Medical Device Technology: Does Federal Regulation of This New Frontier Preempt the Consumer's State Common Law Claims Arising from Injuries Related to Defective Medical Devices?

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MEDICAL DEVICE TECHNOLOGY: DOES FEDERAL REGULATION OF THIS NEW FRONTIER PREEMPT THE CONSUMER'S STATE COMMON LAW CLAIMS ARISING FROM INJURIES RELATED TO DEFECTIVE MEDICAL DEVICES?

SUSAN M. MESNER

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I. INTRODUCTION

Recent advances in medical science and technology have resulted in the availability of a vast array of medical devices for use by physicians, health care professionals, and the ultimate health care consumer. This technological explosion has been described as the "new frontier" in medical science, with

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important implications for our national economy.\(^2\) In 1970, it was estimated that anywhere from five hundred to five hundred thousand medical devices were being produced by thirteen hundred to five thousand different manufacturers.\(^3\) Approximately five thousand medical devices enter the market every year.\(^4\)

The biomedical technology explosion has resulted in the development of many lifesaving technologies. However, these new technologies have also resulted in a rising number of consumer injuries related to defective medical devices. In 1970, a study performed by the Cooper Committee revealed accounts of some 10,000 injuries related to medical devices over a period of six years.\(^5\) Seven hundred thirty-one of these injuries resulted in death: 512 deaths and 300 injuries were attributed to heart valves; 89 deaths and 186 injuries to heart pacemakers, and 10 deaths and 8,000 injuries to intrauterine devices.\(^6\) More recently, approximately 18,000 deaths and illnesses were attributed to medical devices in the first year mandatory reporting was implemented by the FDA.\(^7\) It has been estimated that only forty-six percent of the problems related to medical devices have been reported to device manufacturers in the past.\(^8\)

Many of these injuries have resulted from implantable devices. For example, between 1977 and 1982, 15,000 defective pacemaker units were recalled.\(^9\) Congressional studies of Bjork-Shiley heart valves in 1990 revealed that heart valves were marketed long after defects in their design became evident.\(^10\) In


\(^5\) The Cooper Committee was a panel charged in 1969 with the task of reviewing the need for additional medical device legislation. After hearing the views of the medical community, the industry, and consumer representatives, the Cooper Committee recommended device legislation to provide for standard setting and premarket clearance for medical devices. See S. REP. No. 33, 94th Cong., 1st Sess. 7-8 (1975), reprinted in 1976 U.S.C.C.A.N. 1076-1077.

\(^6\) Id. at 1076.


\(^8\) Id.

\(^9\) STAFF OF SENATE COMM. ON AGING, 97th Cong., 2d Sess. FRAUD, WASTE, AND ABUSE IN THE MEDICARE PACEMAKER INDUSTRY, 26 (Comm. Print 1982).

addition, consumers have reported injuries resulting from other implantable devices, including breast prostheses and collagen implants.  

While recognizing the enormous potential of the medical device industry on our national economy, Congress has acknowledged the need to protect the public from harm related to defective or ineffective medical devices. In 1938, the Food Drug and Cosmetic Act (hereinafter "FD&C Act") provided the Food and Drug Administration (hereinafter "FDA") with limited authority to regulate the medical device industry. In 1976, largely in response to the Cooper Committee findings, Congress enacted a more comprehensive federal regulatory scheme, embodied in the Medical Device Amendments (hereinafter "MDA") of 1976. The 1976 Amendments were subsequently amended by the Safe Medical Devices Act of 1990 and the MDA of 1992. In addition, the FDA has promulgated extensive federal regulations related to medical devices.

Despite these concerted efforts to protect consumers from injuries related to defective medical devices, injuries resulting from defective and dangerous medical devices continue to be reported in the medical and legal literature. Recently, at the Subcommittee on Health and the Environment's November 6, 1989 hearing, General Accounting Office Comptroller General Charles A. Bowsher stated, "Our work reveals several shortcomings in both the premarket review and postmarket surveillance system for medical devices and raises serious questions about the ability of these systems and related regulations to protect the American people from unsafe and ineffective medical devices." In light of the difficulties Congress and the FDA have encountered in regulating the device industry, the issue of consumer injuries resulting from defective devices becomes paramount.

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14 Id.


16 Prior to 1986, a voluntary reporting system of device related injuries revealed 20,000 injuries over a nine year period. In comparison, 18,000 reports were received by the FDA's device surveillance program during the first year in which mandatory reporting was implemented. Speech by Chester Reynolds to the Food and Drug Law Institute (June 25, 1987), cited in Robert B. Leflar, Public Accountability and Medical Device Regulation, 2 HARV. L.J. & TECH., 1, n.223 (1989).

The purpose of this paper is to explore the relationship between federal medical device regulation and state common law tort actions. Specifically, the issue to be addressed is whether the Medical Devices Act and regulations promulgated thereunder preempt state law damage actions brought by injured consumers against device manufacturers.

An analysis of the preemptive provision of the Medical Devices Act and case law construing this provision is set forth below. The United States Supreme Court's recent preemption analysis in *Cipollone v. Ligget Group, Inc.*\(^\text{18}\) will be used as a guide in establishing a useful method for determining whether state tort claims arising out of consumer injuries resulting from defective medical devices are preempted by the Medical Devices Act.

II. PREEMPTIVE EFFECT OF FEDERAL LAWS AND REGULATIONS ON STATE TORT ACTIONS

A. The Federal Preemption Doctrine: Relationship Between Federal and State Laws

The relationship between the federal and state laws is governed by the Supremacy Clause of the United States Constitution.\(^\text{19}\) Under the authority of the Supremacy Clause, Congress has the power to preempt state authority by passing legislation expressly stating its intent to do so. "[T]he purpose of Congress is the ultimate touchstone” of pre-emption analysis."\(^\text{20}\) "Congress’ intent may be ‘explicitly stated in the statute’s language or implicitly contained in its structure and purpose.’"\(^\text{21}\) When Congress has expressly stated its intent to preempt state law in a given area of regulation, courts may be faced with the difficult task of determining the scope of preemption in a given context.\(^\text{22}\) In making this determination, the courts must analyze the specific language of the act in light of a presumption against preemption of state police powers.\(^\text{23}\)

Where Congress has not clearly expressed its intention to preempt state law, courts may determine that Congress impliedly preempted state law in a given area. Preemption may be implied when a court finds that Congress intended

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\(^{19}\) The Supremacy Clause of the U.S. Constitution, art. VI, cl. 2, provides that: This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any thing in the Constitution or the Laws of any State to the contrary notwithstanding.


\(^{21}\) *Cipollone*, 112 S. Ct. at 2617 (quoting Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977)).

\(^{22}\) *See Cipollone*, 112 S. Ct. 2608, discussed infra at 7-17.

