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King v. Collagen Corporation: FDA Approval Insulates Medical Device Manufacturers From State Common Law Liability

By enacting the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA), Congress gave the Food and Drug Administration (FDA) authority to regulate medical devices after their market distribution. The FDA focused exclusively on "quack" devices until the 1960s when manufacturers began introducing new medical devices, such as heart pacemakers and kidney dialysis units, to the medical community. A 1970 study headed by Dr. Theodore Cooper, Director of the National Heart and Lung Institute, found that medical devices contributed to 10,000 injuries and concluded that there was a need for FDA approval of medical devices before their distribution on the market. Medical device manufacturers argued that these injuries were due mainly to misuse, not faulty design or manufacturer. The study's authors disagreed with the manufacturers and called for more legislation that would enable the FDA to regulate and approve medical devices before manufacturers distributed their

2. S. Rep. No. 33, supra note 1, at 3. "Quack" devices were sold to consumers and did not perform as promised and sometimes posed a health risk as well as an economic detriment to the purchaser. Id. The FDA also concentrated on the labeling of medical devices and made numerous seizures of misbranded and fraudulent devices. In the 1940s, the FDA seized a $90 lamp that supposedly could cure diabetes, cancer, tuberculosis, and syphilis. Id. The FDA also seized the "Magic Spike," a gadget that sold for $300, but was worth only one two-thousandths of a cent. The "Magic Spike" manufacturer claimed its radioactive powers could cure any disease known to mankind. Id. at 4.
3. Id. at 5. These medical devices were a result of new medical discoveries made during the post World War II era. Due to the devices' complexity, the FDA could no longer rely on expert testimony to prove that they were unsafe. Consequently, the FDA began testing the devices it suspected of violating the law. This testing was time consuming, and the FDA found itself in long court battles. Id. at 5-6.
4. Id. Of those 10,000 injuries, 731 resulted in death. "For example, 512 deaths and 300 injuries were attributed to heart valves; 89 deaths and 186 injuries to heart pacemakers; 10 deaths and 8,000 injuries to intrauterine devices." Id.
devices to the market.\textsuperscript{6}

In 1976, Congress recognized the need for regulating medical devices before their distribution and amended the FDCA with the Medical Device Amendments (MDA).\textsuperscript{7} Congress intended the MDA to protect the public health by ensuring that all medical devices are safe and effective both before and after market distribution.\textsuperscript{8}

Anticipating the inevitable conflict between the FDA's medical device regulations and state regulations, Congress provided an express preemption clause in the MDA. The clause states that the MDA will preempt any state "requirement which is different from, or in addition to, any [FDA] requirement . . . which relates to the safety and effectiveness of the device."\textsuperscript{9} The FDA promulgated a rule expanding Congress' preemption

\textsuperscript{6} Id. at 423-24.


\textsuperscript{8} H.R. CONF. REP. No. 1090, 94th Cong., 2d Sess. 51 (1976); S. REP. No. 33, supra note 1, at 2; Jerald A. Jacobs, FDA Premarket Approval of New Medical Devices: Confidentiality of Data, 35 FOOD DRUG COSM. L.J. 576, 576 (1980). The enactment of the MDA halted the FDA's practice of classifying devices as drugs for the sole purpose of regulating the devices before market distribution. Paul G. Rogers, Medical Device Law - Intent and Implementation, 36 FOOD DRUG COSM. L.J. 4, 4 (1981).


State and local requirements respecting devices
(a) General rule
Except as provided in subsection (b) of this section, 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.

(b) Exempt requirements
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.

Following Congress' lead, the FDA promulgated regulations providing that:

after May 28, 1976, no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for
provision and defined a "state requirement" as any state "statute, ordinance, regulation, or court decision."¹⁰

In King v. Collagen Corp.,¹¹ the United States Court of Appeals for the First Circuit examined the FDA's definition of "state requirement." The court held that when the FDA regulates any aspect of the claim through its medical device rules, the FDA's "state requirement" definition encompassed judicial decisions resulting from state common law claims¹² brought against medical device manufacturers.¹³ Therefore, the First Circuit concluded that federal law preempts state common law claims against medical device manufacturers in cases where the FDA regulates an aspect of the device the common law claim alleges to be unlawful.¹⁴ This holding effectively allows manufacturers to be insulated against state common law claims when there is a judicial determination that the FDA's rules already regulate the allegations in the claims. As such, not only are medical device manufacturers shielded from liability, but injured plaintiffs are left without an adequate remedy.¹⁵

This Note first explains the FDA's classification system for medical devices. Such an understanding of the system is necessary before beginning an analysis of the King decision. After establishing that foundation, this Note then delves into the facts of the King decision and analyzes it, utilizing other cases involving medical devices. This Note concludes that neither the MDA nor its legislative history intended to create a blanket preemption of state common law claims alleging that FDA-approved medical devices are unreasonably dangerous. Therefore, courts should not preempt, under the guise that the FDA's rules are in compliance with congressional intent, the only effective remedy plaintiffs have against medical device manufacturers.

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¹⁰ 21 C.F.R. § 808.1(b) (1994).
¹¹ 21 C.F.R. § 808.1(b) (1994).
¹² 983 F.2d 1130 (1st Cir.), cert. denied, 114 S. Ct. 84 (1993).
¹³ This Note's discussion of state common law claims is intended to include the term "state tort claims."
¹⁴ Id.
¹⁵ See infra text accompanying notes 66-69.
I. THE STRUCTURE OF THE MEDICAL DEVICE AMENDMENTS

The MDA established a plan in which the FDA categorizes medical devices into three classes.\(^{16}\) The FDA regulates: Class I devices through general controls,\(^{17}\) Class II devices through compliance with FDA performance standards,\(^{18}\) and Class III devices, considered the most risk-laden,\(^{19}\) through premarket approval applications (PMA).\(^{20}\)

