

EXPRESS PREEMPTION AND PRE-MARKET APPROVAL UNDER THE MEDICAL DEVICE AMENDMENTS

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I. INTRODUCTION

Millions of dollars are spent each year in an effort to develop new medical devices designed to help individuals facing serious medical conditions. However, before these devices can reach consumers, they must be reviewed and cleared by the Food and Drug Administration ("FDA"). Innovative medical devices which pose the greatest risks and are aimed at helping the most critically ill consumers are subjected to intense FDA scrutiny under a process known as pre-market approval ("PMA"). Having undergone an extensive, time-consuming, and expensive pre-market review by the FDA, those devices which meet the FDA's strict requirements may then be offered for sale in the United States.

Despite the emphasis placed on safety by the manufacturer and the FDA, consumers have been injured by FDA-approved devices. When the device at issue has been reviewed and approved by the FDA under its rigorous PMA process, courts are heavily divided as to whether injured consumers can bring state law tort claims against device manufacturers or whether such claims are expressly preempted by the Medical Device Amendments of 1976 ("MDA"), one of the statutes which guides and empowers the FDA in its review of medical devices. The resolution of this question has wide-reaching implications for both consumers and manufacturers alike.

Consider the following hypothetical scenario. MediX is a medical device manufacturer located in Illinois. After years of heavily funded research and development, MediX has designed a revolutionary microchip pacemaker called the Pacer2004. It also has plans to develop a second device which can be implanted and which constantly monitors the body for early warning signs of cancer.

Anticipating that its Pacer2004 will need to be reviewed and approved by the FDA under the PMA process prior to being offered for sale, MediX submits an investigational device exemption ("IDE") to the FDA and, after the FDA approves the IDE, MediX conducts numerous studies examining the safety and efficacy of its pacemaker. When it is satisfied with the safety and performance of its Pacer2004, MediX submits an application seeking FDA approval. As part of the application, MediX submits the results of the clinical investigations; [a sample of its pacemaker]; samples of the proposed labeling; a full statement of its pacemaker's

components, properties, and principles of operation; and a full description of the methods used in, and the facilities and controls used for the manufacture, processing, packing, and installation of its pacemaker. After an extensive six-month review of MediX's Pacer2004, the FDA informs MediX that additional information regarding the components must be submitted and certain changes must be made to the Pacer2004's labeling and manufacturing process before the pacemaker will be approved. MediX makes the required changes and submits the revised Pacer2004 and additional information to the FDA for its approval. The FDA finally approves the device after convening an expert advisory panel and reviewing the Pacer2004 for another four months.

After the Pacer2004 has been on the market for two years, some consumers began experiencing injuries arising out of the Pacer2004's use. Consumers in several states sue MediX, alleging various state law claims. In some states, the courts allow the state law claims to proceed, sometimes resulting in large verdicts against MediX. In other states, the courts conclude that the state law claims are preempted and dismiss the cases against MediX. Confronted with such uncertainty and potentially large liability, MediX takes two actions. First, it raises the price of its pacemakers to help recoup the costs of the litigation. It also considers whether to discontinue the manufacture of its Pacer2004 pacemaker altogether. Additionally, MediX does some projections and analysis and decides not to invest in the development of the cancer detection device it was considering because it appears cost-prohibitive in light of the possible litigation costs.

The above scenario demonstrates the difficult questions that medical device manufacturers face in the current environment of uncertainty and division over the MDA's preemptive effect. This article articulates why this uncertainty must be resolved in favor of federal preemption. To this end, Section II of the article provides an overview of the FDA's regulation of medical devices. Section III then discusses federal preemption of state law claims generally and specifically addresses the division among the courts regarding the MDA's preemptive effect, examining both the majority and minority positions. Section IV of this article focuses on the factors which support the conclusion that state law claims should be preempted by the MDA. Finally, Section V provides a brief summary and conclusion.

II. OVERVIEW OF FDA'S REGULATION OF MEDICAL DEVICES

A. The Medical Device Amendments of 1976

The FDA began heavily regulating medical devices in 1976, when Congress amended the Federal Food, Drug, and Cosmetic Act and enacted the Medical Device Amendments ("MDA").¹ The MDA was enacted, in part, as a response to the numerous injuries caused by the Dalkon Shield,

¹ See 21 U.S.C. § 301, *et seq.* (2004); see also Gail H. Javitt, *I've Got You Under My Skin –and I Can't get Redress: An Analysis of Recent Case Law Addressing Preemption of Manufacturer Liability for Class III Medical Devices*, 49 FOOD AND DRUG L.J. 553, 558-59 (1994); Lars Noah, *Amplification of Federal Preemption in Medical Device Cases*, 49 FOOD AND DRUG L.J. 183, 184 (1994).

a device which was sold as a form of birth control, and consumer concern over other medical devices such as artificial heart valves and pacemakers, which became more commonly used in the 1970s.²

The statutory definition of a "medical device" is very broad and includes any article which is:

intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or . . . intended to affect the structure or any function of the body . . . , and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.³

As part of the process of regulating medical devices, the MDA (and hence, the FDA) divides devices into three categories⁴:

Class I Devices - This class includes those devices that "present minimal potential for harm to the user." For example, elastic bandages are classified as Class I devices.⁵

Class II Devices - Devices in this class pose a greater risk of harm than those in Class I, but less risk than those in Class III. Class II devices include items such as some home pregnancy tests.⁶

Class III Devices - A device is categorized as a Class III device if it sustains or supports life, is implanted, or presents a potential unreasonable risk of illness or injury.⁷ Class II devices also include some low-risk products that lack predicates. Class III devices represent approximately 10% of the medical devices on the market.⁸ Examples of Class III devices include pacemakers and breast implants.⁹

The amount of regulation imposed on any given device depends in large measure on the classification it receives.¹⁰ Class I devices are the least regulated and are only subject to "general

² See *Medtronic Inc. v. Lohr*, 518 U.S. 470, 476 (1996); see also Trent Kirk, *Fraud-On-The FDA & Buckman – The Evolving Law of Federal Preemption in Products Liability Litigation*, 53 S.C. L. REV. 673, 679-80 (2002); Javitt, *supra* note 1, at 558.

³ 21 U.S.C. § 321(h); see also 21 C.F.R. § 60.3 (2004); Javitt, *supra* note 1, at 557.

⁴ The FDA generally classifies devices based on the recommendation of a panel of experts. 21 U.S.C. § 360c(b). The experts appointed by the FDA to the classification panels are from a variety of fields and possess the training and experience necessary to evaluate the safety and efficacy of the devices. *Id.* In addition to experts in various fields such as engineering, biological and physical sciences, and clinical medicine, panels also include non-voting members who represent the public interest and the interests of the device manufacturing industry. *Id.*

⁵ See www.fda.gov/cdrh/consumer/geninfo.html; see also 21 C.F.R. § 860.3(c)(1).

⁶ *Id.*; see also 21 C.F.R. § 860.3(c)(2); see also Noah, *supra* note 2, at 189.

⁷ *Id.*; 21 C.F.R. § 860.3(c)(3); see also Noah, *supra* note 2, at 189.

⁸ See www.fda.gov/cdrh/consumer/geninfo.html.

⁹ *Id.*; 21 C.F.R. § 870.3610.

¹⁰ See also Noah, *supra* note 2, at 189.

controls."¹¹ General controls include provisions that govern adulteration; misbranding; device registration and listing; premarket notification; banned devices; notification, including repair, replacement, or refund; records and reports; restricted devices; and good manufacturing practices.¹² Class II devices, on the other hand, in addition to being subject to general controls are also subject to "special controls" and as a result, may be subject to certain performance standards, post-market surveillance, patient registries and other regulations.¹³ Class III devices are the most heavily regulated and go through one of two review processes -- referred to as "pre-market notification" ("PMN") and "pre-market approval" ("PMA") respectively -- before they are placed on the market.¹⁴

B. The FDA Approval Process

The FDA regulatory process is designed to strike a delicate balance between protecting consumers from potentially dangerous devices while providing a regulatory framework that does not impede or prevent technological innovation and advancement.¹⁵ Class III devices must receive FDA approval prior to being marketed¹⁶ and are generally either subject to review under the PMN process (also known as the "section 510(k) process") or PMA process.¹⁷

A Class III device may qualify for review under the PMN process if the manufacturer can establish that its device is "substantially equivalent" to a legally marketed device that was marketed before 1976.¹⁸ A device is considered "substantially equivalent" to an earlier device where the later device and earlier device are about equally safe and effective.¹⁹ Thus, new Class III devices do not qualify for review under the PMN process. The PMN process is a much less demanding than the PMA process.²⁰ As a result, the majority of manufacturers prefer approval under the PMN process

¹¹ 21 U.S.C. § 360c(a)(1)(A); *see also* 21 C.F.R. § 860.3(c)(1); *Kirk, supra* note 2, at 680-81.

