil liability,¹²⁶ but Congress needs to state this principle clearly in the preemption clause. Congress taking the initiative to change the preemption clause is easier said than done because the manufacturers and their lobbyists would likely fight any change intensely.¹²⁷

C. Congress Should Then Adopt a System of Medical Review Panels to Evaluate Consumers' Claims of Defective Products

Indiana has adopted a system that "provides for the establishment of medical review panels to review proposed malpractice complaints against health care providers."¹²⁸ These review panels consist of one attorney and two doctors.¹²⁹ The attorney serves as a non-voting chairman.¹³⁰ The statute states that all medical professionals licensed to practice in the state, except for health care administrators, are eligible to serve on the panels.¹³¹ The panels are charged with requesting and compiling the information they need

Medicine to study the way it monitors the safety of drugs on the market.)

Id.

A prominent personal injury lawyer has commented that the problem with following a court decision like *Horn* is that it bestows a "god-like" status on the FDA, citing the Vioxx debacle to show the FDA is capable of failing to protect the public health. Robert A. Clifford, *Courts Split on Federal Preemption after FDA Approval*, CHICAGO LAWYER, Nov. 2004, at 21.

124. Sasha B. Rieders, *State Law Tort Claims and the FDA: Proposing a Consumer-Oriented Prescription in Medical Device Cases*, 25 CARDOZO L. REV. 1159, 1196-97 (2004).

125. See *supra* notes 8-9 and accompanying text (noting that there is a split in the circuits to whether claims were preempted or not).

126. See *supra* note 93-96 and accompanying text (discussing the principles and functions of a savings clause and the different ways in which courts interpret them). Some commentators argue that courts should give the words used in a statute their ordinary meaning and if a savings clause states, "compliance with a federal safety standard does not exempt any person from any liability under common law," the court should rule against preemption. Ausness, *supra* note 51, at 974.

127. See *supra* note 4 and accompanying text (noting that in 1999, a proposed bill in Congress that would have limited Congress' ability to preempt state and local laws was dropped because big business opposed the legislation).

128. IND. CODE ANN. § 34-18-10-1 (Lexis/Nexis 2004).

129. IND. CODE ANN. § 34-18-10-3(a).

130. IND. CODE ANN. § 34-18-10-3(b).

131. IND. CODE ANN. § 34-18-10-5.

to aid their decisions.¹³² The report that a panel formulates is admissible (although not conclusive) evidence in a subsequent trial and the panel members may be called to testify.¹³³

A system such as the one formed in Indiana would serve the interests of the public without causing the end of medical device development.¹³⁴ Injured consumers would, before filing a lawsuit, bring their claims in front of one of these panels for the panel to evaluate. If the panel finds that a consumer has a valid cause of action and would likely recover at trial, the manufacturer would know that settlement may be in its best interest, therefore avoiding the potential of so-called “runaway jury verdicts.”¹³⁵ If the panel finds the consumer does not have a strong chance of success, the consumer may still go forward with his case, but the manufacturer has the benefit of the expert opinion of the review panel. Also, following an approach similar to Indiana would take the review panels out of the political arena, unlike the FDA.

For example, in *Horn v. Thoratec*,¹³⁶ Mrs. Horn would have first filed a claim with a medical review panel. That panel would then evaluate her claims to see if she stated a cause of action. The panel would then apply the Restatement Second of Torts, § 402A to determine if the manufacturer is liable.¹³⁷ Based on the facts of her case, it seems that a panel would find that she stated a cause of action and would likely recover at trial. The court in that case acknowledged that the failure of the ring connecting the device to Horn’s body caused the air embolus that killed him.¹³⁸ At that point, Thoratec would be on notice that settlement and product modification would likely be in its best interest.

A court applying preemption after recognizing that the device in question killed a patient is inconsistent with the goal of protecting consumers from unsafe medical devices. FDA approval should be viewed merely as a manufacturer ensuring that a device is *reasonably* safe, but should not

132. IND. CODE ANN. § 34-18-10-21(a-d).

133. IND. CODE ANN. § 34-18-10-23.

134. Congress passed the MDA with two purposes in mind. First, it was intended to protect public health by promoting safe and effective medical devices. The second aim of the MDA was to create a uniform regulatory scheme, which would encourage innovation in the field and to prevent overregulation. See *supra* notes 2-5 and accompanying text. “The threat of crushing litigation and skyrocketing insurance rates would force them to either pull products from the market or not conduct any business at all.” Barlow, *supra* note 118.