The MDA allows a manufacturer two routes to obtain FDA premarket approval for a new medical device.\(^{21}\) Under the simpler route, known as "510(k) notification,"\(^{22}\) the manufacturer may avoid extensive review.\(^{23}\) Before marketing a medical device, a manufacturer must submit a notification to the FDA demonstrating that the new device is "substantially equivalent" to a 'predicate' device marketed before enactment of the 1976 Amendments or to a post-1976 product that [has] already been found by the FDA to be substantially equivalent to a pre-1976 device."\(^{24}\) To help demonstrate that the device is substantially equivalent to a device already

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17. Id. § 360c(a)(1)(A).
18. Id. § 360c(a)(1)(B).
20. 21 U.S.C. 360c(a)(1)(C). With pre-existing devices, the FDA failed to establish performance standards for Class II devices and did not require PMAs from many Class III devices. Consequently, Congress enacted the Safe Medical Devices Act of 1990. Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511 (codified as amended in scattered sections of 21 U.S.C.). It requires manufacturers to submit any information relating to pre-existing medical devices, including adverse safety or effectiveness data. It also requires the FDA to conduct a rule making by December 1, 1995, in order to classify pre-existing devices into one of the three classes. Any device which remains classified as a Class III device will have to submit a PMA to be approved by the FDA. Flannery, supra note 19, at 135.
22. Flannery, supra note 19, at 130.
23. Jacobs, supra note 8, at 577.
24. Flannery, supra note 19, at 130. In the Safe Medical Devices Act of 1990, Congress added a section to the Federal Food, Drug, and Cosmetic Act, codifying the definition of "substantial equivalence." 21 U.S.C. § 360c(i) (1988). "A new device is 'substantially equivalent' to a predicate device if it has the same intended use and the same technological characteristics as the predicate device." Id. § 360c(i)(1)(A)(i); Flannery, supra note 19, at 132. Nevertheless, "substantial equivalence" may still be found even if the technological characteristics are different as long as two conditions are met: clinical data is submitted demonstrating the device's safety and effectiveness, and questions of safety and effectiveness are not raised that are different from those of the predicate device. 21 U.S.C. § 360c(i)(1)(A)(ii); Flannery, supra note 19, at 132. If the predicate device has been removed from the market, the new device cannot be found to be "substantially equivalent." 21 U.S.C. § 360c(i)(2); Flannery, supra note 19, at 132.
on the market, the manufacturer must submit to the FDA data on the type and use of the device, as well as labels, inserts, and/or advertisements.\textsuperscript{25}

If a manufacturer's new device is not determined to be substantially equivalent, it automatically will be classified as a Class III device, and the manufacturer must submit a PMA, taking the more difficult route to receiving FDA premarket approval of its device.\textsuperscript{26} The manufacturer may attempt to have the new device reclassified into Class I or Class II to avoid the requirement of submitting a PMA; however, the FDA requires the "same quality and quantity of information and data before down classing a device from Class III as is demanded in a [PMA] full safety and efficacy review."\textsuperscript{27} When submitting its PMA, the manufacturer must also submit "a 'full' statement of the components, ingredients, and properties of the device; a 'full' description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of the device."\textsuperscript{28} The FDA utilizes the data detailed in the PMA, including clinical studies, to examine the device's safety and effectiveness.\textsuperscript{29} Advisory panels that study the PMAs have "the important statutory role of peer review of medical and scientific results achieved with the product in pre-clinical and clinical testing."\textsuperscript{30}

\section*{II. FACTS OF \textit{KING v. COLLAGEN CORP.}}

Jane King brought suit against Collagen Corporation (Collagen), alleg-
ing that she was injured by its medical device, Zyderm. Collagen developed Zyderm in the early 1970s and began marketing it in the early 1980s. The FDA classified it as a Class III medical device. Consisting of processed cow tissue, Zyderm is sold to correct wrinkles and other skin deformities through injection underneath the skin.

In 1987, soon after Ms. King received a test dose of Zyderm, she began to suffer from muscle and joint pains. Ms. King’s doctor diagnosed her with an autoimmune disease known as dermatomyositis/polymyositis, which causes one’s immune system to attack “skin and muscle tissue as if it were a foreign substance.”

Ms. King brought her claim against Collagen in 1990. She alleged seven claims: Collagen was strictly liable for her injuries because Zyderm was unsafe for its intended purpose and was unreasonably dangerous to users; Zyderm was sold in breach of the warranty of merchantability because it was not safe for its intended use; Collagen was negligent in designing, manufacturing, marketing, and selling Zyderm; Collagen misbranded and/or mislabeled Zyderm; Collagen made misrepresentations of material fact; Collagen failed to warn her of any defective condition; and, Collagen fraudulently obtained FDA approval. Granting Collagen’s motion for summary judgment, the United States District Court for the District of Massachusetts held that “the implants in this case are subject to the specific, detailed requirements of the Food, Drug, and Cosmetic Act and, therefore, the plaintiff’s claims are pre-empted.”

Ms. King appealed the district court’s decision.

The United States Court of Appeals for the First Circuit affirmed summary judgment in favor of Collagen on the basis of the express preemption clause in the MDA. The appellate court held that the FDA’s approval process provided a reasonable assurance that medical devices are safe and that § 360k of the MDA preempts plaintiff’s common law

32. Id. at 1131.
33. Id.
34. Id. Usually six applications over several weeks are needed. Id.
35. Id. at 1134.
36. Id.
37. Id.
38. Id.
40. King, 983 F.2d at 1132.
41. Id. at 1137.
claims of strict liability, breach of warranty of merchantability, negligence, misbranding, misrepresentation, failure to warn, and fraud because the FDA regulates not only the labeling and packaging of the device, but also the manufacturing methods. The court stated that Ms. King's claims, if successful, would create a state requirement in addition to, and different from, the FDA's regulations concerning the safety and effectiveness of Zyderm. The court found Ms. King's claims expressly preempted because § 360k forbids state requirements that differ from or surpass the FDA's regulations of medical devices, unless exempted by § 360k(b).