¹² *See* 21 U.S.C. §§ 350, 352, 360, 360(f), 360(h), 360(i), 360(j); *see also* <http://www.fda.gov/cdrh/devadvice/363.html>.

¹³ 21 U.S.C. § 360c(a)(1)(B); 21 C.F.R. § 860.3(c)(2); *Kirk, supra* note 2, at 681.

¹⁴ 21 U.S.C. §§ 360c(a)(1)(C), 360e(b), 360(k); *see also* 21 C.F.R. §§ 807.81, 807.85; 814.1(c); *Kirk, supra* note 2, at 681.

¹⁵ *See* Kenneth T. Sigman, *Medtronic, Inc. v. Lohr: Bad Medicine for Manufacturers of Unproven Medical Devices*, 47 CATH. U. L. REV. 721, 724-25 (1998); Mark Herrman and Geoffrey J. Ritts, *Preemption and Medical Devices: A Response to Adler and Mann*, 51 FOOD & DRUG L.J. 1, 4-5 (1996).

¹⁶ *See* 21 U.S.C. §§ 360c(a)(1)(C), 360e(b), 360(k). Under the MDA's grandfather clause, devices which were on the market prior the enactment of the MDA may remain on the market without going through the PMN or PMA processes. 21 U.S.C. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c). However, if the device is modified, it may need to be reviewed by the FDA prior to sale.

¹⁷ The FDA also allows devices to be distributed under the "investigational devices exception" ("IDE"). 21 U.S.C. § 360j(g) (2003); 21 C.F.R. §§ 812.1-812.2; 812.20. Devices distributed pursuant to an IDE are exempted from some of the more rigorous requirements imposed by the FDA. *See Id.* The purpose of the IDE is to "encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators for their pursuit of that purpose." 21 U.S.C. § 360j(g)(1); 21 C.F.R. § 812.1(a).

¹⁸ 21 U.S.C. § 360c(i); *see also* 21 U.S.C. §§ 360e(b)(1)(B), 360(k), 360(o); 21 C.F.R. §§ 807.87, 807.92; Brian J. Donato and Mary Beth Neraas, *Federal Preemption of Product Liability Claims Involving Drugs and Medical Devices Regulated Under The Federal Food, Drug, and Cosmetic Act*, 48 FOOD & DRUG L. J. 305, 313-14 (1993).

¹⁹ *Medtronic*, 518 U.S. at 493; *see also* 21 C.F.R. §§ 807.87, 807.92; Donato and Neraas, *supra* note 16, at 314.

²⁰ *Medtronic*, 518 U.S. at 478-79; *see also* OFFICE OF DEVICE EVALUATION AND OFFICE OF IN VITRO DIAGNOSTIC DEVICE EVALUATION AND SAFETY ANN. REP. FISCAL YEAR 2003, Pt. 7, Table 3, *available at*

because it allows manufacturers to bring their devices to market much more quickly than would be possible if their devices were subject to review under the PMA process.²¹ For example, in 2002, the FDA received 49 original PMA applications compared with 4,320 original PMN applications.²²

A Class III device which does not qualify for PMN review will be required to pass the FDA's stringent PMA process.²³ To satisfy the PMA requirements, the manufacturer must demonstrate the device's safety and effectiveness.²⁴ Under the MDA, the safety and effectiveness of a device will be: determined with respect to the persons for whose use the devices is represented or intended, . . . with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and . . . weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.²⁵

There are several different methods of applying for PMA. Manufacturers may submit a traditional PMA, a modular PMA, a streamlined PMA, or a Product Development Protocol.²⁶ The traditional PMA requires the manufacturer to submit all of the information required in the PMA application to the FDA at one time.²⁷ This method is generally used if the device has already undergone clinical testing and is approved in a country that has established medical device regulations.²⁸ In contrast, the modular PMA breaks down the components of the PMA application into modules which may be submitted individually.²⁹ Thus, the PMA applicant completes its PMA over time.³⁰ This method is recommended for products that are in the early stages of clinical study, but is not useful if the applicant is close to having a complete PMA application or if the device design is likely to change.³¹ The modular process begins with a PMA Shell which outlines a custom plan for the submission of the modules.³² The FDA reviews each module separately as soon as it is received which may expedite the review process.³³

www.fda.gov/cdrh/annual/fy2003/ode/part7.html; FDA Device Advice, PMA OVERVIEW, p. 1, available at www.fda.gov/cdrh/devadvice/pma/index.html#introduction.

²¹ *Id.*; see also OFFICE OF DEVICE EVALUATION AND OFFICE OF IN VITRO DIAGNOSTIC DEVICE EVALUATION AND SAFETY ANN. REP. FISCAL YEAR 2003, Pt. 7, Tables 4 and 15, available at www.fda.gov/cdrh/annual/fy2003/ode/part7.html.

²² See also OFFICE OF DEVICE EVALUATION AND OFFICE OF IN VITRO DIAGNOSTIC DEVICE EVALUATION AND SAFETY ANN. REP. FISCAL YEAR 2003, Pt. 7, Table 3, available at www.fda.gov/cdrh/annual/fy2003/ode/part7.html.

²³ 21 U.S.C. § 360c(a)(1)(C); see also 21 C.F.R. §§ 814.1, 814.20.

²⁴ *Id.*; see also 21 C.F.R. § 814.2.; FDA Device Advice, PMA OVERVIEW, p. 1, available at www.fda.gov/cdrh/devadvice/pma/index.html#introduction.

²⁵ *Id.*; see also 21 C.F.R. § 860.7.

²⁶ See FDA Device Advice, PMA APPLICATION METHODS, available at www.fda.gov/cdrh/devadvice/pma/index.html.

²⁷ See *Id.* This information includes a description of the device and its intended use, clinical and non-clinical studies, case report forms, manufacturing methods, labeling information and other required data. *Id.*

²⁸ See *Id.*

²⁹ See *Id.*

³⁰ See *Id.*

³¹ See *Id.*

³² See *Id.* The shell outlines the modules and identifies information necessary to support the filing and approval of a specific Class III product. *Id.* The review team works with the applicant to create a customized shell for each specific product that includes module contents and suggested timelines. It is developed individually with the manufacturer for a specific device. *Id.*

³³ See *Id.* By reviewing each module as soon as it is received, the FDA is able to provide manufacturers with timely feedback during the review process, which may allow the PMA to be closed more rapidly when the last components

The streamlined PMA is currently a pilot program in the Division of Clinical Laboratory Devices and is only used to review devices whose technology and uses are well known to the FDA.³⁴ Finally, a device manufacturer may obtain PMA by filing and obtaining approval of a Product Development Protocol ("PDP").³⁵ The PDP is basically an agreement that covers the details of the design and development process, the outputs of these processes, and the criteria governing the acceptance of the device which results.³⁶ "A PDP that is declared completed by [the] FDA is considered to have an approved PMA."³⁷

To complete a PMA application, the device manufacturer must submit an enormous amount of information to the FDA, including a summary of the information contained in the application, information regarding product specifications, intended use, manufacturing methods, results of clinical and non-clinical testing and studies, proposed labeling, and samples of the device.³⁸ To understand the breadth and depth of the information provided, it is useful to examine a few of the PMA sections, beginning with the Summary section, in some detail.

The summary section of the PMA application must give a general description of the disease or condition that the device will diagnose, treat, prevent or, cure and include a description of the patient population for which the device is intended.³⁹ The summary must also describe: (1) how the device functions, (2) the basic scientific concepts which underlie the device, (3) the significant physical and performance characteristics of the device, (4) any alternative practices or procedures for diagnosing, treating, preventing, curing, or mitigating the disease or condition for which the device is intended, (5) the foreign and U.S. marketing history of the device, including, at a minimum, a list of all of the countries in which the device has been marketed and a list of all countries in which the device has been withdrawn from marketing for any reason related to the safety or effectiveness of the device.⁴⁰ Additionally, the summary must

are submitted because much of the review work will already be completed. *Id.* Additional information on the Modular PMA process can be found at www.fda.gov/cdrh/mdufma/guidance/835.html and www.fda.gov/cdrh/mdufma/guidance/835.pdf (information on PMA Application Modular Review) and at www.fda.gov/cdrh/pmat/shellpmat.html (Premarket Approval Application Content Shell).

³⁴ *See Id.* "A streamlined PMA review may be appropriate when there is either an FDA guidance document or other published methods for review which have been evaluated by the FDA or an FDA review history dealing with like products (two or more of a kind)." *Id.*

³⁵ *See Id.*; 21 C.F.R. § 814.19

³⁶ *See* FDA Device Advice, PMA APPLICATION METHODS, available at www.fda.gov/cdrh/devadvice/pma/index.html.

