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PREEMPTION OF CLAIMS RELATED TO CLASS III MEDICAL DEVICES: ARE THE FEDERAL OBJECTIVES OF PUBLIC HEALTH AND SAFETY FURTHERED OR HINDERED?

Ashley W. Warren*

TABLE OF CONTENTS
I. INTRODUCTION .......................................................... 620
II. THE FDA'S REGULATION OF MEDICAL DEVICES ...................... 621
   A. HISTORY OF THE REGULATIONS CONCERNING MEDICAL DEVICES .... 621
   B. THE MEDICAL DEVICES AMENDMENTS OF 1976 ...................... 624
   C. THE MEDICAL DEVICE REGULATORY PROCESS ....................... 626
   D. EXPERIMENTAL DEVICES UNDER THE MEDICAL DEVICES AMENDMENTS .... 628
III. PREEMPTION ........................................................... 629
   A. OVERVIEW .......................................................... 629
   B. PREEMPTION GENERALLY ........................................... 629
   C. PREEMPTION AS RELATING TO MEDICAL DEVICES .............. 632
IV. ANALYSIS OF PREEMPTION IN LIGHT OF CASE LAW ..................... 634
   A. OVERVIEW .......................................................... 634
   B. ARGUMENTS IN FAVOR OF PREEMPTION OF CLAIMS RELATING TO MEDICAL DEVICES .... 636
      1. Federal Objectives Cannot Be Undermined .................. 636
      3. Federal Standards Are Not Mere Minimal Standards .......... 639
      4. Need for Uniformity ........................................... 640
   C. ARGUMENTS IN OPPOSITION TO PREEMPTION OF CLAIMS RELATING TO MEDICAL DEVICES .... 641
      1. Congress' Intent Is Not Completely Clear ................... 641
      2. Promotion of Public Safety .................................... 641

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I. INTRODUCTION

Consider the following situation: you are a woman seeking medical advice about eliminating facial wrinkles. You decide to proceed with a process in which you are injected with Zyderm, an anti-wrinkle treatment containing collagen which has been approved by the Food and Drug Administration (FDA). The intended result is a smoothing out of wrinkles or deformities on the skin surface. The actual result, however, is certainly not one that you had anticipated. Shortly after receiving the injections, you start experiencing a severe pain in your muscles and joints. Suddenly, you are diagnosed with dermatomyositis/polymyositis (DM/PM). It appears that, although your wrinkles may have improved, you have paid a high price: you are suffering from a relatively rare autoimmune disease in which your immune system identifies its own skin and muscle tissue as foreign and attacks them. The anti-wrinkle products have attached to your tissues and have provoked an immune response that has destroyed your body tissue.

Suppose that you then seek legal recourse against the manufacturer of this product to recover damages you have suffered. If nothing else, you seek compensatory damages to cover your medical expenses. Your action is based on defective design, inadequate warnings, and negligent failure to warn. Since the product is regulated by the FDA, however, your claim in state court is preempted. As the product was approved by the FDA, you are faced with two grim facts: the manufacturer of Zyderm is shielded from liability, and thus you have no recourse against the manufacturer because the court system is not permitted to find that the FDA's requirements were not extensive enough.

This fact scenario has occurred in the First Circuit in King v. Collagen Corp. and in the Fifth Circuit in Stamps v. Collagen Corp. The implications of these two cases are far-reaching. In fact, Peter Hutt, former general counsel of the FDA, has stated that "[t]his case [King v. Collagen Corp.] is probably the single most important case to the medical-device industry in American history."3 With Stamps having a nearly identical fact scenario to that in King, the two cases are crucial to understanding whether the public is adequately protected by the FDA with regard to

1. 983 F.2d 1130 (1st Cir.), cert. denied, 114 S. Ct. 84 (1993).
2. 984 F.2d 1416 (5th Cir.), cert. denied, 114 S. Ct. 86 (1993).
medical devices. The question is whether the FDA, a federal regulatory agency, is capable of achieving the goals of public health and safety by preempting state law claims regarding medical devices. Opponents of preemption argue that allowing state tort actions would better achieve both the federal and state governments' objectives of public safety in spite of the fact that the threat of such litigation would certainly interfere with medical device manufacturers' willingness to introduce new products into the marketplace.

Thus, the arguments for and against preemption represent opposing views regarding the roles that both the federal and state governments should play in the regulation of medical devices. The overriding concern at both levels of government is that of public health and safety. That is, the objectives are to ensure that only safe and effective products reach the consumer and that the consumer is adequately informed how to safely use a particular product. The focus of this paper will center upon whether preemption furthers public safety as the federal government advocates, or, on the other hand, whether it hinders this crucial objective at the public's expense.

In order to understand this debate in its entirety, I will first discuss the FDA's process of regulating medical devices. Next, I will explore preemption in general terms. I will then discuss the arguments for and against preemption in light of the case law involving medical devices, with a particular emphasis on cases involving Class III devices. Finally, I will draw a conclusion regarding how best to achieve a balance between consumer protection and the regulatory role of governmental agencies.

II. THE FDA’S REGULATION OF MEDICAL DEVICES

A. History of the Regulations Concerning Medical Devices

The statutory definition of a "medical device" is quite broad.4 Section 321(h) of 21 U.S.C. provides:

The term "device" . . . means . . . [that 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 of man or other animals, 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.5

In essence, any item advanced for a medical purpose that does not rely on chemical or metabolic action to reach its desired result is considered to be a medical device.6 Continued advances in the medical field and in technology have led to an increased availability of medical devices, benefiting

6. Id.
both physicians and consumers. In 1990, studies estimated that approximately 5000 medical devices are introduced into the market every year.7 Medical devices comprise an industry worth billions of dollars in annual sales; in 1988, the figure had reached twenty billion by some accounts.8 Furthermore, over 7000 manufacturers make available to the American medical profession approximately 1700 different types of medical devices, which include over 50,000 separate products.9 As a result, many lifesaving devices have become available to the public. On the other hand, these new devices have periodically harmed the public, as they have given rise to injuries due to defects. In the first year alone that the FDA required mandatory reporting, medical devices were linked to approximately 18,000 deaths and illnesses.10 Although this number seems surprisingly high, it has been estimated that less than half of the problems related to medical devices had been reported to device manufacturers before mandatory reporting was implemented.11

While not underestimating the benefits the medical device industry bestows upon the American economy, Congress has striven to protect consumers from harm caused by defective or ineffective medical devices.12 The regulation of medical devices is certainly not an arbitrary concern of the government, since it is imperative that physicians can rely on safe and effective devices for their patients.13 As a result, Congress has enacted numerous statutes regulating the medical device industry. In 1938, the Food, Drug, and Cosmetic Act (FD&C Act) provided the FDA with restricted authority to govern the medical device industry.14 The FDA, an agency within the U.S. Department of Health and Human Services, has as its primary objective "the protection of the public from potential health hazards resulting from adulterated and mislabeled foods, cosmetics, medical devices and drugs."15

12. Id. at 255.
15. An "adulterated" device is one that is characterized by insanitary storage, packaging, or manufacturing conditions. 21 U.S.C. § 351(a) (1994).
16. A device is "misbranded" if its labeling is false or misleading in any way. Id. § 352(a). Additionally, a device is "misbranded" if it does not specify adequate directions for use. Id. § 352(f).
17. Mesner, supra note 10, at 266.
With the introduction of such items as contraceptive devices—in particular, intrauterine devices (IUDs) and cardiac pacemakers—into the marketplace in the 1960s came the need for more extensive regulation. These devices were seen as more dangerous than the majority of previously introduced devices since they "are implanted into consumers' bodies and present an enormous potential risk." The objective of such additional controls was to ensure that these new products would be proven safe and effective before reaching the public. The late 1960s marked the beginning of a decade in which numerous consumer protection laws were enacted. In fact, of forty-seven federal consumer protection laws enacted between 1891 and 1972, only twenty-one were enacted in the first seventy-five years; the remaining twenty-six laws were enacted between the mid-1960s and the mid-1970s. This ten-year period is often referred to as the "consumer decade." It was at the conclusion of this decade that the FDA sought to introduce a more comprehensive, yet not too rigid, legislative scheme for regulating medical devices. In 1976, Congress implemented its new regulatory plan, embodied in the Medical Device Amendments (MDA) of 1976. The MDA of 1976 were then amended by both the Safe Medical Devices Act of 1990 (SDMA) and the MDA of 1992. Additionally, the FDA has implemented various far-reaching federal regulations related to medical devices.