King is the first federal appellate court decision holding that the FDA's regulations are so encompassing as to automatically preempt any state common law claim brought due to an injury caused by a Class III medical device. Although Class III medical devices are considered the most risk-laden, the appellate court reasoned that preemption of state common law claims was appropriate due to the FDA's extensive regulation of these devices. Therefore, once the FDA approves a Class III medical device, the device manufacturer is ensured against any state common law liability arising from injuries caused by the device.

The King decision prohibits consumers from suing Class III medical device manufacturers whose products have the FDA's premarket stamp of approval, even where design or manufacturing flaws are detected. One of Ms. King's attorneys claims that, "[t]here's no legal recourse for consumers under this decision if something goes wrong. It takes away everything."

42. Id. at 1135-37. The court held that for Ms. King to state a claim of fraud, she would have to be in privity with Collagen. Id. at 1136. The court noted that she was not in privity with Collagen because it sold its product directly to her physician. Id. Nevertheless, the court noted that "the fraud claim is, at bottom, a failure to warn claim. It seeks to show that Collagen had a duty to provide different information in Zyderm's packaging and labeling than that which was approved by the FDA. As such, the claim is preempted expressly by the MDA." Id.

43. Id. at 1135-37.
44. Id. at 1134-37.
46. Flannery, supra note 19, at 130-31.
47. See King, 938 F.2d at 1135-37.
III. Federal Preemption and the MDA

Federal preemption is a well established Constitutional doctrine. It extends from the Supremacy Clause of Article Six, the purpose of which is balancing power between the states and the federal government. The Supremacy Clause grants federal law precedence over state or local law.

However, not every federal law preempts state law. To determine whether federal law takes priority over state law, a court will examine the wording of the federal statute or regulation. A court may find that Congress intended to preempt state law due to the statute's express wording. Furthermore, absent an express preemption clause, a court may infer preemption where a state law conflicts with the federal law. Where the federal law so thoroughly occupies a field, a court may find preemption on the ground that Congress could not have intended to leave room for states to legislate in the same area. Federal law with a preemptive effect not only includes the Constitution, treaties, and statutes, but federal regulations promulgated by federal agencies acting within the scope of their congressionally delegated authority as well. If preemption is based on a federal regulation, the court's inquiry is limited to a determination of whether the administrator "has exceeded his statutory authority or acted arbitrarily."

Balancing the interests of the states with the federal government in the field of health regulation has been challenging for courts. The Supreme Court in 1985 indicated in Hillsborough County, Florida v. Automated Medical Laboratories, Inc. that regulation of health and safety matters

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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.

U.S. CONST. art. VI, cl. 2.

51. U.S. CONST. art. VI, cl. 2; McCulloch v. Maryland, 4 Wheat. 316, 427 (1819).


primarily and historically has been the exclusive concern of the states; therefore, the Court stated that without an express intent of Congress to preempt state law, courts should presume that federal law is not to supersede state law.\(^5\) In 1988, the United States Court of Appeals for the Fourth Circuit expanded this deference to states in Abbot v. American Cyanamid Co.,\(^6\) holding that a court should recognize a strong presumption against preemption of remedies, such as tort recoveries, when federal regulation does not provide an alternative remedy.\(^6\)

The MDA expressly preempts state and local requirements that differ from, or add to, the federal regulation of medical devices which relate to the devices’ safety or efficacy, unless the FDA approves an exception to the MDA’s express preemption clause.\(^6\) The FDA’s regulation expands § 360k and requires preemption of court decisions which are different from, or in addition to, its medical device regulations.\(^6\) Effectively, the FDA increased the preemptive effect of § 360k by including court decisions in its regulations, despite the absence of such a requirement in § 360k.\(^6\) From the Supreme Court’s decision in Hillsborough,\(^6\) that the regulation of health and safety matters has historically been in the exclusive realm of the states, it follows that courts should not allow preemption of common law claims involving medical devices without an express mandate from Congress.

Furthermore, courts have been reluctant to preempt states’ interest in protecting their citizens through the adjudication of traditional common law claims,\(^6\) unless Congress has expressly provided for preemption.\(^6\)

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59. id. at 719.
60. 844 F.2d 1108 (4th Cir. 1988).
61. id. at 1112.
62. 21 U.S.C. § 360k (1988). To qualify for an exception, the FDA must determine that: (1) the state or local government’s regulation is more stringent than the FDA’s requirement; (2) the state or local government’s requirement is compelled due to local conditions; and (3) compliance with the requirement would not cause the device to violate any FDA medical device requirement. id. § 360k(b).
63. 21 C.F.R. § 808.1(b) (1994).
64. 21 U.S.C. § 360k; see supra note 9 for full text of § 360k.
Courts have been hesitant to preempt traditional common law tort actions because injured plaintiffs are left without a remedy and parties engaged in tortious conduct are granted immunity from liability. Preemption of state common law claims involving medical devices in the absence of an express mandate from Congress leaves plaintiffs harmed by medical devices without an adequate remedy and guarantees manufacturers immunity from liability for any damages caused by their products.

In defending common law claims for medical devices other than Class III medical devices, manufacturers have argued that the MDA expressly preempts plaintiffs' claims. Manufacturers have asserted this argument in cases involving tampons, intrauterine devices, and intraocular lenses. Some courts have agreed that the MDA preempts these claims, whereas others have not. This Note discusses the opinions of these cases and incorporates them into the analysis of the King decision.

A. Class II Medical Devices—Tampons

A tampon is a device a woman inserts into the vagina during her menstrual period to absorb menstrual flow. The FDA requires all tampon products to be accompanied by warnings of Toxic Shock Syndrome (TSS), a deadly disease arising from the use of tampons.

1. Inadequate Warnings Claims

Courts have taken three different views as to whether the MDA and the FDA regulations preempt all TSS inadequate warnings claims. The first view is that the MDA requires blanket preemption of all such inadequate warnings claims. The second view is that the MDA does not preclude the ability of states to protect their citizens through the judicial process, they should wait for a "clear statement of congressional intent to work such an alteration." Id. at 1543.