³⁷ *See Id.* The PDP allows the manufacturer to reach an early agreement with the FDA as to what must be done to establish the safety and effectiveness of a new device. *Id.* By interacting with the FDA early in the device's development cycle, the manufacturer is able to address the FDA's concerns before expending expensive and time consuming resources. *Id.*

³⁸ 21 U.S.C. § 360e(c)(1); 21 C.F.R. § 814.20; FDA Device Advice, PMA APPLICATION CONTENTS, available at www.fda.gov/cdrh/devadvice/pma/index.html. If it is impractical to submit a sample of the device, the applicant is to provide the FDA with a location at which the device may be examined and tested. *Id.*

³⁹ *See* FDA Device Advice, PMA APPLICATION CONTENTS, available at www.fda.gov/cdrh/devadvice/pma/index.html. The summary section generally include a short statement of the major points found in the PMA and is usually approximately 10 to 15 pages in length. *Id.*

⁴⁰ *Id.* The manufacturer is encouraged to include the dates the devices was introduced into each country, information about the quantity of devices distributed in each country, and a summary of any reported adverse

contain a summary of the results of technical data (non-clinical and clinical studies) and an abstract of any other data, information, or report described in the PMA and must include a description of the goal of each study, a description of the experimental design of the study, a short discussion of the method used to collect and analyze the data, and a short description of the findings and conclusions, whether positive, negative or inconclusive.⁴¹

The summary must also include an overview of the non-clinical laboratory studies provided in the PMA application and an overview of the clinical investigations which were done using human subjects.⁴² The manufacturer must explain how the data and information in the application constitute valid scientific evidence; how the data establish that the device is safe and effective for its intended use; and provide an analysis of the benefits and risks associated with the device, including a discussion of any adverse effects the device may have on the health of those who use it and any proposed additional studies or surveillance that the applicant intends to conduct following approval of the PMA.⁴³

The technical sections of the PMA application must contain the results of numerous tests, including the non-clinical laboratory studies conducted on the device and microbiological, toxicological, immunological, biocompatibility, stress, wear, and shelf life tests, where appropriate.⁴⁴ The manufacturer must demonstrate that the non-clinical laboratory studies were conducted in compliance with the Good Laboratory Practices for Non-clinical Laboratory Studies, set forth at 21 C.F.R. § 58 *et seq.*⁴⁵ The technical section must also discuss the results of the clinical investigations which involved human subjects.⁴⁶ In this section, the manufacturer must provide the FDA with the results of the clinical protocols, safety and effectiveness data, adverse reactions and complications, patient complaints, device failures and replacements, tabulations of data from all individual subject reporting forms and copies of such forms for each subject who died during a

experiences. *Id.* The marketing description must include the history of the marketing of the device by the applicant and, if known, the history of the marketing of the device by any other person. *Id.*

⁴¹ *Id.*; see also 21 C.F.R. §§ 814.20(b)(6) and (b)(8)(ii).

⁴² See FDA Device Advice, PMA APPLICATION CONTENTS, available at www.fda.gov/cdrh/devadvice/pma/index.html. The summary of the clinical investigations also includes a discussion of the criteria used to select and exclude the subjects participating in the study, the study population demographics, the study period, safety and effectiveness data, adverse reactions and complications, a list of device failures and replacements, tabulations of data from all individual subject reporting forms and copies of such forms for each subject who died during a clinical investigation or who did not complete the investigation, the results of statistical analyses of the clinical investigations, contraindications and the precautions governing the use of the device. *Id.*

⁴³ *Id.* The "summary section should objectively link the medical claim(s) for the device to the hypotheses tested and conclusions drawn from the findings of all studies and investigations." *Id.* When preparing the summary section, the manufacturer should "correct any accountability discrepancies, incomplete reporting and study design deficiencies which an in-depth scientific review would discover." *Id.* A complete and detailed account of the clinical investigations and supporting data is required to satisfy the legal requirements imposed by the Food, Drug & Cosmetic Act. *Id.* See also 21 C.F.R. § 860.7

⁴⁴ See FDA Device Advice, PMA APPLICATION CONTENTS, available at www.fda.gov/cdrh/devadvice/pma/index.html.

⁴⁵ *Id.* If the study was not conducted in compliance with this regulation, the non-compliance must be explained. *Id.*

⁴⁶ *Id.*

clinical investigation or who did not complete the investigation, results of statistical analyses of the clinical investigations, and contraindications and precautions for use of the device.⁴⁷ All clinical studies involving human subjects must be conducted in compliance with the Institutional Review Board regulations, the Informed Consent regulations, and with Investigational Device Exemptions regulations governing sponsors of clinical investigations and clinical investigators.⁴⁸ The manufacturer must provide a bibliography of all published reports, whether adverse or supportive, that are known to or should reasonably be known and that concern the safety or effectiveness of the device.⁴⁹ The manufacture is also encouraged to provide a discussion and analysis of any other data, information, or report relevant to an evaluation of the safety and effectiveness of the device that are known to or should reasonably be known to the applicant from any source, foreign or domestic.⁵⁰ This requirement includes information from investigations other than those proposed in the application and from commercial marketing experience.⁵¹

Once the PMA application is complete, the FDA begins a thorough review of the application to determine whether the device is safe and effective and therefore deserving of approval.⁵² The PMA is first subject to an administrative and limited initial scientific review to determine if the application is sufficiently complete to warrant the filing of the application and the in-depth review which follows.⁵³ If the application is complete, it will be filed and the FDA will begin its scientific and technical review of the application, including a review of the manufacturing information to ensure compliance with the Quality System regulation, a Quality System Inspection by FDA field personnel to ensure that the design and manufacturing process complies with the Quality System/Good Manufacturing Practices requirements, and a Bioresearch Monitoring Audit to audit

⁴⁷ *Id.* The manufacturer must also provide the FDA with information on the number of investigators used in the clinical study and the number of subjects per investigator, a discussion of subject selection and exclusion criteria, study population demographics, the study period, and information related to patient discontinuance. *Id.* The manufacturer's analysis and discussion also addresses the impact, of the studies if any, on the safety and effectiveness measures and any potential biases, including those related to gender and race/ethnicity. *Id.* The manufacturer is required to describe any differences in safety and/or effectiveness in the device's labeling. *Id.*

⁴⁸ *Id.* See also 21 C.F.R. §§ 50 *et seq.*, 56 *et seq.*, 812 *et seq.* The Institutional Review Board and the Informed Consent regulations are designed to protect the welfare of human subjects who participate in clinical investigations. 21 C.F.R. §§ 56.101, 50.1. The manufacturer must provide a statement with its PMA application stating that it has conducted its studies in compliance with all of the above regulations. See FDA Device Advice, PMA APPLICATION CONTENTS, available at www.fda.gov/cdrh/devadvice/pma/index.html. If the study was not conducted in compliance with these regulations, the manufacturer must include a brief statement of the reason for its noncompliance. *Id.* Additionally, if the PMA is supported only by data from one investigator, the manufacturer must provide an explanation demonstrating why data and other information from a single investigator is sufficient to demonstrate the safety and effectiveness of the device and to ensure reproducibility of test results. *Id.*

⁴⁹ *Id.* Manufacturers are encouraged to provide a copy of all of the key articles, a brief summarization of the relevant features of the article, and a brief discussion of how the article relates to the safety and effectiveness evaluation for their device. *Id.*

⁵⁰ *Id.* The manufacturer must be prepared to supply the FDA with copies of published reports or unpublished information in the possession of, or reasonably obtainable by, the manufacturer, if an FDA advisory committee or the FDA requests. *Id.*

⁵¹ *Id.*

⁵² See FDA Device Advice, PMA REVIEW PROCESS, available at www.fda.gov/cdrh/devadvice/pma/index.html.

⁵³ *Id.* The FDA will refuse to accept a PMA for filing if it is incomplete, or if the data are unclear or are not capable of withstanding strict scientific scrutiny. *Id.*

the clinical study data. Additionally, for certain devices,⁵⁴ the PMA application is then referred to a panel of qualified experts who prepare a report and recommendations regarding the approval or denial of the application, along with the reasons for their recommendation.⁵⁵ If the PMA is referred to an advisory panel, the panel must hold a public meeting to review the PMA.⁵⁶

Under the MDA, the FDA has six months to act on an application.⁵⁷ On average, the PMA process takes over 1,200 hours for each application.⁵⁸ In 2002, it took the FDA an average of 161 days to review the PMA applications that were approved, with the total average review time amounting to 213 days.⁵⁹ In 2003, the FDA spent on average 221 days reviewing approved PMA applications was 151 days.⁶⁰

In addition to the significant obligations that the PMA process imposes on device manufacturers, these manufacturers are in some instances also required to comply with post-approval requirements as a condition of obtaining FDA clearance.⁶¹ The post-approval requirements can include: (1) restrictions on the sale, distribution, or use of the device; (2) ongoing evaluation and periodic reporting on the safety and effectiveness of the device; (3) prominent display of any warnings, hazards, or precautions necessary for safe and effective use in the labeling and advertising of restricted device; and (4) batch testing of the device.⁶² Unless otherwise exempted by the FDA, manufacturers are also required to submit post-approval reports at one year intervals from the date of approval which, among other things, identify any changes which affect the safety and effectiveness of the device arising from new indications for the use of the device; labeling changes; the use of new facilities to manufacture the device; extensions of the expiration date; changes in the performance or design specifications, components, ingredients, or principles of operation; and changes in packaging.⁶³ Post-approval reports must also contain a bibliography and summary of any new information regarding unpublished reports of data from clinical investigations and non-clinical laboratory studies involving the device and reports in the scientific literature concerning the device.⁶⁴

⁵⁴ Some repetitive PMA's don't require panel review prior to approval. 21 C.F.R. § 814.44.