Despite the vast array of regulations whose goal is to protect consumers from injuries related to defects in medical devices, consumers remain susceptible to injuries stemming from defects and dangers of medical devices. The fact that Congress and the FDA have implemented so many

20. Benson et al., supra note 8, at 495.
21. Adler, supra note 19, at 511 n.3.
26. At the hearing of the Subcommittee on Health and the Environment on November 6, 1989, General Accounting Office Comptroller General Charles A. Bowsher declared: "[O]ur work reveals several shortcomings in both the premarket review and postmarket surveillance systems for medical devices and raises serious questions about the
regulations in the hopes of protecting consumers when, in actuality, injuries continue to occur, is of major concern to the government, to the medical profession, and to the public.

B. THE MEDICAL DEVICES AMENDMENTS OF 1976

The heart of the MDA is a regulatory scheme that allows for prospective evaluation. The rationale underlying the proposal for the MDA of 1976 was "the need to overcome deficiencies in the existing Federal Food, Drug, and Cosmetic Act, which allowed the FDA to initiate regulatory action against a hazardous medical device only after it was in commercial use and after it was demonstrated to be misbranded or adulterated."27 Thus, the 1976 amendments broadened the FDA's regulation of consumer and medical products with the hopes of increasing consumer protection and thus furthering the federal objectives of public health and safety.

The three goals of the MDA are to: "(1) assure public protection against unsafe and ineffective devices; (2) ensure that health practitioners can be confident about the medical equipment they use or prescribe for their patients; and (3) provide market protection for pioneers of new medical technologies."28 In other words, the MDA strive to protect innovation and advancement of certain medical devices from severe governmental restrictions29 while concurrently protecting consumers against unsafe and ineffective products.

The MDA are uncommonly prescriptive as they specify to a remarkable degree the different procedures that must be followed in order to market a device.30 The necessary procedures required to market a particular device are determined according to the classification of that device. Each device may belong to one of three classes. The FDA is responsible, with the aid of nongovernmental experts, for classifying devices entering the market into the category that will offer the minimum level of regulation necessary to ensure their safety and effectiveness.31 Although the decision as to classification rests with the FDA, the MDA permit a manufacturer to petition for a device to be reclassified into a less-regulated class.32

Class I devices merely require general controls.33 By the terms of the MDA, the devices in this class are to be subjected only to general controls, provided that (1) such controls are adequate to supply a reasonable

27. Benson et al., supra note 8, at 496.
28. Id.
29. Id.
30. Id. at 496-97.
32. Id. § 360c(d)(1).
33. Benson et al., supra note 8, at 497.
assurance of safety and effectiveness, and that (2) the purpose of the device is not to support or prolong human life or significantly act as an impairment to human health, and does not introduce a potentially unreasonable risk of illness or injury. Class I controls apply to medical devices in all three categories. Examples of controls include pre-market notification, reporting, registration and listing, adulteration, misbranding, and banning. Medical devices that fall into this category include tongue depressors, elastic bandages, ice bags, and bed pans.

Class II includes devices for which safety performance standards may be required because Class I controls are inadequate. A prerequisite for placing devices into this category is that sufficient information exist to establish special controls to provide assurance of the safety and effectiveness of the device. Class II medical devices include bone plates, hearing aids, syringes, resuscitators, and electrocardiograph electrodes.

The most regulated class, Class III, requires pre-market approval because the controls of Class I are inadequate and insufficient information prevents the establishment of a safety performance standard. Pre-market approval acts as an assurance that devices with the greatest potential risk do not enter the market until their safety and effectiveness have been thoroughly demonstrated through both laboratory and clinical testing. Such testing is crucial since a device in this class is “purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or [the device] presents a potential unreasonable risk of illness or injury.” Devices in this class include pacemakers, IUDs, artificial joints, and artificial hearts.

The SDMA of 1990 and the MDA of 1992, enacted to complement the MDA of 1976, prescribe, among other things, more stringent reporting requirements by manufacturers and users for device-related injuries. Furthermore, the 1990 amendment substitutes an assortment of “special controls” for Class II devices which may be prescribed in place of or in addition to the prior “performance standards” approach imposed under

35. Id. § 360c(a)(1)(A).
36. Id.
37. Adler, supra note 19, at 512.
38. Id. at 512-13. Once a performance standard has been established for a type of medical device, any such device that fails to meet that standard will be blocked from entering the marketplace. Id.
40. Id.
41. Adler, supra note 19, at 513.
42. 21 U.S.C. § 360c(a)(1)(C).
43. Benson et al., supra note 8, at 497.
45. Adler, supra note 19, at 513.
46. Mesner, supra note 10, at 270.
the MDA of 1976. Additionally, the SDMA more clearly defines the "substantial compliance" needed before a device is permitted to enter the market through mere notification rather than through a more extensive approval process, and it incorporates "design validation" as an additional "good manufacturing practice" concept.

The MDA of 1992 made revisions primarily in sections 360i and 360l of the original MDA, and include several changes concerning the record and reports of medical devices. For example, in regard to user reports, a device user facility must notify the FDA whenever it "receives or otherwise becomes aware of information that reasonably suggests that a device has or may have caused or contributed to the serious illness of, or serious injury to, a patient of the facility." The 1992 amendment also added a provision requiring a device user facility to report to the FDA whenever it "receives or otherwise becomes aware of . . . other significant adverse device experiences as determined by the Secretary [of the FDA] by regulation to be necessary to be reported."

In regard to post-market surveillance, the MDA of 1992 added a provision requiring that each manufacturer ordered to conduct a surveillance of a device at the discretion of the FDA shall, within thirty days after receiving such notice, submit for approval a protocol for the required surveillance.

C. THE MEDICAL DEVICE REGULATORY PROCESS

The FDA's primary purpose is to exercise enough regulatory control over new products to prevent dangerous products from entering the market without simultaneously hindering technological innovation. As a result, the FDA recognizes only two paths that a medical device can follow in order to meet FDA approval and enter the market: pre-market notification and pre-market application approval. The purpose behind pre-market notification is to decrease the amount of time between the submission and eventual consumer use of a device. Thus, the FDA allows pre-market notification to suffice in order for a "new" device to be marketed if it is characterized by a "substantial equivalence" to a similar device that was approved before 1976. The term "substantial equiva-
ence" involves some amount of ambiguity. David Kessler, the present head of the FDA, has stated that Congress apparently intended for the term to apply to products that have undergone changes that do not affect their safety and effectiveness.\textsuperscript{58} The consequence of allowing a manufacturer to use pre-market notification is that the manufacturer's new "look alike" product will not be more highly regulated than a near-identical device that was manufactured before 1976.\textsuperscript{59} Under this process, a manufacturer of a substantially equivalent device must notify the FDA of its desire to market the device.\textsuperscript{60} The FDA is to deny or approve the petition within ninety days from the date the Secretary receives the recommendation of a panel as to the petition, but not later than 210 days after the manufacturer has filed the petition.\textsuperscript{61} The pre-market notification concept is also referred to as "substantial equivalence."\textsuperscript{62}

The second process by which a device can be approved is pre-market approval. As compared to pre-market notification, it offers more protection to consumers since it involves more extensive regulation. As a result, it requires more time, effort and money on the part of the manufacturer in order for the product to meet FDA standards. Pre-market approval requires that new medical products without analogous predecessors be permitted to enter the market only after their clinical safety and effectiveness have been proved.\textsuperscript{63} Safety and effectiveness are evaluated in a specific manner:

The safety and effectiveness of a device are to be determined with respect to the persons for whose use the device 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.\textsuperscript{64}

The ratio of probable health benefits against probable risks of harm must be satisfactory, but evidence that the device will never cause injury or will be effective in every situation is not required.\textsuperscript{65} Under the pre-market approval requirements, a manufacturer must submit a detailed application to the FDA, including information pertaining to product specifications, intended use, manufacturing methods, and proposed labeling.\textsuperscript{66} The FDA refers each application to a panel of qualified experts that prepares a report and recommendation.\textsuperscript{67} The FDA has six months to either accept or reject the application.\textsuperscript{68} However, even though the law

\begin{itemize}
\item \textsuperscript{58} Kessler et al., \textit{supra} note 4, at 359-60.
\item \textsuperscript{59} \textit{Id.} at 359; 21 U.S.C. § 360c(f)(2)(B).
\item \textsuperscript{60} Kessler, et al., \textit{supra} note 4, at 359; 21 U.S.C. § 360c(f)(2)(A).
\item \textsuperscript{61} 21 U.S.C. § 360c(f)(2)(C).
\item \textsuperscript{62} See Adler, \textit{supra} note 19, at 513.
\item \textsuperscript{63} Benson et al., \textit{supra} note 8, at 500.
\item \textsuperscript{64} 21 U.S.C. § 360c(a)(2).
\item \textsuperscript{66} 21 U.S.C. § 360e(c)(1) (1994).
\item \textsuperscript{67} \textit{Id.} § 360e(c)(2).
\item \textsuperscript{68} \textit{Id.} § 360e(d)(1)(A).
\end{itemize}
sets the deadline at 180 days, the FDA generally takes approximately one year to approve the application. In particular, poorly prepared applications can lead to delays in the application approval process. If the device passes the pre-market approval process, the manufacturer is required to file a supplement to its application before making any alterations affecting the safety and effectiveness of the device. In addition, the manufacturer has a never-ending duty to discern whether the product, as well as its labeling, continue to be both safe and effective for consumer use.