69. 21 U.S.C. § 360h (1988). The MDA provides a remedy for a device the Secretary determines is unreasonably dangerous; these remedies include requiring the manufacturer to repair the device, replace the device, or refund the device's purchase price. However, the MDA's remedy is inadequate because it does not provide compensation for a plaintiff's injury or expenses therefrom.

70. 21 C.F.R. § 801.430 (1994).

empt inadequate warnings claims because there is still a question of fact as to whether the manufacturer complied with the FDA’s rules. The third view is that the MDA does not preempt inadequate warnings claims because tampon warnings are not an FDA requirement due to the fact manufacturers may draft them in their own words.

The first view on preemption of tampon inadequate warnings claims is that the MDA preempts all the claims. The United States District Court for the District of South Carolina offered two reasons in Stewart v. International Playtex, Inc. for MDA preemption of plaintiff’s TSS inadequate warnings claims. The court stated that the goal of the MDA is to achieve uniform regulations of medical devices. It also noted the FDA’s expansion of the statute to include court decisions within the definition of a state rule that can be preempted by the MDA. The court found that plaintiff’s claim sought to establish a tort labeling requirement through a court decision which could differ from, or add to, the existing FDA requirement; therefore, it decided that the MDA’s goal of uniform regulations could be achieved only if the MDA preempted the claim.

The Stewart court rejected the plaintiff’s argument that the case should be decided in accord with Ferebee v. Chevron Chemical Co. in which the United States Court of Appeals for the District of Columbia Circuit held that the Federal Insecticide, Fungicide, and Rodenticide Act requirements represent only minimum guidelines which leave room for states to adopt additional requirements for pesticide labeling. The district court stated that the MDA, unlike the Act in Ferebee, did not have a savings clause allowing for state regulations.


75. Id. at 909.

76. Id.

77. Id. at 910.

78. 736 F.2d 1529 (D.C. Cir. 1984).


80. Stewart, 672 F. Supp. at 910 (citing Ferebee, 736 F.2d at 1542-43).

81. Id.
O'Gilvie v. International Playtex, Inc.\textsuperscript{82} in which the United States Court of Appeals for the Tenth Circuit upheld jury instructions requiring the jury to consider a manufacturer's compliance with the FDA's regulations as evidence of due care, but allowed the jury to find a tampon manufacturer negligent if the jury believed a reasonable tampon manufacturer would have taken additional precautions.\textsuperscript{83} The Stewart court held that the MDA preempted the plaintiff's inadequate warnings common law claim; therefore, it granted the tampon manufacturer summary judgment.\textsuperscript{84}

In Moore v. Kimberly-Clark Corp.\textsuperscript{85} the United States Court of Appeals for the Fifth Circuit agreed with the Stewart court's holding that the MDA expressly preempted plaintiff's inadequate warnings claim.\textsuperscript{86} The court found that the MDA and the FDA's regulations expressly precluded any contrary state requirement regardless of the source.\textsuperscript{87} Likewise, in Edmondson v. International Playtex, Inc., the United States District Court for the Northern District of Georgia preempted plaintiff's inadequate warnings claim on the basis of a magistrate's report stating that a state court judgment imposed on a medical device manufacturer is no different than a state legislature imposing a requirement.\textsuperscript{88}

The second view on the preemption of inadequate warnings common law claims is that the claims are preempted, provided that the manufacturer has complied with the federal warning requirements. In Rinehart v. International Playtex, Inc.,\textsuperscript{89} the United States District Court for the Southern District of Indiana held that the MDA's preemption clause establishes the FDA's regulation of tampons as the standard to be applied in common law claims.\textsuperscript{90} The Rinehart court denied the manufacturer's motion for summary judgment.\textsuperscript{91} It found that material issues of fact still existed as to whether the tampon manufacturer complied with the federal requirements because manufacturers could choose their own wording for the TSS warnings.\textsuperscript{92} In Ignace v. Playtex Family Products, Inc.,\textsuperscript{93} the

\begin{itemize}
  \item 82. 821 F.2d 1438 (10th Cir. 1987).
  \item 83. Stewart, 672 F. Supp. at 910 (citing O'Gilvie, 821 F.2d at 1442).
  \item 84. Id.
  \item 85. 867 F.2d 243 (5th Cir. 1989).
  \item 86. Id. at 247.
  \item 87. Id. at 245.
  \item 89. 688 F. Supp. 475 (S.D. Ind. 1988).
  \item 90. Id. at 477.
  \item 91. Id. at 478.
  \item 92. Id.
\end{itemize}
United States District Court for the Western District of Wisconsin held that the federal regulations for tampons establish the standard by which the adequacy of warnings is to be judged; therefore, the plaintiff must show only that the tampon manufacturer’s warnings were in violation of the applicable federal regulations.\textsuperscript{94}

The third view on the preemption of inadequate warnings common law claims was promulgated by the United States District Court for the Eastern District of Wisconsin in \textit{Muzatko v. International Playtex, Inc.}\textsuperscript{95} The \textit{Muzatko} court held that the MDA could not preempt plaintiff’s inadequate warning claim because the contents of the warnings were not an FDA requirement due to the fact tampon manufacturers were allowed to draft the TSS warnings in their own words.\textsuperscript{96} The court concluded that the MDA preemption clause did not apply because the warnings were not a requirement as the “term was intended by Congress to be preempted.”\textsuperscript{97}

2. \textit{Design Defect Claims}

Unlike challenges based on inadequate warnings, it is not disputed that common law claims based on the design, composition, and construction of tampons are not preempted. The courts in \textit{Moore} and in \textit{Rinehart} held that the FDA did not intend to preempt all state laws and regulations pertaining to tampons because the FDA’s regulations only provide for preemption when the FDA has promulgated counterpart regulations or when there are other specific requirements applicable.\textsuperscript{98} Because the FDA’s requirements for tampons only concern labels and warnings, the courts held that the MDA did not preempt plaintiff’s claims based on design, composition, and construction of the tampon.\textsuperscript{99}