⁵⁵ See FDA Device Advice, PMA REVIEW PROCESS, available at www.fda.gov/cdrh/deviceadvice/pma/; see also 21 C.F.R. § 814.44.

⁵⁶ *Id.*; see also 21 C.F.R. § 14.22.

⁵⁷ 21 U.S.C. § 360e(d)(1)(A); 21 C.F.R. § 814.44(c).

⁵⁸ *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 344-45 (2001); *Martin v. Medtronic, Inc.*, 254 F.3d 573, 576 (5th Cir. 2001); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 905 (7th Cir. 1997).

⁵⁹ See OFFICE OF DEVICE EVALUATION AND OFFICE OF IN VITRO DIAGNOSTIC DEVICE EVALUATION AND SAFETY ANN. REP. FISCAL YEAR 2003, Pt. 7, Table 4, available at www.fda.gov/cdrh/annual/fy2003/ode/part7.html.

⁶⁰ *See Id.*

⁶¹ FDA Device Advice, POSTAPPROVAL REQUIREMENTS, available at www.fda.gov/cdrh/deviceadvice/pma/; see also 21 C.F.R. §§ 814.80-84.

⁶² FDA Device Advice, POSTAPPROVAL REQUIREMENTS, available at www.fda.gov/cdrh/deviceadvice/pma/; see also 21 C.F.R. § 814.82. Other requirements can include the inclusion of identification codes on the device if necessary to protect public health; the maintenance of records that will enable the application to submit information to the FDA necessary to track patients. 21 C.F.R. § 814.82.

⁶³ FDA Device Advice, POSTAPPROVAL REQUIREMENTS, available at www.fda.gov/cdrh/deviceadvice/pma/; see also 21 C.F.R. § 814.84; see also 21 C.F.R. 814.39.

⁶⁴ FDA Device Advice, POSTAPPROVAL REQUIREMENTS, available at www.fda.gov/cdrh/deviceadvice/pma/; see also 21 C.F.R. § 814.84.

Finally, manufacturers may also be required to conduct post-market surveillance studies.⁶⁵ The manufacturer must draw up a plan for their post-market surveillance and the plan must be approved by the FDA.⁶⁶ The post-market surveillance may last up to 36 months and may address issues such as significant changes in the device technology; long-term follow up; the evaluation of rare events; and public health concerns resulting from reported problems with the device.⁶⁷ Post-market surveillance may include non-clinical testing; telephone or mail follow-up of a specific sample of device users; cross-sectional studies; and randomized controlled trials.⁶⁸

As the above discussion demonstrates, the FDA's review of devices approved under the PMA process is very thorough and extensive and is designed to protect consumers by ensuring the safety and effectiveness of FDA-approved devices. The FDA's review of medical devices is an effective method of safeguarding the health and safety of the consumers who use those devices. However, it is nevertheless inevitable that some consumers will be injured by FDA-approved devices. When a consumer suffers an injury arising out of his or her use of an FDA-approved medical device, one of the critical questions raised by the MDA's regulatory framework is whether, when, and to what extent state law claims are preempted by the MDA. The next section of this article will address the various approaches that courts have adopted in resolving the issue of federal preemption and the public policies which are implicated by these approaches.

III. FEDERAL PREEMPTION OF STATE LAW CLAIMS – LAW AND PUBLIC POLICY

A. Overview of Federal Preemption and the MDA's Express Preemption Provision

To understand the issues raised by the MDA's express preemption provision, it is first necessary to understand preemption generally. Preemption is a doctrine, derived from the United States Constitution's Supremacy Clause, which provides that a federal law can "supersede or supplant any inconsistent state law or regulation."⁶⁹ In applying the preemption doctrine, courts

⁶⁵ FDA Device Advice, POSTAPPROVAL REQUIREMENTS, available at www.fda.gov/cdrh/deviceadvice/pma/; see also 21 C.F.R. Part 822.

⁶⁶ 21 C.F.R. §§ 822.8-822.14. The plan must include the following information: (1) the manufacturer's name and address; (2) the generic and trade names of the device; (3) the name and address of the contact person for the submission; (4) the premarket application/submission numbers for the device; (5) the table of contents identifying the page numbers for each section of the submission; (6) a description of the device (this may be incorporated by reference to the appropriate premarket application/submission); (7) product codes and a list of all relevant model numbers; and (8) indications for use and claims for the device, along with the actual post-market surveillance plan. 21 C.F.R. § 822.9.

⁶⁷ FDA Guidance for Industry, Review Staff and the Clinical Community, GUIDANCE ON CRITERIA AND APPROACHES FOR POSTMARKET SURVEILLANCE, pp. 1-2 (Nov. 2, 1998), available at <http://www.fda.gov/cdrh/modact/critappr.pdf>.

⁶⁸ *Id.* at pp. 3-4. Post-market surveillance may also include a detailed review of the complaints arising from the use of the device and recorded in the scientific literature; the use of registries to track the performance of the device; case-controlled studies of patients using the device; non-randomized controlled cohort studies; and consecutive enrollment studies. *Id.*

⁶⁹ Black's Law Dictionary, 1197 (7th Ed. 1999).

assume that Congress did not intend to displace the States' police powers, unless it is the "clear and manifest purpose of Congress" to accomplish this result.⁷⁰ There are four circumstances under which a court will conclude that Congress has evinced a "clear and manifest" intention to preempt state law. First, the court will find that state law is preempted when the federal regulation or statute at issue expressly provides for such preemption.⁷¹ Additionally, a court may conclude that Congress intended to preempt state law where the federal regulation or statute at issue is very comprehensive in nature, where there is an dominant federal interest in a particular area or field, or where there is a direct conflict between state and federal law.⁷²

In drafting the MDA, Congress included a provision which expressly preempts competing state laws or regulations.⁷³ Section 360k(a) of the MDA provides:

Except as provided in subsection (b) of this Section, no State⁷⁴ or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –

- (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
- (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.⁷⁵

The FDA has promulgated regulations interpreting Section 360(k)'s preemption provision.⁷⁶ Under the FDA regulations, "state requirements are preempted only when the FDA has established specific counterpart regulations or . . . other specific requirements applicable to a particular device . . .".⁷⁷

Given the express preemption provision contained in the MDA, it might appear at first glance that the issue of federal preemption would not be particularly difficult or controversial. However, courts interpreting this provision are strongly divided on the meaning of Section 360(k) and whether and when it preempts state law claims arising out of injuries caused by FDA-regulated medical devices which have been approved under the PMA process. The judicial schism over the proper interpretation and application of Section 360(k) will be discussed in the next section.

⁷⁰ *Lohr*, 518 U.S. at 485; *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977).

⁷¹ *Jones*, 430 U.S. at 525.

⁷² *Hillsborough County v. Automated Medical Lab.*, 471 U.S. 707, 713 (1985).

⁷³ 21 U.S.C. § 360k(a); *see also* 21 C.F.R. § 808.1.

⁷⁴ The statute allows States to petition for an exemption to the preemption provision under certain circumstances. 21 U.S.C. § 360k(b); 21 C.F.R. § 808.1. The 22 exemptions which have been allowed to date apply to state statues and regulations regarding the sale of hearing aides. 21 C.R.F. § 808.53-808.101.

⁷⁵ 21 U.S.C. § 360k(b); *See also* 21 C.F.R. § 808.1(d).

⁷⁶ *See* 21 C.F.R. § 808.1(d).