D. EXPERIMENTAL MEDICAL DEVICES UNDER THE MEDICAL DEVICES AMENDMENTS

In certain instances, manufacturers can evade going through either pre-market notification or pre-market approval and still make their medical devices available to the public. The MDA contain provisions for experimental or investigational medical devices. Investigational devices are exempted from some of the more stringent requirements related to safety and effectiveness mandated by the MDA. The objective behind this exemption 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 in their pursuit of that purpose." Thus, the investigational device exemption helps foster innovation consistent with the public's health and safety. The 1976 Senate Report relating to investigational medical devices stated:

The Committee recognizes the necessity to encourage scientific investigation in the medical devices field and has attempted to provide optimum freedom for individual scientific investigators in their pursuit of that objective. The Committee has therefore provided an exemption to qualified scientific investigators from the requirements of this Section during the time of the investigational use of devices in order that they may collect sufficient data to establish that the device should be on the market.

Consequently, an investigational medical device is not required to undergo the stringent pre-market approval process generally applicable to medical devices. However, an investigational device does have to meet certain requirements before it is permitted to enter the market. Manufacturers must submit an application to the FDA describing the device and pronouncing a plan for examining the device's use on human subjects.

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69. Kessler et al., supra note 4, at 359 (citing CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FDA, PMA CRITICISMS TASK FORCE REPORT 1985).
70. Id.
72. Id.
73. See generally 21 U.S.C. § 360j(g).
74. Id. § 360j(g)(1).
The FDA can, of course, either accept or reject the application. Furthermore, once a product obtains FDA approval, the FDA continues to monitor the device's clinical investigation in order to ensure that its presence in the market was well founded.77

III. PREEMPTION

A. Overview

As previously discussed, the FDA maintains strong control over the introduction of new medical devices into the market. In particular, the pre-market approval process provides for the regulatory control of medical devices so that a device's safety and effectiveness can be reasonably assured before it enters the market. Furthermore, the post-approval regulation ensures that the FDA continues to receive information relating to devices after they become available to the public. Manufacturers of devices rely upon such controls to immunize them from tort liability lawsuits. In fact, as previously mentioned, several recent cases have granted manufacturers of Class III medical devices immunity from essentially all product liability claims based on alleged defects in the design or labeling of the devices.78

The courts in both King and Stamps held that the plaintiff's product liability claims were based on state law requirements that were "different from" or "in addition to" those requirements promulgated by the FDA. Allowing the claims would require the manufacturer to redesign the product, remove it from the market, or be subject to strict liability. The courts held that such consequences were not permitted due to the existence of the MDA. The rationale for these two circuit court decisions was based on preemption, which will now be addressed.

B. Preemption Generally

Preemption is defined as a "[d]octrine adopted by [the] U.S. Supreme Court holding that certain matters are of such a national, as opposed to local, character that federal laws preempt or take precedence over state laws. As such, a state may not pass a law inconsistent with the federal law."79 Put another way, one author defines preemption as "the authority granted to the Congress by the U.S. Constitution to assume partial or total responsibility for a governmental function, thereby delimiting the

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77. See, e.g., id. § 813.66(a)(5).
roles of the states and their political subdivisions." Federal preemption is rooted in the United States Constitution, specifically the Supremacy Clause. This clause establishes the framework for the balance of powers between the federal government and the state governments. The Supremacy Clause provides:

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 Law of any State to the Contrary notwithstanding.

Thus, the preemption doctrine is based on the language of the Constitution which states that the laws of the federal government are "the supreme law of the land," so that federal laws are given priority over state or local law. The Supreme Court has stated that the purpose for the enactment of the Supremacy Clause was to "avoid the introduction of disparities, confusions, and conflicts which would follow if the Government's general authority were subject to local controls." In short, preemption requires that federal law take priority over state and local law.

The underlying rationale of the Supremacy Clause is that a unified national government is contingent upon supreme federal power. In other words, "[b]ecause Congress alone of the three federal branches represents the states as states, the Framers gave it the authority to balance, by choosing whether to preempt state laws with federal legislation, the competing interests of federal power and states' rights." The tension between federalism and congressional supremacy becomes visible when analyzing the conflicting interests of Congress and the states in regards to health and safety legislation.

On one side are the state's police powers, signifying state supremacy, that embody the state's goal of protecting the safety and health of its citizens. Early in this century, the Supreme Court held that "the police power of a State embraces regulations designed to promote the public convenience or the general prosperity, as well as regulations designed to promote the public health, the public morals or the public safety." On the other side is Congress' interest in protecting public health and safety,

81. U.S. CONST. art. VI, cl. 2.
85. Id. at 1432-33 (footnotes omitted).
86. Id. at 1433.
87. Id.
especially where it considers state laws to be inadequate. This concern led to the establishment of federal standards for medical devices. Of course, the courts presume that Congress does not endeavor to supersede police powers at the state level unless it is the "clear and manifest purpose of Congress" to do so. In Hines v. Davidowitz, the Supreme Court stated its complicated task in determining whether claims are preempted. The Court said: "Our primary function is to determine whether, under the circumstances of this particular case, [the state] law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." The purposes and objectives of Congress to which the Court refers are synonymous with those presently at issue in this discussion, namely, public health and safety.

Both federal and state law encompass broad definitions. The general view is that federal preemption will not be lightly imposed upon the states. Federal law encompasses not only the United States Constitution, treaties, and statutes, but also federal regulations as established by federal agencies. The Supreme Court discussed the preemptive power of federal agencies in Louisiana Public Service Commission v. Federal Communications Commission. In that case, the Court held that preemption may result not only from congressional action, but also from federal agencies acting within the scope of their congressionally delegated authority. For purposes of the preemption doctrine, state law includes not only state constitutions, statutes and regulations, but also state common-law tort actions.

In order for the preemption doctrine to be applicable, certain elements must be present. The primary factor in determining whether federal preemption exists involves a determination by the court to discern Congressional intent to preempt. In fact, the Supreme Court has declined to find preemption when Congressional intent to supersede state law is not "clear and manifest."

There are two ways in which a court may determine Congressional intent. The more obvious of the two occurs when the wording in a regula-

89. Foote, supra note 84, at 1433.
90. See supra part II.A.
92. 312 U.S. 52, 67 (1941).
97. Id.
98. Landen, supra note 94, at 86.
100. Id. (assuming historic police powers of the states are not superseded by federal laws unless it is the clear and manifest purpose of Congress).
tion expressly provides an intent to preempt state law. Thus, Congress can preempt state law by specifically stating its intent to do so. The second way occurs when a court finds an implied intention to preempt based on any number of factors, such as the comprehensive nature of the regulations, a dominant federal interest in the particular field, or a direct conflict between state and federal law.

C. PREEMPTION AS RELATING TO MEDICAL DEVICES

When Congress significantly expanded federal regulatory control of medical devices by the MDA in 1976, it expressly preempted competing state requirements. Thus, this paper focuses on express preemption rather than implied preemption. The pertinent part of the MDA relating to preemption is section 360k(a) which provides:

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 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.

Some potential relief, however, is afforded to the states. The statute permits states to petition for an exemption in certain circumstances. The exemption requirements are set forth in section 360k(b):

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if —

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement —

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

The exemption applies to both state and local statutes and regulations,
and the FDA regulations provide specific examples of state and local medical device provisions not preempted by the FDA for twenty-one states. For example, the FDA has decided that a Texas provision regarding the duty of persons engaged in the fitting and dispensing of hearing instruments is not preempted by the MDA.