\(^{23}\) *Cipollone*, 112 S. Ct. at 2618.
to occupy a given field to the exclusion of state law,24 when state and federal laws conflict,25 or when compliance with both the state and federal law is impossible.26

Courts are less likely to find federal preemption in areas traditionally relegated to state police powers.27 In these types of cases, Congress must exhibit a "clear and manifest" intent to preempt state law governing the same subject matter.28 When Congress has not expressly stated its intention, there is a presumption against preemption.29 The presumption against preemption is stronger with respect to state and local regulation of matters related to health and safety, which are traditionally regulated by the states.30

The growth of federal regulatory agencies requires courts to also consider the preemptive effect of federal regulations issued pursuant to Congressional statutory authority. In general, when Congress has given an agency authority to act, the resulting federal regulations have no less preemptive effect than the federal statutes.31 However, judicial deference to administrative interpretations of a statute is not total. The courts remain the final authorities on issues of statutory interpretation and are not required to approve an administrative interpretation.32 Regulations which are unauthorized by the enabling legislation or inconsistent with the underlying statute should not be

24 Abbot v. American Cyanamid, 844 F.2d 1108 (4th Cir. 1988), cert. denied, 488 U.S. 908 (1988) (federal preemption of state law occurs if Congress implies that it has preempted state law by occupation of entire field of regulation, but concluding that there is no preemption of vaccine-related design defect and failure to warn claims).

25 See Florida Lime & Avocado Growers v. Paul, Inc., 373 U.S. 132 (1963) (statute governing maturity of avocados was not preempted by federal marketing laws since there was no actual conflict between state and federal law).

26 Abbot, 844 F.2d at 1109 (federal preemption of state law occurs if compliance with state and federal law is impossible, but failing to find preemption of vaccine-related tort claims).


32 New Jersey Guild of Hearing Aid Dispensers v. Long, 75 N.J. 544, 384 A.2d. 795 (1978) (analyzing the preemptive scope of the federal regulatory scheme under the Medical Device Amendments of 1976, and concluding that the regulatory scheme permits a wide variety of conceivable state regulations to remain in effect).
A regulation should not be given preemptive effect if it appears from the statute or its legislative history that the regulation is not one that Congress would have intended.\(^3\)

Traditionally, the federal preemption doctrine has been applied to determine whether a positive federal enactment or regulation preempts a positive state enactment in a given area. In addition, on at least two occasions the Supreme Court has considered the issue of whether federal regulations preempt state tort law claims.

In *Silkwood v. Kerr-McGee Corp.*,\(^3\) the United States Supreme Court considered the preemptive effect of federal regulations on state tort law. The plaintiff claimed injuries related to unsafe practices at a nuclear power plant. The Court found that federal law regulating nuclear power plants did not preempt a claim for punitive damages against a plutonium manufacturer. Emphasizing the fact that Congress had not provided a federal remedy for persons injured by the manufacturer's conduct, the Court stated that it was difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by such conduct.\(^3\)

**B. The Cipollone Analysis: Federal Preemption of Tort Claims**

Recently, in *Cipollone v. Ligget Group Inc.*,\(^3\) the United States Supreme Court set forth an intricate analysis of federal preemption of state common law tort actions with respect to federal labeling requirements on cigarette packages and cigarette advertising. The *Cipollone* decision sets forth a useful analysis for determining the preemptive effect of federal regulation on tort law in other areas as well. Accordingly, the *Cipollone* analysis will be used to consider the preemptive effect of the Medical Devices Act on state tort law actions brought by consumers who have been injured by defective medical devices.

In *Cipollone*, the plaintiff, Rose Cipollone, was a lifetime cigarette smoker who discovered that she was dying of cancer. She and her husband brought a common law products liability suit against three cigarette companies alleging, *inter alia*, strict liability, negligence, intentional tort, and breach of warranty.\(^3\)

The complaint alleged nine counts arising from state tort law.\(^3\) On the whole, the complaint was grounded in negligence, strict liability, breach of express and implied warranty, and negligent and intentional misrepresentation.\(^4\)
negligence claims alleged that the defendant was negligent in testing, researching, promoting and advertising the cigarettes. The strict liability claims alleged design defect based on alternative design and risk-utility theory. In addition, the plaintiff alleged strict liability on the basis of failure to warn of the hazards of cigarette smoking. Finally, the Cipollones alleged that Liggett Group had conspired to deprive the public of medical and scientific knowledge reflecting the dangers associated with cigarettes. The manufacturers asserted that all of the plaintiffs' claims were preempted by federal warning and labeling requirements set forth in the Federal Cigarette and Labeling Act.

The Federal Cigarette Labeling and Advertising Act of 1965 (hereinafter the "1965 Act") required a conspicuous label warning of the health hazards of smoking to be placed on every package of cigarettes sold in this country. Section 5 of the Act was a preemptive provision, which provided that:

(a) No statement relating to smoking and health, other than the statement required by section 4 of this Act, shall be required on any cigarette package.

(b) No statement relating to smoking and health shall be required in the advertising of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.

This preemptive provision was amended in 1969 to replace section 5(b) with the following provision: "(b) No 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 Act."

After a tortuous course of litigation in the lower courts, the United States Supreme Court recognized the manifest importance of the preemption issue

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41 Id. at 665-67.
and granted *writ of certiorari* in order to resolve the conflicting state and federal rulings on the preemptive effect of federal statutes.\(^4\)

The specific issue reviewed by the United States Supreme Court was whether cigarette manufacturers could be subjected to state tort liability when they had complied with the warning and labeling requirements required by the 1965 Act and the Public Health Cigarette Smoking Act of 1969 (hereinafter the "1969 Act").\(^4\) The Court reviewed the nature of the plaintiffs' claims, the procedural history of the case, the history of the 1965 Act, and the context in which the amendment to the Act was made.\(^4\)

The Supreme Court's preemption analysis began with the Supremacy Clause of the United States Constitution. First, the Court noted that "[c]onsideration of issues arising under the Supremacy Clause 'start[s] with the assumption that the historic police powers of the States [are] not to be superseded by ... Federal Act unless that [is] the clear and manifest purpose of Congress.'"\(^4\)

The Supreme Court noted that, in the absence of an express congressional command, state law may be preempted only if the law actually conflicts with the federal law, or it so thoroughly occupies the legislative field that Congress left no room for the states to supplement it.\(^5\) The Court rejected the court of appeals' implied preemption analysis, and instead stated that, "the preemptive scope of the 1965 Act and the 1969 Act [was] governed entirely by the *express language* in section 5 of each Act."\(^5\) Applying the principle of *expressio unius est exclusio alterius*,\(^5\) the Court found that "Congress' enactment of a provision defining the preemptive reach of a statute implies that matters beyond that reach are not preempted."\(^5\) The Court found no reason to look beyond the express words of the statute to employ an implied preemption analysis.\(^5\)

Since the provisions of the 1965 Act and the 1969 Act differed substantially, the Court analyzed the claims separately under each Act. With respect to the

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\(^{4}\) *Cipollone*, 112 S. Ct. at 2608.