⁷⁷ *Id.*

B. Judicial Interpretation of the MDA's Preemption Provision.

Questions about the preemptive effect of Section 360(k) most frequently arise in two situations: 1) when the injury-causing medical device was cleared by the FDA under the PMN process, and 2) when the injury-causing device was approved under the PMA process. In *Medtronic, Inc. v. Lohr*, the U.S. Supreme Court addressed the first situation and provided a general answer to the question of whether state law claims are preempted when the medical device at issue is cleared under the PMN process by holding that the MDA did not expressly preempt state common law claims under those circumstances.⁷⁸ However, with no guidance from the Supreme Court on the applicability of federal preemption when the medical device at issue is approved under the much more rigorous PMA process, courts remain strongly divided on the preemptive effect of the MDA in the second situation.⁷⁹

1. Federal Preemption of State Law Claims Relating to Devices Approved Under the Pre-Market Notification Process

Perhaps creating more confusion than it resolved, in 1997, the Supreme Court addressed the issue of preemption under the MDA where the device at issue was cleared by the FDA under the PMN process.⁸⁰ Highlighting the difficulty courts face in resolving the preemptive effect of the MDA, the Supreme Court's opinion in *Lohr* was heavily divided and left many questions unanswered.⁸¹ Nevertheless, the *Lohr* Court did provide clear guidance on certain issues by holding that: 1) the MDA does not expressly preempt all common law causes of action; 2) any common law cause of action that mirrors federal requirements is not preempted; and 3) under the facts in the case before it, the MDA did not expressly preempt state common law claims when the device was cleared under the PMN process.⁸² In reaching the conclusion that the MDA did

⁷⁸ 518 U.S. at 487-502.

⁷⁹ Compare *Brooks v. Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001) (en banc); *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001); *Kemp v. Medtronic Inc.*, 231 F.3d 216 (6th Cir. 2000); *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997) (all holding that the MDA preempts state law claims which impose additional or inconsistent requirements when the device received PMA clearance) with *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999); *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995); *Weiland v. Telectronics Pacing Sys. Inc.*, 721 N.E.2d 1149 (Ill. 1999) (reaching the opposite conclusion). The confusion over the MDA's preemptive effect was exacerbated by the Supreme Court's decision in *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). In *Buckman*, the plaintiffs alleged that bone screws inserted into their spines injured them and that the FDA approved the bone screws based on false information provided to the FDA by Buckman, a consulting company hired by the screw manufacturer. 531 U.S. at 346-47. In addressing the plaintiffs' fraud on the FDA claim, the Supreme Court held that the claims were impliedly preempted because the federal statutory scheme empowered the FDA to punish and deter fraud, authority which was given to the FDA to preserve a delicate balance of statutory objectives. *Buckman*, 531 U.S. 348-52. Prior to *Buckman*, it was presumed that implied preemption did not apply where there was an express preemption provision. See *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992). By finding that the plaintiffs' fraud on the FDA claims were impliedly preempted, *Buckman* magnified the confusion over preemption under the MDA by opening the door to the possibility that the MDA may impliedly preempt state law claims in a variety of situations.

⁸⁰ See *Medtronic Inc. v. Lohr*, 518 U.S. 470 (1996).

⁸¹ *Lohr*, 518 U.S. 472; *Martin*, 254 F.3d at 578-79 (describing *Lohr* opinion as "fractured" and noting that "extracting the final meaning of *Lohr* is no easy task").

⁸² *Lohr*, 518 U.S. at 486-489; 492-501.

not preempt the state law claims asserted in the case before it, the *Lohr* Court noted that the PMN process was focused on "equivalence" rather than safety.⁸³ Observing that the PMN process was not very rigorous, the Court found that the process did not impose any specific federal requirements which could conflict with state tort law duties.⁸⁴ Accordingly, the Court found that the plaintiffs' state law claims were not preempted.⁸⁵

While the *Lohr* opinion leads to the likely conclusion that common law claims regarding devices cleared under the PMN process are not preempted by the MDA, the Supreme Court has not answered the question of the MDA's preemptive effect when the device at issue is approved under the FDA's PMA process. As a result, courts remain strongly divided about the preemptive effect of the MDA under these circumstances.⁸⁶

2. The Preemptive Effect of MDA When the Device is Approved by the FDA Under the PMA Process.

When confronting the issue of whether the MDA preempts state law claims when the device at issue has been approved by the FDA under the PMA process, courts fall into two distinct camps. The majority of federal courts addressing this issue have concluded that the MDA preempts state law claims which impose additional or inconsistent requirements where the device receives PMA clearance.⁸⁷ Several state supreme courts have also adopted this view.⁸⁸ In contrast, courts adopting the minority position have found that the MDA does not preempt state law claims in the above circumstances.⁸⁹

⁸³ 518 U.S. at 492-502.

⁸⁴ *Lohr*, 514 U.S. at 492-502.

⁸⁵ *Id.*

⁸⁶ Shortly after *Lohr*, the FDA issued a proposed rule stating specifically that a 510(k) notification, PMA, or IDE would not itself preempt state common law requirements. See Medical Devices; Preemption of State Product Liability Claims, 62 Fed. Reg. 65384 (proposed December 12, 1997). However, the FDA withdrew that rule in 1998. See Medical Devices; Preemption of State Product Liability Claims, 63 Fed. Reg. 39789 (withdrawn July 17, 1998). Thus, the issue of preemption in the wake of *Lohr* has not been clarified further by the FDA through its rule-making authority.

⁸⁷ See e.g. *Brooks v. Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001) (en banc); *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001); *Kemp v. Medtronic Inc.*, 231 F.3d 216 (6th Cir. 2000); *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997); *Talbott v. C.R. Bard, Inc.*, 63 F.3d 25 (1st Cir. 1995); *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir. 1993); *Davenport v. Medtronic, Inc.*, No CIV. A. 00-6105, 2004 WL 193197 (E.D. Pa. Feb. 3, 2004); *Steele v. Depuy Orthopaedics, Inc.*, 295 F. Supp. 2d 439 (D. N. J. 2003); *Horn v. Thermo Cardiosystems, Inc.*, 229 F. Supp. 2d 381 (M.D. Pa. 2002); *Gilleon v. Medtronic USA, Inc.*, No C01-20460 RMW, C01-20497 RMW, C01-20693 R/mw, 2002 WL 31300694 (N.D. Cal. Aug. 28, 2002); *Baker v. Medtronic, Inc.*, No 2:99-CV-1355, 2002 WL 485013 (S.D. Ohio March 28, 2002); *Enlow v. St. Jude Medical, Inc.*, 210 F. Supp. 2d 853 (W.D. Ky 2001); *In re Medtronic Polyurethane Insulated Pacing Lead Product Liability Litigation*, 96 F. Supp. 2d 568 (E.D. Tex. 1999); *Rogerson v. Telectronics Co.*, No. 94 C 5477, 1998 WL 559788 (N.D. Ill. Aug. 25, 1998); *Isbell v. Medtronic, Inc.*, 97 F. Supp. 2d 849 (W. D. Tenn. 1998); *Carey v. Shirley, Inc.*, 32 F. Supp. 2d 1093 (S.D. Iowa 1998); *Salazar v. Medtronic, Inc.*, No. CIV.A. C-96-425, 1997 WL 1704284 (S.D. Tex. 1997); *Easterling v. Cardian Pacemakers, Inc.*, 986 F. Supp. 366 (E.D. La. 1997); *Estate of LeMay v. Eli Lilly & Co.*, 960 F. Supp. 183 (E.D. Wis. 1997).

⁸⁸ See e.g. *Green v. Dolsky*, 685 A.2d 110 (Pa. 1996); *Fry v. Allergan Med. Optics*, 695 A.2d 511 (R.I. 1997); *Worthy v. Collagen Corp.*, 967 S.W.2d 360 (Tex. 1998).

⁸⁹ See e.g. *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999); *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995); *Woods v. Gliatech, Inc.*, 218 F. Supp. 2d 802 (W.D. Va. 2002); *Webster v. Pacesetter, Inc.*, 171 F. Supp.

a. Majority Approach to Preemption under MDA Where Device Is Approved under the PMA Process.

Courts that find preemption of state law claims which impose additional or inconsistent requirements when the device at issue is approved under the PMA process rely on similar reasoning in reaching their conclusions. These courts often begin their analysis by reviewing the Supreme Court's holding in *Lohr* and focusing on the Court's conclusion that preemption under the MDA arises only when: 1) there is a federal requirement that is specific to the particular device at issue; 2) there is also a specific state requirement which is different from or in addition to the federal requirement; and 3) the state requirement relates to the safety or effectiveness of the device or to "other matter included in [the] requirement applicable to the device."⁹⁰

Applying the preemption prerequisites articulated in *Lohr*, courts find that most⁹¹ state claims relating to devices approved under the PMA process are preempted by the MDA. Many of the courts reaching that conclusion reason that: 1) common law tort suits can impose state requirements for the purposes of determining preemption; 2) common law tort suits impose requirements that are "different from, or in addition to" those imposed by the PMA process; and 3) the PMA process imposes specific federal requirements on the labeling, manufacturing, and design of the products which are reviewed by the FDA.⁹²

Among the reasons advanced by the courts finding preemption, perhaps the two most controversial are: 1) that state tort causes of action impose requirements that are different from or in addition to those imposed by the PMA process; and 2) that the PMA process imposes specific federal requirements on the device at issue. Courts have concluded that, in order to address the first issue, it is "necessary to examine the state law cause of action at a sufficiently precise level of generality to determine whether the final judgment of the state court would impose on the manufacturer a burden incompatible with the requirements imposed by the FDA."⁹³ Thus, where the common law claims asserted threaten to impose different or additional requirements than those imposed by the FDA, the claims will be preempted.⁹⁴

2d 1 (D.C. 2001); *Haidak Collagen Corp.*, 67 F. Supp. 2d 21 (D. Mass. 1999); *Quillin v. American Hospital Supply Corp., Inc.*, No. 94-C-1020-BU, 1997 WL 382095 (N.D. Okla. 1997); *Weiland v. Telectronics Pacing Sys. Inc.*, 721 N.E.2d 1149 (Ill. 1999).