Congress left no question that its intent was for the MDA to have a broad preemptive effect. One reason offered for this broad language is that interstate commerce must not be unduly burdened. An additional justification for the wide scope of the preemption provisions is that Congress strongly suspected that potential state or local requirements pertaining to medical devices, in addition to existing federal controls, would cause an undue burden that could severely interfere with technological innovations. Thus, the preemption of additional state requirements was fundamental for Congress to achieve its objective of fostering research and development, which is tied to its goal of protecting the health and safety of the people. This desire not to restrain growth in the medical device industry relates back to Congress' intent to protect the public from dangerous and ineffective devices with the minimum amount of control by the federal branch of government.

The applicability of preemption is also grounded in the FDA regulations. Section 808.1(b) states:

[The MDA] prescribes a general rule that . . . no State or political subdivision . . . may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.

Thus, when determining whether preemption is applicable, three elements must be present. First, the state must "establish or continue in effect with respect to a device intended for human use any requirement." Next, the requirement must be "different from, or in addition to, any requirement applicable" to a device under the MDA. Finally, the state requirement must pertain "to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act."

108. Id. § 808.53-.98.
110. 21 C.F.R. 808.93 (1994).
112. Id. (citing Massachusetts v. Hayes, 691 F.2d 57, 60-61 (1st Cir. 1982)). The intent of the MDA's express preemption provision was "to prevent an undue burden on interstate commerce through the proliferation of varying state requirements." Id.
113. Noah, supra note 111, at 185.
114. 21 C.F.R. § 808.1(b) (1994).
115. 21 U.S.C. § 360(k).
116. Id.
device” under the MDA.\textsuperscript{117}

IV. ANALYSIS OF PREEMPTION IN LIGHT OF CASE LAW

A. OVERVIEW

It is up to the courts to determine how the preemption doctrine should be interpreted. In suits involving FDA products, the courts must balance the interests of the federal and state governments, keeping in mind the profound effects that their decisions can have on manufacturers and consumers. Furthermore, it is the role of the courts to attempt to determine congressional intent.

One area of tension concerning the FDA regulations is that some view the standards set forth by the FDA to be minimum standards, while others argue that the FDA’s regulation of the medical device industry is so comprehensive as to justify preemption of state law.\textsuperscript{118} These competing views form the backbone of many cases involving medical devices and must be analyzed completely to determine whether the Framers of the Constitution actually intended for a regulatory agency, such as the FDA, to completely preempt state law claims in a particular area such as medical devices.

As previously discussed, the MDA expressly prohibit states and localities from imposing on manufacturers requirements that differ from or are in addition to those promulgated by federal law.\textsuperscript{119} However, ambiguity exists as to whether the federal statutes applicable to product safety should be construed to preempt state tort-law damage claims against manufacturers whose devices meet the federal standards.\textsuperscript{120} One author has stated that “[d]espite the numerous product preemption cases decided over the past five years, federal courts remain hopelessly divided on this issue.”\textsuperscript{121} Generally, however, the courts have opined that section 360k prohibits state damage claims against manufacturers of medical devices. Nevertheless, just last year, the Ninth Circuit departed from this trend.\textsuperscript{122}

The cases that focus on the MDA’s preemptive effect show that, if the FDA regulates and approves a certain aspect of a device, such as labeling, design, or manufacture, “tort claims based on the inadequacy of that aspect of the device are preempted when the claims would pose a requirement that is different from, or in addition to, any requirement imposed on

\textsuperscript{117} Id.
\textsuperscript{119} See supra text accompanying note 104.
\textsuperscript{121} Id.
\textsuperscript{122} See Kennedy v. Collagen Corp., 67 F.3d 1453, 1453 (9th Cir. 1995) (holding that the “MDA does not preempt claims based on state common law of general applicability, including tort law damages claims”).
the device under the MDA.\textsuperscript{123} The next step is to examine the arguments favoring and opposing preemption in light of case law on the subject.

Litigation arising out of federal preemption issues specifically pertaining to the MDA and Class III medical devices has been inextensive.\textsuperscript{124} In fact, only a small number of cases addressing this specific subject have reached the federal court of appeals level. \textit{King, Stamps,} and \textit{Slater v. Optical Radiation Corp.}\textsuperscript{125} are three of the earliest such cases to have reached the circuit courts. These three opinions are consistent in their rationale and their outcomes.\textsuperscript{126}

The general fact pattern of \textit{King} and \textit{Stamps} has been previously laid out.\textsuperscript{127} In the earlier of the two scenarios, Jane King sought Zyderm treatment in 1987. Zyderm is a cosmetic medical device, consisting of the injection of processed cow tissue, that is used to correct wrinkles and other skin deformities. Following the ordinary guidelines, Ms. King's physician administered a small dose of Zyderm before going forward with the entire treatment. A short time after the administration of the test dose, Ms. King complained of muscle and joint pains, in addition to other symptoms. She was then diagnosed with DM/PM, an autoimmune disease in which the immune system attacks skin and muscle tissue as if it were a foreign substance.

Approximately one year after Ms. King was injected with Zyderm, Jennifer Stamps, in March and April of 1988, was injected with two devices: Zyderm and Zyplast. Zyplast is a similar product to Zyderm; both contain processed bovine collagen and are intended for use as an anti-wrinkle treatment. Like Ms. King, Ms. Stamps began suffering from muscle and joint pains shortly after receiving the treatment and was subsequently diagnosed with DM/PM.

\textit{Slater} involves an action based on another Class III medical device, intraocular lenses. However, the device in \textit{Slater} is unique among ordinary Class III devices in that it is an investigational device. The significance of a device being classified as investigational is set forth in a subsequent section.\textsuperscript{128} In light of these three cases in particular, I will now address arguments in favor of and in opposition to preemption of claims relating to medical devices.

\begin{itemize}
\item \textsuperscript{124} Cynthia B. Stewart, Case Note, \textit{Medical Device Litigation: Federal Preemption of State Tort Claims: King v. Collagen Corp., 2 J. PHARMACY \& L.} 357, 365-66 (1994) (citing \textit{Stamps,} 984 F.2d at 1423 n.7).
\item \textsuperscript{125} 961 F.2d 1330 (7th Cir.), \textit{cert. denied}, 113 S. Ct. 327 (1992).
\item \textsuperscript{126} Stewart, \textit{supra} note 124, at 366.
\item \textsuperscript{127} \textit{See} discussion \textit{supra} Part I.
\item \textsuperscript{128} \textit{See infra} text accompanying notes 143-55.
\end{itemize}
B. \textbf{Arguments in Favor of Preemption of Claims Relating to Medical Devices}

1. \textbf{Federal Objectives Cannot Be Undermined}

Allowing claims based on state law as relating to a defect in a medical device could undermine the federal regulatory scheme and pose a threat to the accomplishment of federal objectives. The argument is that "[i]n view of the comprehensiveness and rigor of the federal scheme, courts should defer to the specific scientific and policy judgments made by the FDA."\textsuperscript{129} If courts do not defer to the FDA, the result is that both the states and the courts have no alternative but to second-guess the FDA.\textsuperscript{130}

In the \textit{Stamps} case,\textsuperscript{131} the court discussed the fact that the pre-market approval process allows the FDA to evaluate "whether a proposed product provides 'reasonable assurance of its safety and effectiveness.'"\textsuperscript{132} Thus, the focus of the federal objective is to allow products that have been determined to be safe and effective to enter the marketplace and be used by consumers. Zyderm, the collagen product used by Ms. Stamps, had met the stringent FDA standards, so that the FDA considered the product to be safe and effective for consumer use. The court, therefore, dismissed the plaintiff's claims based on defective design, inadequate warnings, and failure to warn, because these claims were preempted by federal law. If the court had permitted such actions, the federal scheme would have indeed been undermined, and the credibility of the FDA would certainly have been questioned.

The opinion in \textit{King} likewise addressed the federal government's desire to protect the public at the federal level.\textsuperscript{133} Judge Aldrich, in his concurring opinion, wrote, "[s]surely, where the FDA was authorized to render the expert decision on Collagen's use and labeling, it, and not some jury or judge, is best suited to determine the factual issues and what their effect would have been on its original conclusions."\textsuperscript{134} This argument thus addresses the proposition that the FDA, through its extensive research pertaining to medical devices and the rigid requirements that it imposes on manufacturers, can best achieve what is considered to be a federal objective rather than judges or juries at the state level.

2. \textbf{Need for Development and Marketing of New Products}

Permitting state claims against manufacturers who have complied with FDA standards could certainly have a serious effect on their incentive to

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\textsuperscript{131} For a discussion of the facts in \textit{Stamps}, see discussion supra part IV.A.
\textsuperscript{132} \textit{Stamps}, 984 F.2d at 1419 (citing 21 U.S.C. § 360c(a)(1)(C)).
\textsuperscript{133} For a discussion of the facts in \textit{King}, see discussion supra part IV.A.
\textsuperscript{134} \textit{King}, 983 F.2d at 1140.
\end{flushright}
MEDICAL DEVICES

develop and market new products. If manufacturers are confident as to a device's safety and effectiveness after it passes the FDA pre-market approval requirements, but nevertheless are not immune to state claims, they will be reluctant to introduce new devices.