\(^{4}\) *Id.*

\(^{4}\) *Id.* at 2613-17. See Part I and II of the opinion.

\(^{4}\) *Id.* at 2617 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

\(^{5}\) *Cipollone*, 112 S. Ct. at 2617.

\(^{5}\) *Id.* at 2618.

\(^{5}\) Latin phrase meaning "the expression of one thing is the exclusion of another." [BLACK'S LAW DICTIONARY](http://blackslawdictionary.com) 581 (6th ed. 1990).

\(^{5}\) The Court reasoned that, "when Congress has included an express provision explicitly addressing preemption, and that provision provides a 'reliable indicium' of congressional intent, with respect to state authority," (Malone v. White Motor Corp., 435 U.S. 505 (1986)), "there is no need to infer congressional intent to preempt state laws." (California Fed. Sav. & Loan Ass'n v. Guerra, 479 U.S. 272 (1987)).

\(^{5}\) *Cipollone*, 112 S. Ct. at 2618.
1965 Act, the Court found that the express terms of the statute prohibited only *statements* relating to smoking and health, and that the term *statement* referred to the verbatim warning set forth in the statute. Therefore, the 1965 Act "merely prohibited state and federal rulemaking bodies from mandating particular cautionary statements on cigarette labels (s. 5(a)) or in cigarette advertising (s. 5(b)),"55 and did not preempt state damage actions.

In addition to its reliance on the precise words of the 1965 Act, the Court supported its narrow reading of the 1965 Act by noting the presumption against preemption of state police powers.56 The Court stated that the fact that Congress requires a specific warning label does not, of its own effect, foreclose additional obligations under state law.57 The Court concluded that there was no general, inherent conflict between federal preemption of state warning label requirements and the continued vitality of state common law damage actions.58 Finally, the Court stated that the narrow reading of the 1965 Act comported with the Act's statement of purpose, and the regulatory context in which the Act was enacted.59

Based on this narrow reading of the preemptive provision of the 1965 Act, the Court concluded that the 1965 Act did not preempt any of Cipollone's state law damage actions. Justice Stevens delivered the opinion of the Court with respect to Parts I, II, III, and IV, concluding that section 5 of the 1965 Act did not preempt state law damages actions, but superseded only positive enactments by state and federal rulemaking bodies mandating particular warnings on cigarette labels or in cigarette advertising. Justices Rehnquist, White, O'Connor, Blackmun, Kennedy, and Souter joined in the majority opinion with respect to the 1965 Act.60

Justice Stevens, writing for himself and Justice Rehnquist, White, and O'Connor, then proceeded to analyze the preemptive scope of the 1969 Act.61 He found the language of the 1969 Act, which barred "requirement[s] or prohibition[s] . . . imposed under State law" much broader than the language

55 *Id.*

56 *Id.*

57 *Id.*

58 *Cipollone*, 112 S. Ct. at 2618.

59 *Id.* at 2619.

60 Justice Scalia and Justice Thomas dissented from the majority opinion with respect to the 1965 Act. In particular, they rejected the presumption against preemption of state police power regulations. They felt that the preemptive provision should be interpreted in accordance with its apparent meaning, and that doing so with respect to the 1965 Act would preempt the petitioner's failure-to-warn claims. *Cipollone*, 112 S. Ct. at 2632.

61 *Id.* at 2619.
of the 1965 Act. In addition, the Court noted that the 1969 Act reached beyond statements "in the advertising" of cigarettes to obligations "with respect to the advertising or promotion" of cigarettes. Based on the broader language and the context in which these changes were made, the Court concluded that the 1969 Act worked substantial changes in the preemptive scope of the federal law.

Justice Stevens noted that the phrase "requirement or prohibition" suggested no distinction between positive enactments and common law. In the Court's mind, this was the major distinction between the 1965 Act and the 1969 Act. He reasoned that "the common law would not normally require a vendor to use a particular statement, . . . it is the essence of the common law to enforce duties that are either affirmative requirements or negative prohibitions." Furthermore, Justice Stevens concluded that the term "state law" includes common law, as well as statutes and regulations.

Justice Stevens did not find that the 1969 Act preempted all common law claims, however. Instead, he stated that the Court must "fairly but—in light of the strong presumption against pre-emption—narrowly construe the precise language of section 5 (b) and . . . look to each of petitioner's common law claims to determine whether it is in fact pre-empted." The proper inquiry, he announced, was "whether the legal duty that is the predicate of the common law damages action constitutes a 'requirement or prohibition based on smoking and health . . . imposed under State law with respect to . . . advertising or promotion' giving that clause a fair but narrow reading."

Justice Stevens then proceeded to consider each category of the plaintiffs' claims. He found that Cipollone's claims that the cigarette manufacturers were negligent in the manner in which they tested, researched, sold, promoted, and advertised their cigarettes, and the claim that the manufacturers failed to provide "adequate warnings of the health consequences of cigarette smoking"...
were based on claims for failure-to-warn. He concluded that "insofar as claims under either failure to warn theory require a showing that respondents' post-1969 advertising or promotions should have included additional, or more clearly stated, warnings, those claims were pre-empted."73 Cipollone's claims relying solely on testing or research practices unrelated to advertising and promotion, however, were not preempted.74

Next, Justice Stevens addressed the breach of express warranty claim.75 He noted that, although this claim arose under a New Jersey statute, much of the petitioner's evidence with respect to the claim consisted of statements made in respondents' advertising.76 He emphasized, however, that "the test is not whether a claim challenges the 'propriety' of advertising and promotion, but whether the claim would require the imposition under state law of a requirement or prohibition based on smoking and health with respect to advertising or promotion."77 Since the manufacturers' liability for breach of an express warranty arose from a contractual commitment voluntarily undertaken, it was not a duty "imposed under state law."78 Therefore, the post-1969 breach of warranty claim was not preempted.

Next, Justice Stevens turned to Cipollone's fraudulent misrepresentation claims. He found that the petitioner's claim that the manufacturers, through their advertising, neutralized the effect of federally mandated warning labels was predicated on a state-law prohibition against statements in advertising and promotional materials that minimize health hazards related to smoking.79 Therefore, this cause of action was preempted.

Justice Stevens found that petitioner's other claims, based on intentional fraud and misrepresentation, were based both on false representations and concealment of material fact.80 He concluded that the claims based on concealment were not preempted because they were based on a state law duty to disclose such facts through channels of communication other than advertising or promotion.81 In addition, he found that the claims based on false statements of material fact did not arise from a duty "based on smoking and health."82 Instead, they arose from the more general duty not to deceive, and thus, were not preempted.