B. \textit{Medical Devices—Intrauterine Devices}

An intrauterine device (IUD) is a contraceptive, inserted into a woman’s uterus by a physician to prevent pregnancy. In the cases where plaintiffs claimed an injury due to the use of an IUD, defendant manufac-

\textsuperscript{94} \textit{Id.} at *8.
\textsuperscript{96} \textit{Id.} at *6.
\textsuperscript{97} \textit{Id.}
\textsuperscript{99} \textit{Moore}, 867 F.2d at 246; \textit{Rinehart}, 688 F. Supp. at 478.
urers argued that the MDA preempts plaintiffs’ common law defect and failure-to-warn claims. United States District Courts in New Jersey and Minnesota have held that, because the FDA regulates some IUDs as drugs, not medical devices, the MDA cannot preempt state common law claims concerning those IUDs regulated as drugs. In *Allen v. G.D. Searle & Co.*, the United States District Court in Oregon held that the IUD is, at most, both a device and a drug; however, the MDA’s preemption clause only applies to devices. One court could not determine whether the MDA preempted the plaintiff’s claims that the IUD had injured her because there were material questions of fact as to whether the IUD was a drug or a device.

Two courts considering whether the MDA’s preemption clause applied to drug IUDs expressed their views of the preemption clause itself. The United States District Court in Maryland agreed that drug IUDs did not fall under the MDA; however, it stated further that the MDA’s preemption clause did not preempt state common law claims. The court found that the language of § 360k indicates that Congress intended to preempt only state or local legislation and administrative medical device requirements, not state common law claims. As support, the court cited the legislative history of the MDA and a report from the House Committee on Interstate Foreign Commerce. The court found that the accompanying House Report demonstrates congressional intent for the term “requirement” to refer only to state or local legislative and administrative programs regulating devices. The court concluded that the FDA’s regulations extending “requirement” to include “court decision” contradict congressional intent and are not based on a permissible construction of the MDA. The United States District Court in Minnesota agreed, stating that “even if the court credits defendant’s argument that section 360k should apply [to drug IUDs], it is doubtful that the term ‘requirement’ as used in section 360k is broad enough to encompass an action

102. Id. at 1151.
105. Id. at 667.
106. Id.
107. Id.
108. 21 C.F.R. § 808.1(b) (1994).
pursued under state tort law."¹¹⁰

C. Investigational Medical Devices—Intraocular Lens Implants

An intraocular lens is a plastic lens implanted after the removal of cataracts.¹¹¹ The FDA regulates intraocular lenses pursuant to § 520(g) of the FDCA, which exempts the investigational uses of a device from the other provisions of the Act, allowing manufacturers the opportunity to determine the safety and effectiveness of a device.¹¹² Nevertheless, the FDA’s regulations relating to intraocular lenses are still subject to the MDA’s express preemption clause.¹¹³

Courts are split over whether common law claims relating to intraocular lenses are preempted. In Mitchell v. Iolab Corp.,¹¹⁴ the United States District Court of the Eastern District of Louisiana held that the plaintiff’s common law claims were not preempted. It found that common law claims are not a requirement different from, or in addition to, the FDA requirement concerning the implanted lenses because federal regulations clearly state that patients do not waive or release their legal rights by signing an informed consent agreement.¹¹⁵ Therefore, it appears that the Mitchell court restored the plaintiff’s right to bring a common law claim, despite the MDA’s express preemption clause. In Slater v. Optical Radiation Corp.,¹¹⁶ the United States Court of Appeals for the Seventh Circuit agreed with the Mitchell court’s application of the preemption provision to informed consent agreements. However, the court determined that the FDA’s investigational device regulations preempted state common law claims of negligence, strict liability, and breach of implied warranty based on intraocular lenses.¹¹⁷

¹¹⁰ Kociemba v. G.D. Searle & Co., 680 F. Supp. 1293, 1298 (D. Minn. 1988). The court further noted, “[a]bsent statutory or regulatory language or legislative history to the contrary, the Court reads the statute to only preclude state statutes, regulations, or local laws regulating medical devices.” Id.
¹¹¹ Slater v. Optical Radiation Corp., 961 F.2d 1330, 1332-33 (7th Cir. 1992).
¹¹⁴ Id. at 877.
¹¹⁵ Id.
¹¹⁶ Id. at 1130 (7th Cir. 1992).
¹¹⁷ Id. at 1332-33. In the case of breast implants, one court has held that a plaintiff’s claim is not preempted because the MDA was not in effect at the time the implants were received. Desmarais v. Dow Corning Corp., 712 F. Supp. 13, 16 (D.C. Conn. 1989).
IV. Analysis of *King v. Collagen Corp.*

Prior to *King v. Collagen Corp.*, federal courts were split on the application of the MDA’s preemption clause to state common law claims. *King* is the first federal appellate court decision that completely strikes down a plaintiff’s state common law claims related to a Class III medical device.\(^{118}\) In its determination of whether the MDA preempted Ms. King’s state common law claims, the United States Court of Appeals for the First Circuit relied upon the Supreme Court’s decision in *Cipollone v. Liggett Group, Inc.*\(^{119}\) The *King* opinion stated:

In analyzing preemption, the Court [in *Cipollone*] relied only on the specific language of the provision regarding preemption. The Court reasoned that “Congress’ enactment of a provision defining the preemptive reach of a statute implies that matters beyond that reach are not preempted.” The [*Cipollone*] opinion thus analyzed each of petitioner’s claims in light of the express language of the preemption provision . . . \(^{120}\)

In accord with *Cipollone*, the *King* court examined the specific language in the MDA preemption clause.\(^{121}\) The court stated that it could not extend § 360k any further than its language warranted because courts must respect the relationship between the federal government and the states.\(^{122}\) The court reasoned that states’ historic police powers are superseded only when Congress clearly intends that result.\(^{123}\)

Pursuant to § 360k, the court stated, “we must determine whether appellant’s products liability claims give rise to state law requirements in addition to or different from those mandated by the FDA.”\(^{124}\) The *King* court followed the FDA’s interpretation of a state requirement because the Supreme Court has held that a federal agency’s interpretation of its own statute is controlling as long as it is not contrary to the intent of

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\(^{118}\) *Panel Bars Product Liability Suit*, supra note 45, at 70.