In Stamps, the court determined that the manufacturer of the collagen products had followed the proper pre-market approval requirements. In other words, Collagen Corporation had submitted a detailed application to the FDA, including information pertaining to product specifications, intended use, manufacturing methods, and proposed labeling, and the FDA had approved the application. Collagen Corporation thus had every reason to believe that its product was ready for consumer use in a safe and effective manner. If the manufacturer had felt that it was nevertheless susceptible to state tort liability, it very well may have decided that the expected profits of introducing the device would not exceed potential liability damages and that it would not be in the corporation's best interest to market the product.

In King, the court identified health protection as a federal objective. Both parties agreed with this contention; they disagreed, however, as to what exactly such an objective encompasses. King argued that the MDA are aimed at the consumer by prohibiting harmful products from entering the market and assuring that labels contain adequate warnings. On the other hand, Collagen Corporation stated that the statute's purpose also includes benefiting the consumer public by protecting regulated manufacturers from inconsistent state regulation, including lawsuits.

The concurring opinion in King expands the defendant's reasoning by declaring that, if legal risks are too high, potentially beneficial medical devices "may be left in the laboratory, to the public's loss." The concur-rence noted that one of the primary objectives of the MDA was to encourage the research and development of new products and to facilitate the marketing of new and improved devices without delay. Thus, the focus of this argument was on the benefits to the public due to improved technology and new scientific evidence. As a result, the concurring judges' cost-benefit analysis led to their declaration that "[p]erfection is impossible and a few individuals may be denied full protection at the cost of benefiting the rest."

In Slater, the plaintiff brought an action against the manufacturer of intraocular lenses, seeking recovery under state law in negligence, strict liability, and breach of implied warranty for injury to his eye allegedly

135. See Landen, supra note 94, at 118 (noting that "[t]he spectre of liability—despite FDA approval—chills the manufacturer's incentive to develop new products").
136. Stamps, 984 F.2d at 1419.
137. King, 983 F.2d at 1138 (concurs- ing opinion).
138. Id. at 1137.
139. Id. at 1137-38.
140. Id. at 1138.
141. Id.
142. King, 983 F.2d at 1138 (concurs- ing opinion).
caused by lens implantation and removal. Intraocular lenses are specifically classified as Class III medical devices. However, the regulatory controls for intraocular lenses diverge from other Class III devices due to the Investigational Device Exemption Regulation, which "expressly preempts state law claims based on safety or effectiveness of a particular intraocular lens where that lens has been granted an investigational device exemption by the FDA." Specifically, federal regulations provide that:

(a) An intraocular lens is . . . synonymous with "investigational device" lens or lenses.

(b) "Investigational device" means a device that is used in an investigational study involving human subjects, where the study is for the purpose of determining if the device is safe or effective.

Thus, like the collagen product in King and Stamps, the device at issue in Slater was a Class III device. However, intraocular lenses differ from the collagen products in that the lenses are experimental devices. The Seventh Circuit determined that the plaintiff's state law claims failed as they were specifically preempted by federal law. More specifically, the district court in Slater stated that "[t]he imposition of state tort requirements in this case would clearly be 'different from, or in addition to' both the terms of the FDCA [Food, Drug, and Cosmetic Act] and the requirements of the IDE [Investigational Device Exemption] regulations promulgated by the FDA for safety or effectiveness." It is significant in this case that Albert Slater decided for himself to undergo an experimental procedure in which his natural lens was replaced with an intraocular lens implant. He chose to undergo this procedure in an attempt to prevent potential total blindness. Prior to the procedure, Mr. Slater signed a consent form, signifying that he was aware that he was taking part in a clinical operation. Unfortunately, the damage resulting to Mr. Slater's eye was greater than what he would have suffered had he chosen not to undergo the procedure.

To be able to use an experimental device under FDA control, an individual must consent to using the device in its investigational stage. Thus, it is an individual's decision to participate in a clinical investigation program involving an experimental medical device. The individual is made aware of the possibility of injury. The Slater court stated that plaintiffs have no cause of action against a manufacturer of an experimental device arising out of the safety and effectiveness of the device, so that

145. Slater, 756 F. Supp. at 373 (emphasis added).
146. 21 C.F.R. § 813.3(a),(b) (1995).
147. Slater, 961 F.2d at 1333.
state tort remedies are not available to them. Furthermore, the court continued to state that no federal damages remedy exists, either.

The reasoning behind the Slater decision lies in the argument that "[i]t seems fair that if all necessary FDA regulations are met, manufacturers should not be held liable for claims covered by the FDA regulations." This element of certainty is essential for the advancement of new and beneficial medical devices. If manufacturers are not insulated from state law claims, they might determine, at the public's expense, that it is not effective from a cost-benefit standpoint to market new devices. Thus, fear of tort liability may have the severe effect of causing manufacturers to remove existing products from the market. The public is then deprived of products which are FDA-approved, but which are not available because the manufacturers of such products are reluctant to open the door to the slight chance that litigation involving the device might arise.

3. Federal Standards Are Not Mere Minimum Standards

Advocates favoring preemption often argue that FDA standards should not be considered minimum standards that need to be complemented by state laws. FDA standards are the result of extensive research and testing. Thus, the argument continues, courts should not allow juries to undermine the FDA's judgment as to scientific evidence, since "[h]olding a manufacturer liable after it has complied with FDA standards effectively second-guesses the FDA's judgment." Since the FDA is considered the expert on medical devices, the states and courts should defer to the FDA's insight on this subject.

In Stamps, the court held that all three of the plaintiff's causes of action were preempted by the MDA. Stamps's first two causes of action were based on inadequate labeling and failure to warn. The court stated:

The Class III regulatory structure . . . involves the FDA in considerable oversight regarding proposed package labeling of a device. Nor can Stamps's third cause of action . . . , based upon the defective design and manufacture of Collagen's products, survive preemption, as the Class III PMA [pre-market approval] process includes FDA scru-

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150. Slater, 961 F.2d at 1333-34.
151. Id.
152. Stewart, supra note 124, at 368.
153. Id. at 368-69.
154. See Peter W. Huber, Liability: The Legal Revolution and Its Consequences 4 (1988). American manufacturers spend over $80 billion annually in tort liability and insurance costs, the effect being that new and possibly safer products are prevented from being marketed. Id.
155. Landen, supra note 94, at 119.
156. Id. at 112.
157. Jortberg, supra note 130, at 985.
158. Id.; see also Premo Pharmaceutical Labs., Inc. v. United States, 629 F.2d 795, 804 (2d Cir. 1980) (offering the opinion that the FDA, because of its expertise, is generally in a stronger position to make decisions regarding medical devices than the courts).
159. 984 F.2d at 1425.
tiny and approval of these particular aspects of a device.\textsuperscript{160} The court continued by addressing Stamps's argument that "the MDA forms only the floor of regulation; the states are free to construct a regulatory ceiling."\textsuperscript{161} The court agreed with Stamps that, under the Class III regulatory structure, Collagen Corporation could have strengthened its warning labels without first gaining permission from the FDA.\textsuperscript{162} In fact, the FDA's "Conditions of Approval" that it set out with respect to Zyderm provide that:

Changes in labeling, manufacturing, sterilization, packaging, or performance of design specification which enhance safety of the device or safety in the use of the device may be placed into effect by the sponsor prior to the receipt of a written FDA approval of the supplemental PMA [pre-market approval]. . . . Specific examples of changes permitted are: (1) addition of warnings, contraindications, or side effects . . . .\textsuperscript{163}

The court disagreed with the plaintiff's conclusion from the above language in the "Conditions of Approval" that the absence of a direct conflict between the federal and state provisions mandated a finding of no preemption. Instead, the court drew the opposite conclusion and reiterated the presence of the language in the MDA expressly preempting "any requirement" as applicable to medical devices.\textsuperscript{164}

Likewise, in \textit{King}, the court examined the argument that the FDA requirements are merely the minimum, rather than the maximum, protection made available to the consumer. The court examined the MDA's provisions detailing what an application for pre-market approval should contain.\textsuperscript{165} In particular, the court looked at the requirement that "specimens of the labeling proposed to be used for such device" be contained in an application for a medical device.\textsuperscript{166} The concurring judges noted that the MDA as a whole provide "maximum protection and express preemption, leaving no need to seek implications."\textsuperscript{167} Thus, the six claims made by the plaintiff in \textit{King} relating to a failure to warn were preempted, given the 21 U.S.C. § 360e(c)(1)(F) requirement that the FDA must review the proposed labels for the product.