73 Id.
74 Id.
75 Cipollone, 112 S. Ct. at 2622.
76 Id.
77 Id.
78 Id.
79 Cipollone, 112 S. Ct. at 2623.
80 Id.
81 Id.
82 Id. at 2624.
The only remaining claim, conspiracy to misrepresent or conceal material facts, was also not preempted. Justice Stevens found that this claim was based on an underlying duty not to conspire to commit fraud, and was not a prohibition "based on smoking and health." Justice Blackmun, Kennedy, and Souter concurred in the opinion with respect to the express warranty, intentional fraud, misrepresentation, and conspiracy claims. They felt that the 1969 Act did not provide the clear mandate necessary to preempt any of Cipollone’s state common law damage actions. Furthermore, they noted that common law damage remedies exerted only an indirect regulatory effect on manufacturers, and damage actions were not clearly and unambiguously "requirements" or "prohibitions" imposed under state law. In their opinion, neither the 1965 Act or the 1969 Act should have preempted any of petitioner’s claims.

In addition, Justice Blackmun, Kennedy, and Souter criticized the Court for creating a "crazy quilt of pre-emption" from among the common law claims implicated in this case, a result that Congress surely did not intend. Furthermore, they felt that the Court’s opinion readjusted the state-federal relations, and impinged on the state’s traditional ability to protect the health and safety of its citizens.

Justice Scalia and Justice Thomas, on the other hand, felt that all of Cipollone’s failure-to-warn claims were preempted under the 1965 Act and that all of Cipollone’s claims should be preempted under the 1969 Act. They criticized the Court for announcing two "new principles." First, they took issue with the principle that express preemption provisions should be given a narrow construction. Instead, they felt that the language of the statute should be given its plain meaning. Secondly, the dissenters criticized the Court’s reliance on express preemption, and the Court’s refusal to employ the well established rules of implied preemption. Finally, Justice Scalia and Thomas
expressed concern over the "difficulty lower courts would encounter in attempting to implement the decision" announced by the Court.\footnote{Id. at 2637.}

Since the announcement of the United States Supreme Court's decision in \textit{Cipollone}, the Court's preemptive analysis has been applied to other federal regulatory schemes in an effort to determine their preemptive effect on state law damage actions. For example, the preemptive scope of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)\footnote{7 U.S.C.A. §§ 136-136y (1993).}, particularly on state law failure-to-warn claims, has been addressed by the federal courts.\footnote{See, e.g., Ferebee \textit{v. Chevron Chemical Co.}, 552 F. Supp. 1293 (1982), \textit{aff'd}, Ferebee \textit{v. Chevron Chemical Co.}, 736 F.2d 1529 (1984), \textit{cert. denied}, 469 U.S. 1062 (1984).} The pertinent statutory language in FIFRA provides that a state "shall not impose or continue in effect any requirement for labeling . . . in addition to or different from those required under this subchapter."\footnote{77 U.S.C.A. § 136y (1993).} In a pre-\textit{Cipollone} decision addressing the preemptive scope of FIFRA, the Court of Appeals for the District of Columbia, using an implied preemption analysis, affirmed the District Court's ruling granting summary judgment to Upjohn Co. on the issue of preemption.\footnote{\textit{Papas v. Upjohn Co.}, 926 F.2d 1019 (11th Cir. 1991), \textit{vacated and remanded sub. nom, Papas v. Zoecon Co.}, 112 S. Ct. 3028 (1992) (on authority of \textit{Cipollone}, 112 S. Ct. 2608 (1992)); \textit{aff'd}, Papas \textit{v. Upjohn Co.}, 985 F.2d 516 (11th Cir. 1993) (on authority of \textit{Cipollone}, 112 S. Ct. 2608 (1992)).}\footnote{\textit{Papas}, 112 S. Ct. 3020 (1992).} Papas appealed to the Supreme Court and following its decision in \textit{Cipollone} that Court vacated the decision in \textit{Papas} and remanded the case to the Court of Appeals.\footnote{Papas \textit{v. Upjohn Co.}, 985 F.2d 516 (11th Cir. 1993).} On remand, the Court of Appeals for the Eleventh Circuit applied an express preemption analysis and held that FIFRA expressly preempted the Papas' claims.\footnote{Papas \textit{v. Upjohn Co.}, 985 F.2d 516 (11th Cir. 1993).}

The \textit{Cipollone} analysis may also provide a useful framework for evaluating the preemptive scope of the FDA's regulatory scheme governing the manufacture and marketing of medical devices. This issue is of particular concern, given the number of serious injuries and deaths attributable to medical devices. With this in mind, the remainder of this paper will focus on the preemptive scope of the MDA and regulations promulgated thereunder on state law damage actions arising from defective medical products.

A. Legislative Analysis of the 1976 Medical Device Amendments and Subsequent Amendments of 1990 and 1992

The Food and Drug Administration, an agency within the U.S. Department of Health and Human Services, bears primary responsibility for regulation of medical devices. The overriding objective of the agency is the protection of the public from potential health hazards resulting from adulterated and mislabeled foods, cosmetics, medical devices and drugs.

Legislation regulating medical devices was first passed in 1938. The purpose of the 1938 Act was "to prohibit the movement in interstate commerce of adulterated and misbranded food, drugs devices, and cosmetics." A device was considered to be "adulterated" if it was subjected to insanitary storage, packaging, or manufacturing conditions, and "misbranded" if its labeling was false or misleading in any particular, or if the device did not bear adequate directions for use.

In addition to the regulations set forth under the provisions of the Food, Drug, and Cosmetic Act (hereinafter "FD&C Act") of 1938, concerns about the safety and effectiveness of medical electronic and radiation products were addressed by Congress in the Radiation Control for Health and Safety Act of 1968. Under the authority of this Act, the Secretary of Health, Education, and Welfare was directed to prescribe performance standards on a product-by-product basis, as he deemed necessary to reduce the exposure of the public to unnecessary hazardous radiation from electronic products.

Although violation of the provisions of the 1938 FD&C Act was a criminal offense, the enforcement measures under the Act were inadequate because the FDA had no regulatory power under the provisions of the 1938 Act to institute premarket approval measures, or to promulgate specific standards applicable to specific medical devices. Attempts to regulate the industry under the 1938 Act were limited to seizure of misbranded or adulterated devices on a case-by-case basis, injunctive measures, and criminal prosecutions with the imposition of fines on noncomplying manufacturers.

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102 Id.
103 Id. at 1050, § 502(a) and § 502(f) (current version at 21 U.S.C. § 352(a) and § 352(f) (1993), respectively).
As the medical device industry grew, the regulatory measures set forth in the 1938 Act were found to be inadequate. In 1976, a Congressional Committee headed by Theodore Cooper reported a finding of 10,000 recorded injuries resulting from medical devices, with 731 resulting in death.\textsuperscript{107} Research performed by the Emergency Care Research Institute showed that, the problems associated with most medical devices which may lead to adverse effects, including injury or death, are, in order of decreasing incidence: (1) Operator error resulting from inadequate training, (2) deficiencies in repair maintenance inspection and control of devices within health care facilities, (3) fundamental design deficiencies, and (4) deficiencies in manufacturing quality control.\textsuperscript{108}

The Cooper Committee recommended additional legislation to require standard setting and pre-market clearance for medical devices.\textsuperscript{109} These changes were designed to strengthen the FDA's regulatory powers and to provide additional remedies which the FDA could employ to remove defective or dangerous devices from the market.