\(^{119}\) *King v. Collagen Corp.*, 983 F.2d 1130, 1133 (1st Cir. 1993). In *Cipollone*, the plaintiff brought a state common law claim asserting that a cigarette manufacturer failed to warn of the hazards related to smoking; breached warranties contained in cigarette advertisements; fraudulently misrepresented the hazards of smoking to the public; and conspired to deprive the public of important health information. *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608, 2613 (1992).

\(^{120}\) *King*, 983 F.2d at 1133 (citing *Cipollone*, 112 S. Ct. at 2618).

\(^{121}\) *Id.* at 1134.

\(^{122}\) *Id.* at 1133.

\(^{123}\) *Id.* at 1134.

\(^{124}\) *Id.*
Congress.125 Examining the FDA's interpretation of § 360k, the court stated that a state requirement "may emanate from any requirement established by a state including statutes, regulations, court decisions or ordinances."126 The court determined that a state common law claim is a state requirement in the form of a court decision.127 To support its determination, the court cited dictum in a non-tort, non-preemption case in which the Supreme Court stated that a court's ability to award damages and the obligation to pay compensation can be, and is designed to be, a state method of regulating conduct.128

The court determined that the FDA extensively regulates all Class III medical devices, including Zyderm, to ensure that they are reasonably safe for public use.129 The FDA's extensive regulations include packaging and labeling, such as warnings and safety information, of the medical device.130 The FDA must also approve the design and manufacturing process of Class III medical devices.131 The court proceeded to discuss all seven of Ms. King's state common law claims: strict liability, breach of warranty of merchantability, negligence, product misbranding, misrepresentation, failure to warn, and fraud. The court determined that according to *Cipollone*, the MDA preempted all of these claims because the FDA extensively regulated Zyderm as a Class III medical device, and each of her claims would create a state requirement either different from or in addition to the FDA's approval of Zyderm.132

The *King* court's analysis is flawed in four respects. First, the court did not discuss whether Congress intended the term "state requirement" in the preemption clause to include state common law. The court simply assumed that because the FDA's regulations provide that a state requirement may emanate from a court decision, Congress intended the MDA and the FDA's regulations of medical devices to preempt state common

126. *Id.*
127. *Id.* at 1134-35.
129. *King*, 983 F.2d at 1135.
130. *Id.*
131. *Id.* at 1136.
law. In so doing, the court relied on *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*,\(^{133}\) in which the Supreme Court held that an agency's interpretation of its own statute is controlling.\(^{134}\) However, the *King* court did not address the Supreme Court's determination in *Chevron* that the federal agency's interpretation is only controlling if the interpretation is not contrary to congressional intent.\(^{135}\) Moreover, the *King* court failed to recognize the Supreme Court's determination in *Hillsborough County, Florida v. Automated Medical Laboratories, Inc.* that in the area of health and safety regulation, courts should not presume preemption of state law, unless expressly stated by Congress.\(^{136}\)

Neither the language of the MDA's preemption clause\(^{137}\) nor the legislative history demonstrate that Congress intended to preempt state tort law. Section 360k does not mandate that the MDA preempt state common law.\(^{138}\) In fact, the legislative history of the MDA demonstrates that Congress did not intend to preempt state common law. The House Report accompanying the MDA reveals Congress' concern that an undue burden would be imposed on interstate commerce if each state were free to regulate medical devices.\(^{139}\) Consequently, Congress provided for the preemption of state requirements on medical devices. However, the House Report expresses concern only over state administrative programs regulating medical devices.\(^{140}\) The Report does not include state com-

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134. *Id.* at 865-66.
135. *Id.*
137. 21 U.S.C. § 360k (1988); see supra note 9.
140. *Id.* The report states:

The Committee recognizes that 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. For this reason, the reported bill contains special provisions...governing regulation of devices by States and localities... .

In the absence of effective Federal regulation of medical devices, some States have established their own programs. The most comprehensive State regulation of which the Committee is aware is that of California, which in 1970 adopted the Sherman Food, Drug, and Cosmetic Law. This law requires premarket approval of all new medical devices, requires compliance of device manufacturers with good manufacturing practices and authorizes inspection of establishments which manufacture devices. Implementation of the Sherman Law has resulted in the requirement that intrauterine devices are subject to premarket clearance in California.
mon law in its discussion of the MDA’s preemption provision. Recognizing this, the Office of the Chief Counsel for the FDA stated:

[t]here is no indication in the legislative history of section 521a [21 U.S.C. § 360k] that Congress intended that the section preempt State or local requirements respecting general enforcement, including available legal remedies, or State or local remedies that only incidentally apply to devices. Rules or requirements established by States to govern the legal remedies available under the State judicial system are not “requirements with respect to a device” within the meaning of section 521(a) of the act.

The King court’s decision that the MDA preempts state common law is contrary to the legislative history. The decision is based on the mistaken assumptions that Congress intended preemption and the FDA correctly interpreted the preemption provision.

In other preemption clauses where Congress has utilized the word “requirement,” courts have not automatically presumed the preemption of state common law. For example, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) precludes a state from imposing any requirements in addition to or different from those in the Act. The United States Court of Appeals for the District of Columbia Circuit held in Ferebee v. Chevron Chemical, Inc. that FIFRA’s preemption provision expressly preempting “state requirements,” did not preempt state damage actions. Furthermore, the Federal Cigarette Labeling and Advertising Act contains a preemption clause which declares that “[n]o requirement or prohibition . . . shall be imposed under state law with

Because there are some situations in which regulation of devices by States and localities would constitute a useful supplement to Federal regulation, the reported bill authorizes a State or political subdivision thereof to petition the Secretary for exemptions from the bill’s general prohibition . . . .