⁹⁰ See e.g. *Martin*, 254 F.3d at 578-580; *Kemp*, 231 F.3d at 223-225; *Mitchell*, 126 F.3d at 907-11.

⁹¹ State law claims which allege that the FDA's requirements were not satisfied are often allowed to stand because they do not impose additional requirements on device manufacturers. See e.g. *Martin*, 254 F.3d at 585.

⁹² See e.g. *Martin*, 254 F.3d at 580-85; *Kemp*, 231 F.3d at 225-32; *Mitchell*, 126 F.3d at 911-15.

⁹³ See e.g. *Mitchell*, 126 F.3d at 912.

⁹⁴ *Id.* at 912-13. The *Mitchell* court cited with approval the holding of a Pennsylvania court which found that "(1) state claims that allege that FDA requirements have not been observed are not preempted, and (2) state claims that conflict with specific requirements of the FDA are preempted. . . . state common law claims are preempted if they attempt to substitute a reasonableness analysis, characteristic of negligence claims, for the judgment of the FDA in approving the development and distribution of this particular product in the course of the premarket approval process." *Mitchell*, 126 F.3d at 913; see also *Green v. Dolsky*, 685 A.2d 110, 117 (Pa. 1996).

Courts addressing the second issue focus on the significant difference between the PMA process and the PMN process.⁹⁵ Devices which are approved by the FDA under the PMA process go through a comprehensive and thorough examination during which the FDA reviews the device's clinical data, pre-clinical test results, proposed labeling, components, and the methods, controls and the facilities used in the manufacturing and processing of the device.⁹⁶ If the manufacturing does not comply with the FDA regulations or the labeling is found to be false or deceptive or does not adequately reflect the clinical data, the PMA application is denied.⁹⁷ Thus, courts following the majority approach find that the PMA process imposes specific federal requirements that directly affected the safety and effectiveness of the product and therefore trigger preemption under Section 360(k) and 21 C.F.R. § 808.1.⁹⁸

b. Minority Approach to Preemption under MDA Where Device Is Approved under the PMA Process.

Courts which adopt the minority approach and find that the MDA does not preempt state law claims where the device is approved under the PMA process often base their conclusion on the finding that the PMA process does not impose any ascertainable requirement on the device at issue, and thus does not satisfy the Supreme Court's requirement that there be a specific federal regulation focused on safety and effectiveness which applies to the particular device at issue.⁹⁹ While these courts concede that the PMA process focuses on safety and effectiveness and imposes requirements on the PMA applicant, they nevertheless note that the PMA process does not require that the device at issue be manufactured or designed in a specific way.¹⁰⁰ Accordingly, the courts conclude that "because the [FDA's PMA] approval itself neither reveals nor imposes any ascertainable substantive prerequisites for approval that [the court] could compare to a purportedly conflicting state requirement, the approval itself does not fit with section 360k(a)(1)'s demand for a specific federal requirement."¹⁰¹

⁹⁵ See e.g. *Martin*, 254 F.3d at 584-85; *Mitchell*, 126 F.3d at 911-12. In *Martin*, the court noted the findings of both the *Lohr* and *Buckman* Courts, stating "[a]s the Supreme Court itself has observed, the PMA process and the § 510(k) process are clearly distinguishable . . . substantially equivalent devices have never been formally reviewed under the MDA for safety or efficacy and the FDA does not consider the § 510(k) process 'official FDA approval.'" 254 F.3d at 578, fn. 4. See also *Buckman*, 531 U.S. at 347 (stating "Admittedly, the § 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."); *Lohr*, 518 U.S. at 493.

⁹⁶ *Martin*, 254 F.3d at 584, fn 9; 21 U.S.C. § 360e(c)(1)(B)-(C), (F); 21 C.F.R. § 814.20.

⁹⁷ *Id.*; 21 U.S.C. § 360e(d)(2)(A)-(D); see also 21 C.F.R. § 814.45.

⁹⁸ See e.g. *Martin*, 254 F.3d at 580-85; *Mitchell*, 126 F.3d at 911-13.

⁹⁹ See e.g. *Goodlin*, 167 F.3d at 1375; *Weiland*, 188 Ill.2d at 418-20.

¹⁰⁰ See e.g. *Goodlin*, 167 F.3d at 1375-76; *Weiland*, 188 Ill.2d at 420-22. Some appellate courts following the minority approach find that the PMA process imposes specific federal requirements but nevertheless refuse to find preemption on the ground that state common law imposes only general obligations, not the specific state requirements needed to trigger preemption. See *Wutzke v. Schwaegler*, 940 P.2d 1386, 1391-92 (Wash. App. Ct. 1997).

¹⁰¹ *Goodlin*, 167 F.3d at 1376.

Courts following the minority approach further support their refusal to find preemption under the MDA by resorting to a recitation of one of the purposes of the MDA.¹⁰² Noting that the MDA was passed, in part, to provide for the safety and effectiveness of medical devices, courts which find that state law claims are not preempted by the MDA when the device has been reviewed under the PMA process have concluded that, by allowing plaintiffs to bring state law claims, medical devices will be subjected to increased scrutiny which will purportedly insure greater safety.¹⁰³ Accordingly, courts which decline to find that the MDA preempts state law claims relating to devices subject to the PMA process contend that the public policies for passing the MDA are advanced by their interpretation of the MDA.¹⁰⁴

C. Critical Analysis of A Recent Case Addressing Preemption Of State Law Claims Asserted against PMA Approved Devices.

A closer analysis of a recent case which address whether the MDA preempts state law claims against PMA-approved devices highlights the flaws of the minority position and illustrates why the majority of courts addressing this issue have found preemption.

In *Webster v. Pacesetter, Inc*, 171 F. Supp. 2d 1 (D.C. 2001) the plaintiff sued the defendant device manufacturer after a pacemaker made by the defendant perforated the wall of plaintiff's heart, thereby necessitating surgery to repair the damage.¹⁰⁵ Plaintiff alleged state law claims of strict liability, negligent warnings, design, manufacture and follow-up evaluation, breach of warranty; and fraud and deceit.¹⁰⁶ The defendant device manufacturer argued that plaintiffs state law tort claims were expressly preempted by the MDA.¹⁰⁷

In addressing defendant's preemption argument, the court focused first on two basic principles governing preemption: 1) there is a presumption against federal preemption of state regulation and 2) the analysis of a statute's preemptive effect is guided by the principle that the "purpose of Congress is the ultimate touchstone" in each case.¹⁰⁸ After engaging in a detailed and in certain instances, erroneous,¹⁰⁹ review of the Supreme Court's opinion in *Lohr* and the

¹⁰² See e.g. *Goodlin*, 167 F.3d at 1378-79; *Weiland*, 188 Ill.2d at 421-22.

¹⁰³ See e.g. *Goodlin*, 167 F.3d at 1378-80; *Weiland*, 188 Ill.2d at 421-22.

¹⁰⁴ See e.g. *Goodlin*, 167 F.3d at 1378-80; *Weiland*, 188 Ill.2d at 421-22.

¹⁰⁵ *Webster*, 171 F. Supp. 2d at 3.