135. “The onslaught in the late 1980s and 1990s of reports about excessive tort liability and run-away jury verdicts, however accurate or inaccurate, influenced society in ways we may not fully appreciate.” Mary J. Davis, *Unmasking the Presumption In Favor of Preemption*, 53 S.C.L. REV. 967, 1017 (2002).

136. 376 F.3d at 163.

137. The basic elements a plaintiff needs to show are: (1) the defendant is a “seller” engaged in the business of selling a product, (2) the defendant’s product reached the plaintiff without substantial change, (3) the defendant’s product is “defective” under the consumer expectations test, the risk-utility test, or the hybrid risk-utility test, and (4) the defect caused the plaintiff’s harm. RESTATEMENT (SECOND) OF TORTS § 402A (1965).

138. *Horn*, 376 F.3d at 165.

completely insulate a manufacturer from all liability.¹³⁹ Thoratec, for example, has no reason to voluntarily modify the HeartMate that killed Horn because it can keep selling the device as is, and not face civil liability.¹⁴⁰ Some argue that liability will deter manufacturers from developing new medical devices; but potential liability is a concern for manufacturers of every product on the market.¹⁴¹

A system such as Indiana's would allow plaintiffs the chance to present their case in front of a panel of experts in the medical field, who have no connection to the FDA, to evaluate the strength of their claim. Those plaintiffs then have an opportunity to present their case to a jury of their peers.¹⁴² There is no guarantee of recovery, but at least the consumers can have their day in court.¹⁴³ Courts ruling in favor of preemption of all claims impose an irrebuttable presumption that the device in question was completely safe simply because the fallible FDA determined it was after reviewing data that the self-interested manufacturer supplied itself.¹⁴⁴

V. CONCLUSION

Congress passed the Medical Device Amendments to promote the production of safe medical devices while not imposing an overly burdensome regulatory system upon manufacturers. The MDA included an express preemption clause preempting state requirements that are different from, or in addition to, federal requirements in order to reach the MDA's goals. Thirty years after passing the MDA, the debate to determine the breadth of that clause continues. The majority of courts find that many common law claims against device manufacturers who put products through

139. The way to reconcile the view that there is no conflict between the FDA allowing the sale of a device and a state finding that the product is unsafe is to view PMA approval as a "floor" of minimum standards for class III devices, but not a "ceiling." *Id.* at 185-86 (Fuentes, J., dissenting).

140. Imposing civil liability would encourage manufacturers to view the FDA standards as a minimum and would lead them to make their devices as safe as possible. *Id.* at 186-87.

141. "Although the risk of liability may admittedly be a deterrent to TCI's marketing effort, the Supreme Court has held that the incidental regulation incurred by liability under generally applicable state law is less intrusive, and therefore less prone to preemption, than 'direct regulation on the operation of federal projects.'" *Id.* at 186 (citing *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 185-86 (1988)).

142. The expert opinion is admissible in court and could aid the jury in evaluating the facts. One argument pro-preemption parties make is that a jury does not have the expertise to evaluate complicated claims. Scandaglia & Tully, *supra* note 20, at 264. The purpose of expert testimony at trials is to help juries evaluate these claims. FED. R. EVID. 702. Rule 702 also permits "expert opinion even if the matter is within the competence of the jurors if specialized knowledge will be helpful, as it may be in particular situations." JOHN W. STRONG ET AL., MCCORMACK ON EVIDENCE STUDENT EDITION § 13, at 54 (4th ed. 1992).

143. It has been argued that preemption of these claims is consistent with the judicial system because there are times "when a jury finds that the product or person causing the injury has not violated the relevant standard of care, the injured consumer is turned away empty-handed." Scandaglia & Tully, *supra* note 20, at 264. That argument assumes that a plaintiff at least had a chance to prove a case to a judge or jury.

144. See *supra* Part III.B. (explaining courts' bases for finding preemption).

the PMA process are preempted. The minority of courts, led by the Eleventh Circuit, correctly rule that the MDA does not preempt common law claims brought against manufacturers.

Congress needs to address this situation. First, Congress should rewrite the MDA's express preemption clause to clearly state that PMA approval does not preempt state common law claims brought against companies for defective design, manufacturing defects, or failure to warn. Second, Congress should adopt, or allow the states to implement, a system of medical review panels that would evaluate claims against manufacturers before those claims are filed in court. After the panel has evaluated the claims, the parties will then have an admissible expert opinion to help them evaluate their case and determine whether dropping the claim, filing a lawsuit, or agreeing to a settlement is in the best interest of the parties involved. This system will ensure that the goals of providing consumers with safe medical devices while not overburdening a useful industry will both be met.