Id. at 45.

141. Id. at 45-6.
144. Id. § 136v(b).
145. 736 F.2d 1529 (D.C. Cir. 1984).
146. Id. at 1541; cf. Stewart v. International Playtex, Inc., 672 F. Supp. 907, 910 (D.S.C. 1987) (distinguishing the MDA and FIFRA preemption clauses by noting that the latter contains a savings clause allowing for state regulations).
respect to the advertising or promotion of any cigarettes." In *Cipollone*, the Supreme Court held that the federal act preempted state common law inadequate warnings claims. However, in contrast to *King*, the Supreme Court in *Cipollone* did not preempt all of the plaintiff's state common law claims. The Court left intact alternative remedies.

*Webster's Dictionary* defines "requirement" as "something that is wanted or needed" or "something that is called for or demanded." From these definitions, one may argue that common law does not compel or mandate compliance as do legislative or administrative acts. Common law liability may cause the manufacturer to alter its conduct so that it will not be held liable again, but it does not compel the manufacturer's response as does the FDA's mandate that a manufacturer meet a requirement or forego market distribution. Regulated parties must comply with the law; "[t]ort liability, on the other hand, encourages compliance by subjecting the defendant to economic pressure." Therefore, the *King* court's decision to preempt all of Ms. King's common law claims is misguided because it fails to recognize that there is no clear statement from Congress in the MDA or its legislative history which directs the FDA or courts to preempt state common law. Moreover, the *King* court's decision fails to reconcile the theory that common law liability does not

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150. *Cipollone*, 112 S. Ct. at 2625; cf. Ministry of Health v. Shiley, Inc., 858 F. Supp. 1426, 1440 (C.D. Cal. 1994) ("Under *Cipollone*, state claims against class III device manufacturers survive if the legal duty underlying the state claim either has a basis independent of the MDA's focus on the medical device's safety and effectiveness, or arises from the manufacturer and not from the State."). The *Ministry of Health* court held that claims for breach of warranty, fraud, and misrepresentation are not preempted. *Id.* at 1440.
151. *Cipollone*, 112 S. Ct. at 2622-24 (concluding that the Federal Cigarette Labeling and Advertising Act does not necessarily preempt claims against cigarette manufacturers for breach of express warranty, misrepresentation, or conspiracy).
153. Ausness, *supra* note 149, at 254 (noting Justice Blackmun's dissent in *Cipollone*, 112 S. Ct. at 2627-28). Justice Blackmun, joined by Justices Kennedy and Souter, dissented in *Cipollone*, asserting that common law damage awards are not the same as administrative regulations. *Cipollone*, 112 S. Ct. at 2627-28. Moreover, Blackmun noted that common law claims are different from statutes and administrative regulations because their primary concern is compensating injured parties. *Id.* at 2628.
155. *Id.* at 254. See Nace, *supra* note 128, at 28.
require compliance in the same manner as a law or regulation with its holding to preempt all of Ms. King’s claims.

The second flaw in the King decision is that it leaves plaintiffs without an adequate remedy. In Abbot v. American Cyanamid,156 the United States Court of Appeals for the Fourth Circuit stated that there is a strong presumption against preempting remedies, such as tort recoveries, when federal regulation does not provide an alternative remedy.157 Moreover, the Supreme Court has been reluctant to allow preemption by federal regulations without an express statement from Congress to “remove all means of judicial recourse for those injured.”158 Although the MDA provides remedies for plaintiffs aggrieved by devices proven to be unreasonably dangerous by the FDA, these remedies only provide for the device’s repair, replacement, or refund price.159 The MDA does not provide remedies to compensate plaintiffs for their injuries, such as pain and suffering, and additional medical care. Hence, plaintiffs are left without an adequate remedy. One court notes that, “[i]f the intent of Congress were to nullify an entire body of state consumer protection law, and leave the victims without a remedy, it would have specifically said so.”160

The King decision goes further in its opinion than any prior medical device common law claims. In the Class II medical device tampon cases where courts held that the MDA preempted plaintiffs’ state tort claims for inadequate warnings, the courts allowed claims to go forward based on negligent design and/or manufacture.161 The courts held that the

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156. 844 F.2d 1108 (4th Cir. 1988).
157. Id. at 1112.

This Court remains concerned with the lack of a criterion—such as an analysis under the Seventh Amendment—by which these courts are evaluating the reasonableness of a Congressional policy to foreclose victim’s common law rights in exchange for the common good. Therefore, it refuses to join any holding or dicta that finds Congress has acted in a wise manner in enacting § 360k.

MDA did not preempt these claims because the FDA did not regulate those aspects of the device. Therefore, the plaintiffs' claims could still be heard by juries with the chance of compensation for their injuries. The King court takes this chance of compensation away from plaintiffs injured by a Class III medical device. The King decision prohibits states from using their police powers to protect citizens' health and safety in this area, and it does so without regard for the lack of an alternative federal remedy. As such, King is contrary to the Supreme Court's decisions in Hillsborough, Silkwood, and Laburnum.

The third flaw in the King decision is that it conflicts with the MDA itself. Section 360h clearly denotes that the MDA's remedies, allowing for repair, replacement, or refund, will not "relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account." If Congress intended to preempt state common law, state damages would not be included in this section of the Act. It appears from this provision that Congress foresaw coexistence between state law, the MDA, and FDA medical device regulations, yet the King court does not address this section.