In response to the findings of the Cooper Committee, Congress passed the MDA of 1976.\textsuperscript{110} The 1976 Amendments set forth a comprehensive regulatory scheme, setting forth rulemaking procedures for the development of general controls and performance standards for many medical devices.\textsuperscript{111} A formal licensing scheme for premarket approval of the most dangerous products was also established.\textsuperscript{112} In addition, the 1976 MDA regulatory scheme established postmarket remedial measures\textsuperscript{113} and procedures for judicial review of actions undertaken by the agency.\textsuperscript{114}

The regulatory scheme of the MDA of 1976 establishes three broad classifications of medical devices. First, the Amendments set forth general regulatory controls applicable to all medical devices. These include product registration,\textsuperscript{115} product reporting requirements,\textsuperscript{116} good manufacturing

\textsuperscript{108}Id. at 1077.
\textsuperscript{109}Id.
\textsuperscript{111}Id. For a thorough analysis of the formal and informal rulemaking processes established in the MDA. See Leflar, \textit{supra} note 16, at 1.
\textsuperscript{112}See FD&C Act § 515, codified at 21 U.S.C. § 360e.
\textsuperscript{113}See FD&C Act § 517, codified at 21 U.S.C. § 360h.
\textsuperscript{114}See FD&C Act § 517, codified at 21 U.S.C. § 360g.
practices, and regulations governing adulterated and misbranded devices.

Under the provisions of the 1976 MDA, the least hazardous devices were classified as Class I medical devices. These devices were to be regulated only through the general regulatory controls, provided that, (1) the controls were sufficient to provide a reasonable assurance of safety and effectiveness, and that (2) the device was not purported 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, and does not present a potential unreasonable risk of illness or injury.

Under the initial regulatory scheme, if general controls were deemed to be insufficient to provide a reasonable assurance of safety, the product was classified as a Class II medical device, provided that there was sufficient information available to establish a performance standard to provide the assurance of safety. The FDA was given the authority to promulgate performance standards for Class II devices, mainly through informal notice and comment procedures. The development of performance standards under the 1976 Amendments, was not mandatory, however, and the FDA had the option of adopting existing standards, or of accepting proposals by industries or outside organizations to develop performance standards.

Class III devices, the most hazardous category, are defined as those devices for which there is insufficient information to establish a performance standard for the reasonable assurance of safety, and the device was "purported . . . 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 presents a potential unreasonable risk of illness or injury." Class III medical devices were subject to full premarket approval by the FDA.

Under the provisions of the 1976 Act, the FDA was charged with the authority to classify all medical products into one of the three categories, and

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119 Boguslaski, supra note 3, at 422.
120 Id. at 425.
122 MDA of 1976, § 514(f), as codified at 21 U.S.C. § 360d(f), providing that "the Secretary may . . . proceed to develop a proposed performance standard."
to promulgate appropriate performance standards and premarket approval procedures as required for the reasonable assurance of safety of a medical device marketed in interstate commerce. This task proved to be more difficult than anticipated. The original panels which reviewed all preenactment medical devices placed 62% of the currently marketed devices into Class II, which required the development of performance standards for the reasonable assurance of safety to the consumer of the product.\footnote{Boguslaski, supra note 3, at 426 (citing Medical Devices Law & Regulation 216 (S. Weitzman ed. 1981)); 21 U.S.C. § 360(a)(1)(B).}

In addition to classification according to the degree of hazard a device posed, the Act created seven other categories of devices.\footnote{For an excellent discussion of the significance of each of these classifications, see generally David A. Kessler, et al., The Federal Regulation of Medical Devices, 317 NEW ENG. J. MED. 357 (1987).} Devices were grouped according to whether they were pre-amendment, post-amendment, or substantially equivalent. Pre-amendment devices\footnote{Pre-amendment devices refer to devices marketed before the effective date of the Medical Devices Act on May 28, 1976.} were to be classified into one of the three groupings discussed above. The Act created a presumption that a pre-amendment device would be placed in Class I unless greater regulation was necessary to ensure the safety and effectiveness of a device.\footnote{FD&C Act, § 513, codified at 21 U.S.C. § 360(c)(2)(c)(i).} Post-amendment devices\footnote{Post-amendment devices refer to those devices that were new and were placed on the market after the effective date of the Medical Devices Act on May 28, 1976.} were automatically to be placed in Class III unless the device was shown to be "substantially equivalent" to a device already on the market.\footnote{FD&C Act, § 513(f), codified at 21 U.S.C. § 360c(f).} Upon a showing of substantial equivalence, devices were to be placed in the same category as their pre-amendment counterpart.\footnote{See Kessler, et al., supra note 126, at 358.}

Furthermore, the Act created separate categories for implantable, custom, investigational, and transitional devices.\footnote{Id.} Implantable devices, such as pacemaker generators were placed in Class III.\footnote{21 C.F.R. § 812.3(d) (1992).} Devices which had been regulated as drugs prior to the enactment of the Medical Devices Act were labeled as "transitional" devices, and were automatically placed in Class III, but could be reclassified into Class I or II upon a specific showing by the manufacturer that the lesser classification was sufficient to ensure a reasonable degree of safety.\footnote{FD&C Act, § 520(l)(1), codified at 21 U.S.C. § 360j(l)(1).} Custom devices specifically designed for a particular patient were exempt from performance standards and premarket testing, and

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\footnote{For an excellent discussion of the significance of each of these classifications, see generally David A. Kessler, et al., The Federal Regulation of Medical Devices, 317 NEW ENG. J. MED. 357 (1987).}

\footnote{Pre-amendment devices refer to devices marketed before the effective date of the Medical Devices Act on May 28, 1976.}

\footnote{FD&C Act, § 513, codified at 21 U.S.C. § 360(c)(2)(c)(i).}

\footnote{Post-amendment devices refer to those devices that were new and were placed on the market after the effective date of the Medical Devices Act on May 28, 1976.}

\footnote{FD&C Act, § 513(f), codified at 21 U.S.C. § 360c(f).}

\footnote{See Kessler, et al., supra note 126, at 358.}

\footnote{Id.}

\footnote{21 C.F.R. § 812.3(d) (1992).}

\footnote{FD&C Act, § 520(l)(1), codified at 21 U.S.C. § 360j(l)(1).}
upon proper application and approval, investigational devices could also be exempted from regulation.135

Due 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. Congressional Oversight Hearings which took place in 1982 and 1983 revealed that the FDA had failed to carry out the Congressional intent.136 Performance standards for Class II medical devices had not been promulgated. Furthermore, many manufacturers of Class III products availed themselves of the abbreviated premarket notification procedure set forth in section 360k of the Act, rather than the more thorough, burdensome premarket approval process set forth in section 360c of the Act.137 As a result, unsafe and defective medical products continued to be marketed in interstate commerce and abroad.138