4. Need for Uniformity

There are dominant and superseding federal interests in establishing uniformity in the design and manufacture of medical products. This need for uniformity was addressed by the United States District Court for the
Eastern District of Texas in *Hurley v. Lederle Laboratories*. The Fifth Circuit ultimately reversed the decision; however, the policy reasons for uniformity are illustrated nevertheless. Manufacturers in all states should be forced to adhere to the same standards when marketing a new medical device. In addition, manufacturers in all states should be bound by the same laws; it seems unjust for manufacturers of similar products to be held to conflicting state tort laws and regulations.

C. ARGUMENTS IN OPPOSITION TO PREEMPTION OF CLAIMS RELATING TO MEDICAL DEVICES

1. *Congress' Intent Is Not Completely Clear*

Opponents of the theory that preemption bars state tort-law claims pertaining to medical devices point out that the legislative history of the MDA does not state whether Congress intended to preempt such claims. Opponents advocate that “[t]his legislative silence is strong evidence that Congress did not intend section 360k(a) to preempt state tort law.” Nevertheless, proponents of preemption point to section 360k(a) of the MDA, which expressly provides for the preemption of state requirements. Proponents of preemption stress that “the FDA has specifically interpreted this section to preempt state tort law as well as legislative and administrative regulations.” Furthermore, although one might argue that section 360k(a) does not provide the FDA with the power to preempt state tort law, the Supreme Court’s holding in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.* mandates that courts defer to an agency’s interpretation if the interpretation is based on a permissible construction of the statute in question. Therefore, the argument continues, “because the FDA’s interpretation of section 360k(a) is apparently permissible, the courts should defer to the FDA’s judgment and rule that tort claims against manufacturers who comply with the requirements of the MDA are preempted.”

2. *Promotion of Public Safety*

Certainly a much stronger, if not the strongest, argument in opposition to preemption is that holding manufacturers liable for state tort claims will encourage them to develop products that are safer for consumer

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170. *Id.*
171. *Id.* at 283; see 21 C.F.R. § 808.1(b) (1994).
173. *Id.* at 842-45.
Opponents of preemption argue that “[t]he federal government’s interest in the protection of the public would be badly served by preem- pting the state’s power to protect its citizens.”176 If the manufacturer knows that preemption will protect him as long as he meets FDA standards, he may very well stop there. On the other hand, if faced with the risk of potential liability claims, the manufacturer may be more inclined to maximize safety and effectiveness to an even higher degree. Furthermore, such a risk imposed on the manufacturer would most likely induce that manufacturer to continue trying to improve the product after it has entered the marketplace. But manufacturers not faced with such a risk would feel protected against tort claims and could find it more cost-effective to stop trying to improve the product. The manufacturer relying on preemption may attempt to continue maximizing a product’s safety after its entry into the market only if it would be profitable for him to do so.177

The argument that liability provides an incentive for manufacturers to produce safer products can be applied to the King and Stamps cases. Opponents of the preemption doctrine would argue that fear of tort liability may have caused Collagen Corporation to have used more caution before marketing Zyderm. Obviously, the product was far from completely safe for consumer use. Perhaps more research and testing would have led to the conclusion that the product was indeed capable of causing the autoimmune disease.

Furthermore, Collagen Corporation, if faced with liability arising out of state law claims, may have withdrawn the product once King, the earlier of the two cases, surfaced. It is unfortunate that Collagen Corporation was not threatened more seriously by King’s claim; if it had been, the similar scenario in Stamps may have been avoided.

As discussed previously, advocates favoring preemption stress that preemption is essential to the development and marketing of new products.178 However, the converse of this argument is not necessarily true. By not preempting state tort claims, the development and marketing of new products would not be hindered. In fact, a lack of preemption and the introduction of new products could coexist. The FDA provides protection to manufacturers who pioneer devices that pose a certain amount of risk due to the need for more testing by classifying such devices as experimental or investigatory devices.179 Such devices fall outside of the general category of medical devices because they are presented to consumers as experimental, and a consumer must provide explicit consent

175. Jortberg, supra note 130, at 982; see Graham v. Wyeth Labs., 666 F. Supp. 1483, 1493 (D. Kan. 1987) (state tort action viewed as actually enhancing the national goal of optimum vaccine safety); MacGillivray v. Lederle Labs., 667 F. Supp. 743, 745 (D.N.M. 1987) (in rejecting a drug manufacturer’s preemption defense, the court reasoned that the objective of the FDA regulations is to promote distribution of safe and effective pharmaceutical products to the public).
176. Westerfield, supra note 118, at 283.
177. See Jortberg, supra note 130, at 982.
178. See discussion infra part IV.B.2.
that he understands the risk involved with such a product before it may be used.\textsuperscript{180} An example of a plaintiff's claim being preempted because of a device's experimental status is illustrated in \textit{Slater}. In \textit{Slater}, the device, an intraocular lens, was an experimental product, and Mr. Slater signed a consent form indicating that he understood the device to be in the experimental stages and that its safety and effectiveness were not thoroughly proven.

Devices labeled as experimental can be used by consumers only with their consent and understanding of the limitations of the product; thus, the risk of using such a product falls on the consumer rather than on the manufacturer. If courts were to decide that preemption is not applicable to state law claims based on defective medical devices, manufacturers would still be inclined to introduce new devices to the public since they could offer the devices as experimental until they gain assurance that the devices are indeed safe and effective. In this way, manufacturers would not be inclined to deprive the public of new technologies just so that they could protect themselves from tort liability.

3. \textit{Spreading the Loss}

An additional argument that state tort claims should not be preempted involves spreading the loss caused by defective products. This argument stresses that "[i]mposing liability on manufacturers also allows the risks of products to be shifted from the injured plaintiff to everyone who benefits from the product."\textsuperscript{181} The argument may stem from the rationale for strict product liability that loss-spreading internalizes accident expenses by assimilating them into the price of the product, so that potential liability is spread among all who consume the product.\textsuperscript{182}

Thus, loss-spreading permits an injured consumer to divert the expenses incurred as a result of the injury onto the entire consuming public.\textsuperscript{183} This is "justified in part by the fact that future consumers benefit from information gathered during the period prior to their own use of the product."\textsuperscript{184} This justification is easily understood in situations involving experimental medical devices, such as in \textit{Slater}. While a product is in its initial experimental stage, consumers can be compared to "guinea pigs."\textsuperscript{185} Assuming that the product eventually passes the pre-market approval process, consumers in the future will enjoy a product that has passed the experimental stage and will thus benefit from the knowledge gained from use of the product during its experimental period.\textsuperscript{186}

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\footnotetext{180} See \textit{id.} § 360(g)(3)(D); 21 C.F.R. § 812.1.
\footnotetext{181} Jortberg, \textit{supra} note 130, at 999.
\footnotetext{183} Jortberg, \textit{supra} note 130, at 983.
\footnotetext{184} \textit{id.}
\footnotetext{186} Jortberg, \textit{supra} note 130, at 999.
\end{footnotes}
argument is that it is only fair to pass compensation costs onto future consumers. Finally, holding the manufacturer liable for state tort claims is a process by which this cost can be passed to the consumer public, since the cost of injuries can be figured into the price of the product.

4. Injured Plaintiffs Need a Remedy

A final argument is that preemption of state law claims involving defective medical devices leaves injured plaintiffs without a remedy. In Abbott v. American Cyanamid Co., the Fourth Circuit held that a strong presumption exists against preempting remedies, such as tort recoveries, when federal regulation does not provide an alternative remedy. This lack of recourse, however, did not prevent the courts in King and Stamps from holding that the state tort claims were preempted.