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ For example, in discussing the *Lohr* opinion, the court incorrectly states that "the majority agreed that Section 510(k) review and premarket approval did not result in preemption of state common law claims." *Webster*, 171 F. Supp. 2d at 6. In fact, the *Lohr* Court did not address preemption of state common law claims when the device at issue was approved under a PMA. 518 U.S. at 492-502. Further, in contrasting the PMA process with the PMN of 510(k) approval that was at issue in *Lohr*, the Court emphasized the detailed and rigorous nature of the PMA review,

majority position on MDA preemption for PMA-approved devices, the court then focused on and adopted the analysis advocated by the Eleventh Circuit in *Goodlin v. Medtronic*.¹¹⁰ Specifically, the *Webster* court found that the MDA preemption provision only came into play when there was a specific counterpart FDA regulation or requirement that applied to the particular device in question and further concluded that the PMA process did not impose any ascertainable requirement on the device approved thereby.¹¹¹ The court observed that the FDA does not issue any regulation, order or other statement of its substantive benchmark when it approves a device under the PMA process and does not provide any indication of the substantive requirements the FDA imposed on the device in granting the approval.¹¹² The *Webster* court concluded that, to trigger the preemption provision of the MDA, the FDA had to promulgate an "ascertainable precondition to regulatory approval" and because neither the MDA nor the PMA process provided requirements dictating the design, manufacturing, or materials used to develop the device, but rather left those decisions to the manufacturers, there were no requirements imposed by the PMA process and thus no preemption.¹¹³ In finding against preemption, the court also seemed influenced by its conclusion that the FDA, in its PMA review, did not appear to consider alternative designs that might further enhance the safety of the device and did not suggest design changes.¹¹⁴ The *Webster* court also seemed heavily influenced by the *Lohr* opinion and by the *Webster* court's mistaken observation that "the 510(k) and PMA processes serve the same purposes . . .",¹¹⁵ which led to the Webster court's heavy reliance on *Lohr*.

The conclusions which form the foundation of the minority position, as illustrated by the *Webster* court, are flawed for several reasons. As an initial matter, the conclusion that the PMA process does not impose any requirements on device manufacturers ignores the realities of the PMA process. The PMA process is designed to ensure that a device is safe and effective for its intended use before being offered for sale to the public.¹¹⁶ Thus, in reviewing and approving the design, components, manufacturing process, and labeling of a device during the intensive PMA process, the FDA is, through its approval or rejection of the device, imposing specific requirements on that device related to each of these areas.¹¹⁷ When the FDA has approved a device under the PMA process, it has made the judgment that the design, manufacturing methods, labeling and composition of the device render the device safe and effective for the proscribed use and that all of the requirements which are relevant to that determination have

thus possibly foreshadowing the Court's intention to find state law claims preempted when the device at issue has been reviewed under the PMA process. 518 U.S. at 477.

¹¹⁰ *Webster*, 171 F. Supp. 2d at 5-9.

¹¹¹ *Id.* at 8-10.

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ *Id.* at 10.

¹¹⁵ *Id.* at 11.

¹¹⁶ 21 U.S.C. § 360c(a)(1)(C); see also 21 C.F.R. §§ 814.1, 814.2; FDA Device Advice, PMA OVERVIEW, p. 1, available at www.fda.gov/cdrh/deviceadvice/pma/index.html#introduction; *Lohr*, 518 U.S. at 477.

¹¹⁷ See e.g. *Mitchell*, 126 F.3d at 911-15; *Kemp*, 231 F.3d at 225-32; *Martin*, 254 F.3d at 580-85.

been satisfied.¹¹⁸ Thus, in light of the numerous requirements imposed by the FDA on device manufacturers who seek PMA approval and the rigorous safety and efficacy standards that the device must satisfy before being approved, it is clearly erroneous to conclude that the PMA process does not impose device-specific requirements.

The *Webster* and other minority courts improperly fixate on the lack of a specific design or manufacturing directives applicable to Class III devices undergoing PMA review.¹¹⁹ These courts have concluded that, because the FDA does not tell device manufacturers how to design their products and how to produce them by providing manufacturers with a recipe or list of requirements which dictate, for example, that manufacturers must use component X but not component Y, that there are no specific federal requirements that are created by the PMA process.¹²⁰ However, this simplistic analysis ignores the FDA's purpose – which is to ensure that a given device is safe and effective – and instead charges the FDA with obligations which are properly left to manufacturers – namely, developing innovative and cost-efficient new devices and ways of producing them.¹²¹ By leaving manufacturers unfettered to create the design and manufacturing process for new devices, with the critical limitation being that the devices must be safe and effective under the FDA's standards, the MDA strikes the proper balance between the Act's dual purposes of fostering innovation and protecting consumers.¹²² The *Webster* court's refusal to find preemption in the absence of FDA-dictated design and manufacturing requirements for PMA-approved devices abrogates the FDA's ability to balance the advancement of innovation and the protection of consumers.

In addition to ignoring the realities of PMA approval and the balance the FDA seeks to strike in its review and regulation of devices, the *Webster* court also errs in its analysis by relying too heavily on the *Lohr* opinion, based on the *Webster* court's erroneous conclusion that the PMA and 510(k) processes serve the same purpose.¹²³ This conclusion is patently incorrect. As

¹¹⁸ *Id.* In *Mitchell*, the Seventh Circuit observed, in the course of determining that the PMA process was a specific federal regulation, that the PMA process "involved a review of all the ingredients, components, manufacturing methods, and labeling to be used in conjunction with the [device]. We think rather than expressing entirely generic concerns of safety, the FDA has expressed explicit concerns toward this[device]. We conclude that the premarket approval process constitutes a specific federal interest as contemplated in *Medtronic* and that, therefore, the FDA approval served to impose strict FDA requirements upon the defendant." *Mitchell*, 126 F.3d at 911. The *Mitchell* court further held that, "during the PMA process, the federal government, it can truly be said, has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers." *Id.* (citations omitted).

¹¹⁹ *Webster*, 171 F. Supp. 2d at 8-10; *see also Goodlin*, 167 F.3d at 1274-76; *Woods*, 218 F. Supp. 2d at 808; *Weiland*, 721 N.E.2d at 1152-53.

¹²⁰ *Webster*, 171 F. Supp. 2d at 8-10; *see also Goodlin*, 167 F.3d at 1274-76; *Weiland*, 721 N.E.2d at 1152-53.

¹²¹ It also ignores the purpose of the PMA process, which is to review devices that are new and thus not substantially equivalent to products already on the market. It is unclear how the FDA is supposed to promulgate detailed and specific design and manufacturing requirements for a device which may just have been invented.

¹²² *See Sigman*, 47 CATH. U. L. REV. at 724-25; *Herrman and Ritts*, 51 FOOD & DRUG L.J. at 4-5.

¹²³ *Webster*, 171 F. Supp. 2d at 11.

the *Lohr* Court itself pointed out "[t]he § 510(k) notification process is by no means comparable to the PMA process . . . [t]he 510(k) process is focused on *equivalence*, not safety. As a result, "substantial equivalence determinations provide little protection to the public."¹²⁴ In contrast, the PMA process is very rigorous and is designed to provide reasonable assurances that a given device is safe and effective.¹²⁵ The difference in both the purpose and the substance of the review at issue in *Lohr* renders the opinion of limited use in assessing whether state law claims against a device approved under the PMA process are preempted by the MDA. By ignoring or treating as unimportant the significant differences in the scope and purpose of FDA approval under the PMA process versus the PMN or 510(k) process – differences that were highlighted, not ignored by the *Lohr* Court -- the *Webster* court came to the erroneous conclusion, shared by other courts adopting the minority position, that the MDA does not preempt common law claims against devices approved by the FDA under the PMA process.¹²⁶

As illustrated above, the pronounced division among the courts over the MDA's preemptive effect when the device at issue is approved under the PMA process makes it almost certain that the Supreme Court will eventually provide some guidance on this issue. However, in the interim, medical device manufacturers and distributors will continue to face uncertainty regarding their potential exposure to state common law liability arising out of injuries caused by devices approved under the FDA's rigorous PMA process. The final section of this article will articulate the factors which mandate a finding that state law claims are preempted by the MDA where the device is reviewed and approved by the FDA under the PMA process.

IV. ANALYSIS SUPPORTING A FINDING OF FEDERAL PREEMPTION UNDER THE MDA.

As supported by the voluminous precedent discussed earlier, state law claims which impose additional or different requirements should be preempted by the MDA when the device at issue was approved by the FDA under the PMA process. Several factors strongly support such a conclusion.

First, permitting the assertion of state law claims against medical device manufacturers would be contrary to one of the purposes of the MDA, which is to provide protection for inventors of new medical technologies. The MDA was enacted in part to provide a safe harbor

¹²⁴ *Lohr*, 518 U.S. at 479, 493. These *Lohr* Court further noted that the 510(k) "determinations simply compare a post-1976 device to a pre-1976 device to ascertain whether the later device is no more dangerous and no less effective than the earlier device. If the earlier device poses a severe risk or is ineffective, then the later device may also be risky or ineffective." *Lohr*, 518 U.S. at 493; see also Robert S. Adler, *The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 Food Drug Cosm. L.J. 511, 516 (1988). Thus, the design of the a device approved under the 510(k) process, as with the design of pre-1976 and other "substantially equivalent" devices, has never been formally reviewed under the MDA for safety or efficacy. *Lohr*, 518 U.S. at 493.

¹²⁵ *Lohr*, 518 U.S. at 477.