Congress has repeatedly attempted to strengthen the FDA's compliance and implementation of regulatory activities under the MDA. Despite these regulatory attempts, marketing of products which are hazardous to consumer safety has continued. Congress' most recent attempts to strengthen FDA regulatory activities are reflected in the Safe Medical Devices Act of 1990 and the MDA of 1992.139 These amendments impose more stringent reporting requirements for device related injuries on device manufacturers and users.140 In addition, the 1990 enactment substitutes a variety of "special controls" for Class II devices which may be imposed in lieu of or in addition to the prior "performance standards" approach required under the 1976 MDA.141 The 1990 Act also clarifies the definition of "substantial compliance" required in order to qualify for the abbreviated section 510 premarket notification process, and incorporates "design validation" as an additional "good manufacturing


137Premarket notification procedures, 21 U.S.C. § 360(k); premarket approval requirements, 21 U.S.C. § 360e.


practice" concept. The 1990 legislation also imposes a timetable for classifying all preenactment devices and submitting them for premarket approval.

Neither the 1990 or the 1992 amendments altered the preemptive provision of the MDA, as originally set forth in the 1976 Medical Devices Act. A careful examination of this provision is the first step in the analysis of whether state tort law damage actions are preempted by the Medical Devices Act.

B. Examination of the Precise Language of § 521(a) of the Medical Device Amendments

According to the analysis set forth by the United States Supreme Court in *Cipollone v. Liggett Group, Inc.*, an examination of preemption "start[s] with the assumption that the historic police powers of the States [are] not to be superseded by... Federal Act unless that [is] the clear and manifest purpose of Congress." Therefore, the first consideration in the preemption analysis of the MDA is an examination of the purpose of Congress in enacting the MDA.

The MDA was enacted in response to growing concerns about injuries related to defective medical devices. Recognizing that the measures defined in the FD&C Act of 1938 were inadequate to ensure that devices on the market were safe and effective, Congress enacted the MDA to protect the public and promote safety in the manufacture of medical devices.

In addition, Congress recognized the importance of encouraging research and development of new devices, and was concerned that multiple and conflicting state standards or regulations might impede interstate commerce with respect to medical devices. Section 521(a) of the MDA reflects the balance that Congress struck in weighing these competing considerations.

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145112 S. Ct. at 2608.

146Id. at 2617 (quoting Rice v. Sante Fe Elevator Corp., 331 U.S. 218, 230 (1947)).


Section 521 of the MDA of 1976 governs state and local requirements respecting devices.\textsuperscript{151} Section 521(a) establishes a three-part test which must be satisfied in order for preemption to apply.\textsuperscript{152} First, the state must "establish or continue in effect with respect to a device intended for human use any requirement."\textsuperscript{153} (emphasis added). Second, the requirement must be "different from or in addition to, any requirement applicable" to a device under the Act.\textsuperscript{154} (emphasis added). Third, the state requirement must relate "to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device" under the Act.\textsuperscript{155} (emphasis added).

The first question which must be addressed in analyzing section 521(a) is whether this provision is intended to preempt state tort law. The proper inquiry is whether the legal duty that is the predicate of the common law damages action constitutes "a requirement which is different from or in addition to any requirement applicable to the device under the MDA, . . . and relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device," giving that clause a fair but narrow reading.\textsuperscript{156}

\textsuperscript{151} MDA of 1976, § 521, Pub. L. No 94-295, 90 Stat. 539 (1976) codified at 21 U.S.C. § 360(k) provides as follows:

\textbf{General Rule}

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

(1) which is different from, or in addition to, any requirement applicable under this 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.

\textbf{Exempt requirements}

(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.

\textsuperscript{152} Id.

\textsuperscript{153} Id.

\textsuperscript{154} Id.


\textsuperscript{156} Id.
This analysis requires a determination of whether state tort law constitutes a state "requirement" within the meaning of § 521. The legislative history of the MDA does not contain any direct evidence that Congress, in enacting section 521(a), intended to preempt state tort law.157

The original version of the MDA was introduced in 1973.158 The preemptive provision of the amendments, as originally introduced, referred to "standard[s] or regulation[s]," instead of using the term "requirement."159 This version, introduced as S. 2368, was recommended for passage by the Senate in 1974, but the House of Representatives was unable to complete its deliberations on the legislation that year.160 Identical legislation was reintroduced in 1975 as S. 510. S. 510 was passed by the Senate, but upon introduction to the House of Representatives, an amendment was proposed which struck out all of the Senate Bill after the enacting clause and inserted the substitute text of H.R.


158Senator Kennedy introduced S. 2368 in 1973. Two other versions of the legislation known as the Javitz-Administration Bill (S. 1446) and the Nelson Bill (S. 1337) were introduced for consideration. Neither the Javitz nor the Nelson version of the 1973 Act contained a preemptive provision comparable to the current version of § 521 of the Medical Devices Act. The Kennedy version was reintroduced as S. 510 in 1975, and was approved by the Senate. However, the House substituted the current version of § 521 during its deliberations. Hearings on S. 2688, S. 1446, S. 1337 Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare, 93d Cong., 1st Sess. 1079-1116 (1973) (comparison of legislation).

159The 1973 version of the Act is published in Medical Device Amendments, 1973: Hearings on S. 2368, S. 1446, S. 1337, Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare, 93d Cong., 1st Sess. 78-79 (1973). The 1975 version of the Act is published in the Hearings Before the Subcomm. on Health and the Env't of the Comm. on Interstate and Foreign Commerce of the U.S. House of Representatives, 94th Cong., 1st Sess. 76-78 (1975). The 1973 and 1975 versions of the Amendments also contained exemption provisions which were similar to the exemptions in § 521(b). The 1973 preemptive provision provided that,

Sec. 903 (a) Whenever a standard pursuant to section 513 or scientific review pursuant to section 514 under this Act is in effect, no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision of a standard or regulation which prescribes any requirements as to the performance, composition, content, design, finish, construction, packaging, or labeling of such product which are designed to deal with the same device unless such requirements are identical to the Requirements of the Federal requirements. (emphasis added).

Section 903(a) was intended to,

[Prohibit] States from establishing or maintaining standards or regulations for any device which is specifically subject to an official Federal standard or scientific review, unless State requirements are identical to the Federal requirements.


161id.
This version of the Amendments contained the preemptive provision which was ultimately enacted as section 521 of the Medical Devices Act of 1976. The legislative history of section 521(a) indicates that the Senate version was intended to preempt state "standard[s] or regulation[s]." The term "regulation" generally refers to positive enactments, and not to common law damages actions. Therefore, it seems that Congress did not originally intend the Medical Device Amendments to preempt state tort law.