In Stamps, the plaintiff urged the court to allow her state tort law claims to stand since no federal remedy existed. In other words, Stamps argued that, if her claim was preempted by federal law, her claim in state court would be dismissed. She would not have a valid claim in federal court either because the manufacturer had complied with federal laws regarding its medical device. Stamps cited Silkwood v. Kerr-McGee Corp. for the proposition that a strong presumption exists against preemption of state law remedies when federal remedies are absent. But the Stamps court held that this presumption “is more appropriately addressed in the context of implied preemption.” Thus, the presumption discussed in Silkwood was not applicable in Stamps or in any other case relating to a medical device, since the MDA expressly preempt state law claims. The Stamps court’s conclusion on this issue was that “where Congress has expressly preempted state common law damages actions, as in . . . the MDA, its failure to provide a federal remedy will not defeat its intent to preempt state law.” The court was merely interpreting Congress’ intent as to whether state law was preempted. Concluding that state law was indeed meant to be preempted in this situation, the court did not attempt to provide an answer, if it deemed one necessary, for

187. Id.
188. Pratt & Parnon, supra note 185, at 537-38.
189. The MDA does provide remedies for plaintiffs harmed by medical devices that the FDA proves to be reasonably dangerous. 21 U.S.C. § 360h (1994). However, plaintiffs are limited to recovering costs only for the device’s repair, replacement, or refund price. Id. Conspicuously absent from the text of the MDA is the mention of any remedies meant to compensate plaintiffs for their injuries, such as pain and suffering, and additional medical care. Kronenberg, supra note 78, at 584.
191. Id. at 1112.
192. Stamps, 984 F.2d at 1425.
193. Id.
195. Stamps, 984 F.2d at 1425.
196. Id.
197. Id.
plaintiffs who contend that they are left remediless when their state tort claims are preempted by the MDA. The Slater court alluded that there are remedies other than legal ones, although it did not provide any examples. The court stated, "It would be a mistake to conclude that preemption in these circumstances leaves the consuming public remediless, at least if we have concern for economic substance rather than legal formality and do not suppose that the only 'remedies' (preventives, protections, correctives) are those that the law provides."

One criticism of preemption of state law claims relating to medical devices is that injured plaintiffs have no remedy available to them since they are denied recourse in state courts and no federal remedy exists. To injured plaintiffs such as the women in King and Stamps, this lack of any remedy whatsoever seems extremely unjust.

5. Flaws in the Medical Devices Amendments

Finally, opponents of preemption in medical devices cases point to flaws in the MDA. The basis of this argument is that the preemption doctrine should not be invoked in this line of cases because the MDA are far from perfect in achieving the federal objective of public health and safety. The MDA have been criticized for serious shortcomings. One commentator stated that, "[d]ue to the overwhelming complexity of the classification scheme, as well as inertia on the part of the FDA, the MDA of 1976 never accomplished their intended goal." In 1982 and 1983, congressional oversight hearings plainly showed that the FDA had not been successful in executing congressional intent. One problem was that performance standards for medical devices in Class II had not yet been put into force. In addition, too many products were entering the market having merely gone through the pre-market notification procedure rather than the more thorough pre-market approval process. The effect of these problems on consumers was that unsafe and defective medical devices continued to be marketed. In fact, forty-four percent of the device recalls between the years of 1983 and 1988 were connected to product design problems. Congress itself has tried to correct problems with the MDA by imposing additional regulations. For instance, since the MDA of 1976, Congress has passed the Safe Medical

Flaws present in the pre-market approval process have especially been subject to attack. Absent are procedures detailing how to determine whether a device is merely a substantial equivalent of an existing device or an altogether new device. The result is much debate over the kind and amount of information required to identify a "substantial equivalence" to a pre-1976 device.207 In addition, even if a device is deemed a substantial equivalent, critics of the pre-market notification scheme question its effectiveness. However, others argue that, if this more simple type of approval is eliminated, many devices will unnecessarily have to undergo the rigors of the entire pre-market approval mechanism. In fact, approximately fifty-five "substantially equivalent" pre-market notifications are filed for every one pre-market approval application.208 The consequence of such a disparity between these two figures is that the more devices that are not classified as substantial equivalents, the more serious the delay will be in such devices reaching the consumer.

The fact that flaws are present in the pre-market approval process for medical devices constitutes one of the strongest attacks against preemption. It seems unjust for the courts to automatically dismiss state tort claims when the system is far from perfect. Of course, the courts are merely applying the FDA regulations. The focus of the attack, therefore, should be on the FDA and its enactment of the express preemptive language of the MDA. With a flawed system by which medical devices become available to the public (the scenarios of King and Stamps are just two instances where persons have been injured due to non-investigational medical devices), express preemption seems unfair to the public.

Furthermore, the flaws in the pre-market approval process are not restricted to only one type. Some flaws are due to negligent behavior. The argument here is that the system as a whole is susceptible to occasional breakdowns. Negligent acts of manufacturers, such as the misreading of injury reports, although not intentional, have the potential to cause severe harm to consumers. The FDA surely does not want to encourage, or even to ignore, such behavior which can seriously undermine the federal objective of public health and safety. Therefore, opponents of preemption could argue that preemption of claims based on manufacturers' negligence should not be express so that manufacturers will be more accountable for their actions.

Unfortunately for the public, some flaws in the pre-market approval process for medical devices can arise out of fraudulent behavior by the manufacturer. In this instance, express preemption should not be permit-


207. Benson et al., supra note 8, at 500.

208. Kessler et al., supra note 4, at 359 (citing 1985 FDA, OFFICE OF DEVICE EVALUATION, CENTER FOR DEVICES & RADIOLOGICAL HEALTH ANN. REP.).
ted due to a standard based on intentional torts. Manufacturers that are so profit-driven may be inclined to falsify or suppress relevant data, causing the FDA to grant market clearance for a medical device that is not safe or effective for consumer use. It is this type of situation in which an argument in favor of preemption seems inherently unjust. Thus, express preemption should not be applicable across the board since it is possible for the system to be manipulated or perverted.

D. Preemption Cannot Be Extended Further Than the Statutory Law Justifies

In Moore v. Kimberly-Clark Corp., the plaintiff brought a products liability suit against a tampon manufacturer. Although a Class II product was involved, the court's reasoning in the case is similar to that of the later Class III devices cases, notably King and Stamps. In Moore, the court of appeals held that some of the plaintiff's claims were preempted, while others were not. More specifically, the court held that the MDA and underlying regulations declaring tampons to be a medical device and outlining liability and warning requirements with respect to toxic shock syndrome (TSS) preempted state law tort claims against the defendant manufacturer for inadequate warning and labeling. The court determined, however, that the "plaintiff's state law claims based on design, composition and construction of tampons were not preempted."

After reviewing the governing statutes and regulations, the Moore court found no clear intent on the part of Congress or the FDA to preempt the whole field of tort liability with the TSS labeling requirements. The court was guided by the specifically limited preemptive effect of the regulations, which state that "[s]tate 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." The court’s holding, which affirmed in part and reversed in part the district court’s holding, is as follows:

The district court’s opinion which dismissed plaintiff’s state law claims based on inadequate warning and labeling is affirmed. Since we have concluded that plaintiff’s state law claims based on design, composition and construction of tampons were not preempted by federal law to the extent that such claims do not wholly or partially depend on inadequate or improper warning or labeling, the opinion of the district court which dismissed these claims is hereby reversed.

The King court based its decision involving a Class III device to a large extent on the Supreme Court's holding in Cipollone v. Liggett Group,

209. 867 F.2d 243 (5th Cir. 1989).
210. Id. at 247.
211. Id.
212. 21 C.F.R. § 808.1(d) (1995).
213. Moore, 867 F.2d at 247.
In *Cipollone*, the plaintiff had lung cancer and brought suit against cigarette manufacturers, asserting breach of warranty, failure to warn, fraudulent misrepresentation, and conspiracy to deprive the public of important health information. The Supreme Court looked to the explicit language of the Federal Cigarette Labeling and Advertising Act of 1965 that states that "[n]o requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter." The Court examined each of the plaintiff's claims in light of the specific language of the statute, which resulted in the holding that the plaintiff's failure-to-warn claims were preempted as to advertising practices, but not as to testing or research practices. The fraudulent misrepresentation claim was also preempted. But the express warranty and conspiracy claims were not preempted because the Court determined that these two claims did not arise out of state law.

The *King* court was guided by the Supreme Court's decision in *Cipollone* not to expand the scope of preemption to an improper degree and, specifically, not to extend it further than the language of the statute justified. The circuit court in *King* specifically voiced its intention to similarly interpret the preemption provision applicable to medical devices under the MDA.

In light of the *Cipollone* case, the *King* court purposely analyzed each of Ms. King's claims individually. As for the strict liability claim, the court determined that "[s]ubsection (a) [of section 360c of the MDA] protects manufacturers of medical devices approved by the FDA under the MDA from such state law intrusion." The express warranty claims based on the labeling and packaging of Zyderm were likewise considered to infringe upon FDA regulation. The court dismissed the implied warranty claims, stating that "[a]s an implied warranty is a requirement upon a product that arises exclusively from the operation of state contract law, this claim is preempted expressly by the MDA."