The fourth flaw in the King decision is its assertion that the preemption clause was "broad, but limited . . . [and that] the MDA does not preempt such claims as negligent implantation or removal of devices, or claims arising out of contaminated devices." While the court recognized that the preemption clause is limited, it failed to define those limitations other than excluding from preemption medical malpractice suits against doctors who negligently implant or remove a medical device. As far as the court's limitation on preemption of claims arising out of contaminated devices, the court's own decision could be read to disregard this limitation, at least for Class III medical devices. The court found that Class III medical devices are extensively regulated by the FDA, from their labeling and packaging, to their design and manufacturing. If a plaintiff alleges

162. Moore, 867 F.2d at 246-47; Rinehart, 688 F. Supp. at 478.
167. King v. Collagen Corp., 983 F.2d 1130, 1134 (1st Cir. 1993) (citing Slater v. Optical Radiation Corp., 961 F.2d 1330, 1334 (7th Cir.), cert. denied, 113 S. Ct. 327 (1992)).
168. Id. at 1135.
169. Id. at 1135-36.
that a Class III medical device is contaminated, the plaintiff is ultimately alleging that the manufacturing was negligent because contamination would only occur during the manufacturing process. According to the King court, because the FDA regulates the manufacturing of Class III medical devices, the MDA and FDA regulations would preempt the contamination claim. 170

One must also question the court’s refusal to preempt state common law claims arising from negligent implantation or removal of medical devices. 171 If a Class III medical device manufacturer included instructions to physicians on the proper implantation or removal of the device; and the FDA, in its approval of the device’s labeling and packaging, approved those instructions as “reasonably safe” for the implantation and removal of the device, would an injured plaintiff be allowed to make a state common law claim against a physician for negligence? King instructs courts to rule that state common law claims are preempted when the FDA has regulated the aspect of the medical device that a plaintiff claims injurious. 172 Applying the King decision, a court may preempt the plaintiff’s medical malpractice claim because it could result in a state requirement that would add or change the medical device’s labeling/packaging—already approved by the FDA. In this situation, a court should inquire whether the physician followed the FDA’s approved instructions included in the medical device’s packaging. If the physician did not follow the FDA-approved instructions, plaintiff’s claim would not be barred.

The courts in Rinehart and Ignace question the reason for preempting state common law claims based on negligent design, manufacturing, mislabeling, and inadequate warnings without considering whether the medical device manufacturer followed the FDA-approved design, manufacturing, labeling, and warnings regulations. 173 These courts agree with the King decision in that the FDA’s regulations of medical devices are the standard to be applied in state common law claims and neither the court nor the jury can impose additional requirements. 174 In contrast to King, these courts held that there is still a question of fact as to whether the medical device manufacturer complied with the FDA regulations. 175

170. Id. at 1136.
171. Id. at 1135.
172. Id. at 1134-37.
Therefore, to avoid preemption, plaintiffs alleging negligent manufacturing, mislabeling, or inadequate warnings would have to allege that the medical device manufacturer violated the applicable FDA regulations because it did not follow the FDA’s standards. Applying the Rinehart and Ignace rationale to Class III medical device common law claims, a plaintiff would also have to allege that the manufacturer did not follow the FDA’s applicable standards, as well as prove that the manufacturer deviated from its particular FDA-approved regulations.

The United States Court of Appeals for the Fifth Circuit soon followed King. It held in Stamps v. Collagen Corp. that the MDA preempts state common law claims in a suit arising from the use of Zyderm. Both King and Stamps have impacted health and safety. In a similar situation, Shiley, a manufacturer of heart valves (a Class III medical device), offered a $500 million settlement in 1992 to injured recipients of its FDA-approved devices. Had the King decision already been rendered, this settlement may have never occurred, and the recipients would have been deprived of compensation for their injuries. In fact, defendant Shiley is presently raising the King preemption defense in another case brought by 300 heart valve recipients. If King is followed, these plaintiffs will not be compensated for their injuries. “Indeed, the legal and economic impact of the courts’ decisions could be staggering, with hundreds of cases pending nationwide involving everything from optical implants to hip prostheses.”

176. Ministry of Health v. Shiley, Inc., 858 F. Supp. 1426, 1439 (C.D. Cal. 1994) (stating that the MDA “would not preempt claims that the manufacturer negligently failed to comply with the FDA’s regulations, since a finding of wrongdoing would merely impose those regulations already imposed by the statute, and would not be ‘different from or in addition to’ those imposed by the MDA.”) (citing Reiter v. Zimmer, Inc., 830 F. Supp. 199 (S.D.N.Y. 1993) (preempting plaintiffs strict liability claim, but not its negligent manufacture claim against manufacturer of Class III bone cement)) (emphasis in original).

177. 984 F.2d 1416 (5th Cir.), cert. denied, 114 S. Ct. 86 (1993).

178. Id. at 1422-23. The United States Court of Appeals for the Third Circuit also adopted the reasoning of the King and Stamps courts, holding that the MDA preempts a plaintiff’s state common law claim against an intraocular lens manufacturer. Gile v. Optical Radiation Corp., 22 F.3d 540, 542-44 (3d Cir.), cert. denied, 115 S. Ct. 429 (1994). Cf. Ministry of Health v. Shiley, Inc., 858 F. Supp. 1426 (C.D. Cal. 1994). The Ministry of Health court disagreed with the King court, and stated that the MDA does not create nor does Cipollone support complete preemption of all state common law claims. Id. at 1440.

179. Himelstein, supra note 48, at 73.

180. Id.

181. Id.
V. CONCLUSION

The Supreme Court’s decision to deny Ms. King’s petition for certiorari leaves her, having been injured from use of a Class III medical device, without an adequate remedy. Congress did not intend such a harsh result. It did not expressly preempt state common law, nor did it intend to preempt plaintiffs’ state protection through the judicial process.

A more equitable approach was taken by the courts in Rinehart and Ignace, where plaintiffs would have the burden of proving that manufacturers did not abide by the FDA-approved standards. In contrast, King gives manufacturers of Class III medical devices a government insurance policy. Once a manufacturer’s medical device is approved, plaintiffs’ state tort law claims are preempted. Under King, plaintiffs injured by a Class III medical device must rely upon the results of their complaints to the FDA and hope that others will not be injured as they have.

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