Section 521(a) as enacted, however, preempts any state "requirement" that is "different from or in addition to a requirement applicable" to the device under the MDA. The language of the enacted version of the MDA has been given a broad reading. For example, the FDA has promulgated regulations defining the scope of preemption under section 521. The Code of Federal Regulations, Chapter 21 Part 808.1(b) interprets section 521(a) in the following manner:

Section 521(a) ... 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.

Under the FDA's interpretation of section 521(a), state "court decisions" having the full force and effect of law are preempted. The FDA's reading of section 521 as preempting court decisions has generally been interpreted by the courts to include state tort law.

However, one federal district court has rejected the FDA's broad interpretation of the term "requirement" within the meaning of section 521 of
In Callan v. G.D. Searle & Co., the plaintiff brought an action to recover for injuries she sustained as the result of the use of an intrauterine device. The IUD was a transitional device under the MDA, since it had been regulated as a drug prior to the 1976 Amendments. The plaintiff sued to recover for her injuries on the theories of negligence, strict liability, fraudulent misrepresentation, and breach of warranty.

The court in Callan analyzed the language and the legislative history of the preemptive provision of the MDA, and concluded that the provision does not preempt state tort claims. Although the court took note of the FDA regulation, 21 C.F.R. § 808.1(b), cited above, it found that the regulation conflicted with the plain language of the statute, contradicted Congressional intent, and was not based on a permissible construction of the statute.

The court in Callan stated that,

The plain language of § 360k indicates that Congress intended to preempt state or local legislation and administrative regulations governing devices, not state tort law. The common law is never mentioned, and there is no provision of a federal remedy for those wrongfully injured by the devices.

The legislative history of § 360k further supports the view that Congress did not intend to preempt state tort law. In a report by the House Committee on Interstate and Foreign Commerce, this "supremacy" provision is specifically discussed and establishes that Congress intended the term requirement to refer to legislative and administrative "programs" governing the sale and distribution of devices, not to state common law.

The court in Callan concluded that the plaintiff's state tort claims were not preempted either by the FD&C Act or by the MDA to the FD&C Act.

More recently, however, Judge Posner, writing for the Seventh Circuit Court of Appeals, has reached the opposite conclusion. In Slater v. Optical Radiation Corp., the plaintiff sustained injuries as the result of a defective intraocular lens implant which had subsequently been removed from the market. The intraocular implant was an investigational device, which had been exempted from the premarket approval process pursuant to section 520(g) of the MDA.
The plaintiff sued the manufacturer of the implant, alleging that the device had not been adequately tested, that the device was defectively designed, and that the manufacturer had failed to warn the consuming public of the dangers of the implant.

The district court in *Slater* dismissed the suit on the ground that the plaintiff was seeking to impose, in the name of Illinois tort law, requirements relating to the effectiveness of an intraocular lens that were different from the requirements imposed by FDA regulations governing the experimental use of intraocular lenses. The Court of Appeals affirmed. With respect to the plaintiff's claim that the device had not been adequately tested, Judge Posner concluded that "[i]f the FDA in a valid regulation under the Medical Device Amendments requires X, and X relates to safety or effectiveness, a state cannot, whether through statute, regulation, or common law decision, require non-X, or X + Y." Judge Posner concluded that state tort law is a "requirement" with respect to the preemption provision of the MDA.

The *Slater* decision is consistent with the Supreme Court's analysis in *Cipollone v. Liggett*. In *Cipollone*, the Court analyzed the preemptive effect of a federal statute which stated that "[n]o requirement or prohibition... shall be imposed under State law." After examining the language of the statute, the Court concluded that the "[t]he phrase '[n]o requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common law rules." Furthermore, the Court stated that, "[w]hereas the common law would not normally require a vendor to use any specific statement on its packages or in its advertisements, it is the essence of the common law to enforce duties that are either affirmative requirements or negative prohibitions." Therefore, under *Slater* and *Cipollone*, a state "requirement" within the meaning of section 521(a) should be interpreted to include state tort law requirements.

Not all state and local "requirements" are preempted by the MDA, however. The regulations promulgated by the FDA interpreting section 521(a),

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177 *Slater*, 961 F.2d at 1330.

178 *Id.* at 1333.

179 *Id.*


182 *Id.* at 2620.

183 *Id.*
specifically exclude certain state or local "requirements" from preemption under section 521(a).\textsuperscript{184}

For example, the regulations expressly preclude laws of "general applicability" from the scope of preemption under section 521(a).\textsuperscript{185} It is not clear whether state product liability laws should be considered as "local requirements of general applicability" which "are not limited to devices" within the exception noted in 21 C.F.R. § 808.1(d)(1).\textsuperscript{186} Courts which have addressed the issue of preemption under the MDA have not specifically addressed this

\textsuperscript{184}21 C.F.R. § 808.1 (d)(1)-(9) (1992), provides in pertinent part:
There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521(a) of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates to other products in addition to devices (e.g. requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

(2) Section 521(a) does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

\ldots

(6)(ii) Generally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices. Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, e.g. a specific labeling requirement, then the prohibition will be preempted if the requirement is different from, or in addition to, a Federal requirement established under the act. In determining whether such a requirement is preempted, the determinative factor is how the requirement is interpreted and enforced by the State or local government and not the literal language of the statute, which may be identical to a provision in the act.

The Proposed Rules, which were published prior to the formal adoption of 21 C.F.R. § 808.1(d)(1), provide additional background on this section. See 42 Fed. Reg. 30,383, 30,384 (proposed June 4, 1977). The Proposed Rule applicable to § (d)(1) states that,

[i]nduced in this category are general fire and electrical codes, the Uniform Commercial Code warranty requirements, and State or local unfair trade practice laws and regulations whose requirements apply to commodities in addition to medical devices . . . . There is no indication in the legislative history of section 521 . . . . that Congress intended that the section would preempt general purpose safety codes and similar statutes that only incidentally apply to devices.


\textsuperscript{186}The Commissioner of the FDA issued Proposed Rules for Exemptions from Federal Preemption of State and Local Requirements that provide a further explanation of the interpretation of § 521(a). The Commissioner expressed his opinion that § 521(a) was intended to preempt only State or local laws that directly and specifically relate to devices. 42 Fed. Reg. 30,383 (proposed June 14, 1977).
issue. Instead, they have concluded that state tort law "requirements" are preempted to the extent that they "relate to safety and effectiveness of a device," within the meaning of section 521(a)(2).\(^{187}\)

In *Slater v. Optical Radiation Corp.*,\(^{188}\) for example, the Seventh Circuit held that the plaintiff's state law claims based on negligence, strict liability, and breach of implied warranty were preempted by investigational device exemption to the extent that the state law claims were based on safety or effectiveness. Similarly, in *King v. Collagen Corp.*,\(^ {189}\) the First Circuit concluded that the plaintiff's strict liability claims would impose requirements related to the safety and effectiveness of the product Zyderm, and were therefore, preempted.