¹²⁶ *Webster*, 171 F. Supp. 2d at 8-12.

for the advancement and innovation of medical devices.¹²⁷ Thus, the MDA represents Congress' attempt to develop a balance between protecting the health and safety of consumers and creating an environment that fosters innovation and the development of new devices.¹²⁸ When manufacturers who have satisfied the strict requirements of the FDA's PMA review process are still subject to uncertain and variable potential state law liability, manufacturers may become reluctant to develop new devices and to offer them in the market place.¹²⁹ As the concurring judges in *King* pointed out, "if the legal risks [are] too great, worthwhile medical devices may be left in the laboratory, to the public's loss."¹³⁰

The second factor which militates in favor of finding federal preemption is the "the need for national uniformity in product regulation, one of the explicit goals of the MDA."¹³¹ A review of the MDA's legislative history indicates that uniformity of "regulation was the reason the preemption provision was included within the MDA."¹³² As the Congressional record states: "if a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened."¹³³ Thus, under the MDA, manufacturers assume the financial and temporal burdens placed upon them by the Act in exchange for a nationally uniform and predictable regulatory and liability climate. It is patently unfair for manufacturers and consumers to face different legal consequences arising from an injury-causing medical device, depending on the fortuity of where they live or sell their products, when an extensive federal regulatory scheme exists -- one that includes an express provision providing for preemption.¹³⁴

The third factor which requires a finding that the MDA preempts state law claims is respect for Congressional intent. By including an express preemption provision in the MDA, Congress clearly articulated its intent to preempt some conflicting state law claims.¹³⁵ However, if the PMA process is not viewed as a specific requirement which triggers application of the express preemption provision, "preemption under § 360k would be exceedingly rare."¹³⁶ Thus, any construction of Section 360k which does not preempt state law claims when the device at issue is approved under the PMA process will eviscerate Section 360k and render it essentially meaningless. Such a construction would be contrary to Congressional intent.

¹²⁷ See, e.g. H.R.Rep. No. 853, 94th Cong., 2d Sess. 10-11 (1976); S.Rep. No. 33, 94th Cong. 1st Sess. 2, 13, 18 (1975).

¹²⁸ *Id.*

¹²⁹ See *King*, 983 F.2d at 1139-40.

¹³⁰ *King*, 983 F.2d at 1138.

¹³¹ *Brooks*, 273 F.3d at 797.

¹³² *Id.*; see also H.R. Report No. 853, 45 (1976).

¹³³ H.R. Report No. 853, 45 (1976).

¹³⁴ When reviewed through the PMA process, Medical Devices are subjected to far more stringent regulation than are other products, such as automobiles. While other product manufacturers must comply with certain regulations, these manufacturers are not required to actually submit their new products, along with enormous volumes of testing and other data, to a federal agency, which reviews every aspect of that product to determine whether it is safe and effective. See 49 U.S.C. §§ 30111-30121. Thus, device manufacturers face a different regulatory environment than do most other product manufacturers. As a result, where device manufacturers have obtained FDA approval for their devices under the PMA process and have complied with the FDA's requirements, they should be provided with the safe harbor created by preemption of state claims which impose additional or different requirements on the manufacturers.

¹³⁵ *Lohr*, 518 U.S. at 508; *Kemp*, 231 F.3d at 227.

¹³⁶ *Kemp*, 231 F.3d at 227.

The fourth and final factor which supports the conclusion that the MDA was intended to preempt state law claims is the risk that the States will undermine the FDA's ability to ensure the safety and effectiveness of medical devices while promoting technological advancement. Any system of regulation, whether it be created and enforced by a federal agency or by jury verdicts, will only be effective to the extent that it successfully balances several competing interests, including consumer safety, product innovation, affordability, and profitability. A regulatory environment which creates extraordinarily safe products that are unaffordable and unable to be profitably produced will benefit no one. Balancing these competing interests is a very delicate process, which is best accomplished by an organization or agency which has expertise, knowledge, experience, accountability and the ability to see the big picture. Because the FDA focuses its time and attention on reviewing medical devices primarily to determine their safety and effectiveness, the FDA possesses expertise and knowledge far greater than that of a jury or a judge.¹³⁷ Additionally, unlike a jury, the FDA is accountable to all groups for its decisions, and thus is more likely to steer a course which balances these competing interests than is a group of jurors whose obligations end at the close of the case. Accordingly, in light of the FDA's accountability, expertise in medical devices, and substantial experience reviewing these devices to determine their safety and effectiveness, it is clear that the FDA is best equipped to achieve the federal objectives of the MDA.¹³⁸

Although opponents of preemption advance several reasons to support their theory that state-law claims should not be preempted, regardless of the type of review applied to the device, a closer examination of these reasons calls into doubt the validity of all or most of them. Certainly one of the most popular arguments against preemption is that medical devices will be safer if suits based on state-law claims such as negligent design are allowed to proceed. This argument assumes that, if device manufacturers face the risk of huge judgments resulting from injuries caused by "unsafe" devices, the manufacturers will improve the safety of these devices in order to reduce their potential liability exposure. However, this assumption ignores two important realities. First, while such an assumption may have some legitimacy in an industry that is either not regulated at all or that is only minimally regulated, it holds less validity in an industry that is as heavily regulated as the medical device industry. When a manufacturer can only market a device after the device has been PMA-approved and has thus passed the FDA's rigorous safety standards, the risk of facing a huge verdict arising from an injury caused by a device which is -- despite the satisfaction of the FDA's rigorous safety standards -- still found unsafe by a jury with no expertise may well motivate the manufacturer to halt sales or production of the device rather than to incur even greater expenses in an effort to litigation-proof the device by making it unassailably safe.

The second reality ignored by the assumption that greater litigation risk results in greater device safety is that of loss-spreading. When faced with huge possible verdicts, despite having properly complied with the FDA's requirements and standards on safety, manufacturers will

¹³⁷ See *King*, 983 F.2d at 1139-40.

¹³⁸ *Id.*

likely pass on to consumers the cost of any estimated liability exposure and may well raise prices to compensate for these possible losses, rather than incur the expense of trying to make their devices more safe. Thus, the risk of large jury verdicts may yield no safety benefit whatsoever, and may instead, result in higher prices that do nothing more than deprive less affluent consumers of the possible benefit of the affected devices.

Another popular argument advanced in opposition to the federal preemption of state law claims arising from injuries caused by PMA-approved devices is that injured consumers should not be left without any remedy. However, the import of this argument is both overstated for two reasons.

First, the import of the argument is overstated because it fails to take into account the relatively small number of individuals who will be affected by the application of federal preemption, as advocated in this article and by the majority of the courts addressing the issue. The majority of devices are approved through the 510(k) process, rather than the PMA process, and it is well established that claims arising from injuries caused by these devices are not preempted. Additionally, the majority of courts have found that, even if the device is approved through the PMA process, state law claims may still proceed as long as the claims do not impose any additional or different requirements on manufacturers. Thus, plaintiffs remain free to sue when their injuries are caused by a deviation from the FDA requirements. Thus, only in cases involving both PMA approved devices and claims which imposes additional or different requirements on manufacturers will MDA preemption be an issue. This is a relatively small universe of cases.

Additionally, the argument ignores the realities already imposed by the judicial system. Injured consumers are denied relief every day by the imposition of various standards of care in cases involving everything from medical malpractice to products liability. Not every injured consumer is entitled to relief under the current judicial system. 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. This harsh reality reflects an attempt to balance the competing interests of consumer safety, innovation, and affordability. Where medical devices are concerned, the FDA is certainly much better equipped to balance these competing interests in a uniform and meaningful way, than are jurors who have neither the expertise or experience to understand the wide-spread implications of their verdicts.

As the above discussion demonstrates, the MDA should be construed to preempt any state tort law claim arising out of an injury caused by a device which has undergone PMA review, when the state tort law claim imposes different or additional requirements on the device manufacturer.

V. CONCLUSION

The MDA provides an extensive regulatory framework for ensuring the safety and efficacy of medical devices approved under the PMA process. At the same time, the MDA

fosters the creation and development of new medical devices by providing guidance for manufacturers and protection from arbitrary state regulation or common law liability. To this end, the MDA contains an express preemption provision which makes manifest Congress' intent to relegate the regulation of medical devices to the federal arena. However, in spite of this extensive regulatory scheme and the MDA's express preemption provision, the courts remain undecided as to the preemptive effect of the MDA when the device at issue has been reviewed and approved under the PMA process. This confusion must be resolved in favor of preemption if the FDA's regulatory authority and the goals behind the passage of the MDA are to be served. Without the safe harbor offered by federal preemption, the risk of inconsistent legal outcomes and liability threatens to discourage innovation, eviscerate the FDA's powers, and destroy the uniformity intended by Congress. Only time and the final word from the Supreme Court or from Congress, amending the Act, will clarify, once and for all, whether the MDA will be interpreted to have the preemptive effect Congress intended.

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