The court also determined that the negligence claim was preempted by the MDA. The court explained that "[i]f the MDA does nothing else, it regulates the design, manufacture, sale and marketing of class III medical

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215. *Id.* at 508.
218. *Id.* at 528.
219. *Id.* at 526-27, 530.
220. *King*, 983 F.2d at 1134.
221. *Id.*
222. *Id.* at 1135.
223. *Id.*
224. *Id.*
225. *Id.*
devices in an extensive way."226 Due to the express language of the MDA providing that a pre-market application will not be accepted based on false or misleading labeling, the court declared that the claims based on inadequate labeling and packaging must fail because of FDA regulation.227 King's final claim that Collagen Corporation obtained FDA premarket approval in a fraudulent manner failed, partly due to the ambiguity in King's pleading, and partly due to the court's determination that the fraud claim was a failure to warn claim.228 The concurring opinion in King noted that, following the opinion of Cipollone, fraud found outside the regulatory realm would not be subject to preemption.229

An additional issue concerning the extent to which preemption applies is the classification of a product as a drug rather than a device. For example, debate surrounds the extent to which claims involving intrauterine devices (IUDs) should be preempted. IUDs belong in the FDA-created Class III category and are thus regulated under the MDA.230 Such regulations require manufacturers of IUDs to warn consumers that the product may cause pelvic inflammatory disease in some users.231 This is of serious concern to consumers since the disease may cause adhesions to build up along the walls of the reproductive organs, with possible damage to the reproductive organs.232 Such damage can lead to ectopic (tubal) pregnancy and infertility.233 Regardless of the warnings to consumers concerning IUDs, some IUD users have brought lawsuits against the IUD manufacturers on the premise that the warnings were not adequate.234

Most of these IUD preemption cases have involved the Cu-7 IUD. The Cu-7 is a plastic and copper IUD that emits small bits of copper into the uterus.235 The copper irritates the lining of the uterus, and thus hinders the implantation of the egg in the uterine wall.236 The FDA approved the Cu-7 in 1974 as a drug, not as a medical device.237

Due to the classification of the Cu-7 as a drug rather than a medical device, many courts have held that the preemptive language of the MDA is not applicable to the Cu-7.238 For example, the court in Allen v. G.D. Searle & Co. pointed to FDA regulations to illustrate that the FDA had made distinctions among IUDs based on their classification as either

226. Id. at 1136.
227. Id.
228. Id.
229. Id. at 1140.
233. Id.
235. Ausness, supra note 120, at 229.
236. Spychala, 705 F. Supp. at 1026.
238. Ausness, supra note 120, at 229.
drugs or devices. In particular, the Allen court cited FDA comments which declared that "[t]he agency's policy of treating some IUDs as drugs and others as devices is unaffected by the revised definition of device found in the federal Food, Drug and Cosmetics Act, as amended by the Medical Device Amendments of 1976." As a result, the court held that section 360k does not expressly preempt state failure-to-warn claims against the manufacturers of Cu-7 IUDs.

A similar finding of non-preemption occurred in Callan v. G.D. Searle & Co. In Callan, the court noted that the Cu-7, unlike plastic IUDs, did not satisfy the statutory definition of a medical device since the Cu-7 depended in part on chemical means to accomplish its contraceptive objective. Thus, the court held that section 360k of the MDA was inapplicable to the Cu-7 IUD.

V. CONCLUSION

In conclusion, I refer back to the King and Stamps cases, whose holdings set out the issues analyzed in this Comment. Even though King and Stamps are binding precedent only in federal courts within the First and Fifth Circuits, respectively, these decisions are significant for both medical device manufacturers and consumers across the nation due to their potential influence on courts in other jurisdictions. The United States Supreme Court has denied certiorari in both cases; the Supreme Court, however, may not be able to ignore an emerging split between the circuits for much longer and may be forced to address this issue.

Manufacturers in the medical device industry, like those in all other industries, face a difficult, if not impossible, task to ensure that every single product is free from potential liability. In addition, manufacturers cannot ensure that consumers correctly use the products, even when the products are labeled in such a fashion as to facilitate safe and effective use. In fact, it is a fair assumption to state that some amount of liability risk is unavoidable for medical device manufacturers since by their very nature the devices are associated, at least for now, with injuries and death. The devices "therefore provide tempting targets for product liability plaintiffs and their lawyers . . . . To some degree, suits are inevitable, and must be considered a cost of doing business in the United

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240. Id. (quoting 52 Fed. Reg. 23,772 (1977)).
243. Id. at 666; see supra text accompanying note 5.
244. Callan, 709 F. Supp. at 666.
245. See Mark H. Lough, Recent Legal Developments Affecting Medical Device Manufacturers, 10 Healthspan 21 (1993).
246. See supra note 122 and accompanying text.
When considering this reality, the focus becomes how to minimize such defects and thus how to protect public health and safety to the greatest extent possible. The crucial issue centers upon the capabilities of the FDA, notably whether the FDA, by imposing requirements across the board for all states, can best achieve the federal objectives of public health and safety. It has been stated that “[t]he basic justification for the exercise of preemptive powers by Congress is the solution of major public problems in the most effective and efficient manner.” Is preemption a near-perfect solution to major problems involving medical device regulation? Or would something be gained by permitting states to impose additional guidelines without compromising the entire federal strategy concerning medical device regulation, which includes the encouragement of the marketing and development of new products and the need for some sort of uniformity across the country? Is it possible for such state standards to work in conjunction with those imposed at the federal level? These are the questions at the heart of the preemption debate, and it is these questions that must be considered when evaluating how medical devices should be regulated in the United States.

I propose that any change in the status quo should begin with a modification of the statutory language. I believe that express preemption should be replaced with a rebuttable presumption of preemption. Such a change could allow for state tort claims to stand, for example, if the approval process for medical devices could be undercut or undermined in a way other than for which it was designed. The dismissal of the express language is consistent with the need to account for flaws in the pre-market approval process. Flaws are potentially present in a number of areas, whether it is the entire design of the system that is defective, a system that works well most of the time but occasionally breaks down, or a system that is capable of being manipulated or perverted. Perhaps a combination of arguments for and against preemption could factor into a new system by which claims involving medical devices are governed.

By changing the treatment of claims such as those brought in King and Stamps from that of automatic dismissal to one involving a rebuttable presumption, perhaps federal and state law could co-exist. Such a change might decrease, if not eliminate, the tension involving the highly centralized regulation of medical devices by the federal government. It is no secret that “[t]he optimal degree of centralization of political power in a federal system is a subject of neverending controversy as dramatic changes in ... technology produce continuing pressures for readjustments in the respective competencies of the national government and the states.”

248. Id.
249. Zimmerman, supra note 80, at 14.
250. Id. at 3.
By allowing a defendant manufacturer to rely to a great extent on the fact that its products are FDA-approved and that preemption is presumed, manufacturers will not be disinclined to introduce and develop new products for the benefit of the public. However, allowing this preemption presumption to be rebuttable would provide the injured plaintiff with recourse if he or she could prove that preemption should not be permitted. This alternative takes the all-encompassing authority away from the FDA, although the FDA would still have most of the regulatory power regarding medical devices. Hopefully, the effect would be to push the FDA to be even more cautious in its regulation of medical devices so that courts would be reluctant to find that particular plaintiffs have rebutted the preemption presumption. Thus, a plan based on qualified immunity for manufacturers would still embody federal objectives but would not automatically preclude plaintiffs in all circumstances from gaining some relief from injuries or death resulting from defective medical devices.

The question then arises under what circumstances a plaintiff would be able to rebut the preemption presumption if such a plan were to be adopted. For example, one argument is that a negligence standard, based on an occasional flaw in the pre-market approval system, should be set. An instance in which the negligence standard could help injured plaintiffs would be when a manufacturer has misread injury reports. This scenario would be a circumstance in which the plaintiff should be allowed to attempt to rebut the preemption presumption. An even stronger argument is that, if nothing else, a standard based on intentional tort should be established. A prime example would be where a manufacturer has falsified data, suppressed injury reports, and so forth in the approval process. Where fraud is involved in a device gaining FDA approval, the plaintiff should be entitled to some sort of recourse against the manufacturer. The overall rationale for a rebuttable presumption is that the FDA should not want manufacturers to be immune from lawsuits involving devices that should not have been FDA-approved in the first place, but nevertheless passed the approval requirements due to fraudulent or negligent behavior.

In conclusion, I propose that the preemptive language of the MDA be modified in order to account for flaws in the pre-market approval process for medical devices. A rebuttable presumption of preemption would not hinder federal objectives such as the need for the development and marketing of new products, and it would further the federal government's overall objectives of public health and safety.
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