The final test for preemption, set forth in section 521(a)(1), is that, in order to be preempted, a state requirement must be "different from or in addition to any requirement applicable under this Act to the device."\(^ {190}\) (emphasis added). This branch of the section 521(a) analysis presents the most difficult part of the preemption analysis.

In this respect, the FDA has promulgated interpretive regulations which provide some guidance.\(^ {191}\) The regulations provide that,

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

Therefore, the general requirements set forth in the MDA are insufficient to warrant a finding of preemption. If a specific regulation or requirement applicable to a particular device has been established by the FDA, however, the specific federal requirement preempts any state requirement which is different from or in addition to the federal requirement.

In order to determine the scope of preemption under the MDA, it is necessary to examine the specific requirement or regulation applicable to a device under the federal regulations. If the state law requirements imposed by a state tort

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\(^{188}\)961 F.2d 1330 (7th Cir. 1992).

\(^{189}\)983 F.2d. 1130 (1st Cir. 1993).

\(^{190}\)FD&C Act, § 510k, as codified at 21 U.S.C. § 360k (1976).

\(^{191}\)121 C.F.R. § 808.1(d) (1992).

\(^{192}\)Id.
claim would be "in addition to or different from" a specific requirement under the MDA, and relate to the "safety or effectiveness of a device," then the state tort claim is preempted under section 521(a). The Cipollone analysis provides a useful method for determining the scope of preemption with respect to particular state tort law claims.

C. Scope of Preemption: Application of Cipollone Preemption Analysis to Specific Devices under the Medical Device Amendments

As noted above, the MDA of 1976 required the FDA to classify all medical devices into three categories. The classification is to be based on the degree of hazard the device posed to a consumer of the product. Class I devices are subject only to general controls set forth in the Act. Class II are subject to "performance standards," other "special controls" which the FDA deems necessary and appropriate to ensure a reasonable degree of safety. Class III devices, the most hazardous products, are subject to the premarket approval procedures prior to marketing the device in interstate commerce.

In order to determine the scope of preemption for a specific medical device, it is necessary to apply the Cipollone analysis to Class I, II and III devices under the MDA. This analysis requires an examination of each common law claim to determine whether it is in fact preempted. The central inquiry in each case is whether the legal duty that is the predicate of the common law damages action constitutes a requirement that is "different from, or in addition to," a specific requirement applicable to the device under the MDA. In addition, an inquiry needs to be made whether the requirement "relates to safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the Medical Devices Act]."

The first step in analyzing the scope of preemption under the Medical Devices Act is a determination of the classification of the device, and the identification of any specific requirements or regulations applicable to the device under the MDA. The classifications applicable to specific medical devices are found in the Code of Federal Regulations. The devices have been organized into sixteen different categories: clinical chemistry and clinical toxicology devices, hematology and pathology devices, immunology and microbiology devices, anesthesiology devices, cardiovascular devices, dental devices, ear, nose and throat devices, gastroenterology-urology devices, general and plastic surgery devices, general hospital and personal use devices, neurological devices, obstetrical and gynecological devices, ophthalmic devices, orthopedic devices, physical medicine devices, and radiology devices.
devices.\textsuperscript{198} The classification of a specific device is listed under the category applicable to that device.

\textit{Class I Devices}

If a device is classified as a Class I product, it is only subject to general regulatory controls under the MDA.\textsuperscript{199} The FDA regulations specifically state that a state requirement is not preempted unless there is a specific requirement applicable to a particular device under the Act.\textsuperscript{200} Since, by definition, Class I products are not subject to any specific requirements applicable to the device, any requirements imposed under state tort law should not be preempted by section 521(a) of the MDA.

\textit{Class II Devices}

Class II products require a more detailed analysis. Approximately 62\% of the devices originally classified under the Act were placed in the Class II category.\textsuperscript{201} By definition, the FDA may promulgate "performance standards" for Class II devices to ensure a reasonable degree of safety. A performance standard may require the use and prescribe the form and content of labeling for the proper installation, maintenance, operation, and use of a device.\textsuperscript{202} A performance standard may also include design specifications.\textsuperscript{203} In addition, in 1990, Congress amended section 513(a) of the Act\textsuperscript{204} to allow the FDA to regulate Class II devices through "special controls" which may or may not include the promulgation of a performance standard applicable to a particular device.

Very few performance standards have actually been promulgated for particular Class II devices, despite their classification as such.\textsuperscript{205} In the absence of a particular performance standard, the device is subject only to the general regulatory controls that govern Class I devices. Therefore, the mere classification of a device as a Class II device is insufficient to warrant preemption.

If the FDA has promulgated a specific "performance standard" or other "special control" that is applicable to a particular device, then state tort claims will be preempted to the extent that they impose requirements that are different

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{198}Id. §§ 862-92.
\item \textsuperscript{199}See Boguslaski, supra note 3, at 428.
\item \textsuperscript{200}See 21 C.F.R. § 808.1(d).
\item \textsuperscript{201}See Boguslaski, supra note 3, at 426.
\item \textsuperscript{203}Id.
\item \textsuperscript{205}See Boguslaski, supra note 3, at 426; Kessler, supra note 113, at 362 (attributing the FDA's failure to develop performance standards to the complex administrative rule-making procedures and noting that the development of performance standards for over 800 types of Class II devices would require 50,000 staff years).
\end{itemize}
\end{footnotesize}
from or in addition to the requirements under the Act, and relate to the safety or effectiveness of the device.\textsuperscript{206}

Under the Cipollone analysis, in order to determine whether a specific state tort claim related to a Class II product is preempted by the Medical Devices Act, it is necessary to compare the specific requirement applicable to the device under the MDA to each of the plaintiff’s common law tort claims. If the legal duty upon which the state tort claim is predicated imposes a requirement that is different from or in addition to the requirement under the MDA, then the tort claim will be preempted.

For example, tampons have been classified as Class II devices by the FDA.\textsuperscript{207} In addition to classifying tampons as a Class II device, the FDA has promulgated warning and labeling requirements specifically applicable to tampons.\textsuperscript{208} Since a state law failure to warn claim would impose requirements different from or in addition to the specific warning and labeling requirements applicable to tampons under the Medical Devices Act, a failure to warn claim is preempted by the Medical Devices Act and the regulations promulgated thereunder.

This analysis is consistent with court decisions which have considered the issue of preemption with respect to tampon-related toxic shock syndrome claims. In those cases, courts have generally found that a plaintiff’s failure to warn claims are preempted by specific warning and labeling requirements that have been promulgated by the FDA.\textsuperscript{209} As long as the manufacturer has complied with the FDA’s labeling and warning requirements, the plaintiff’s claims based on failure to warn are preempted.\textsuperscript{210} Tampon-related claims based on negligent design and testing, defective design, and breach of implied warranty however, have generally been held not to be preempted under the Act.\textsuperscript{211}

Prior to 1989, the FDA had not promulgated any specific requirements applicable to tampons that related to the design or manufacture of the product.

\textsuperscript{206}See FD&C Act, § 521(a), as codified at 21 U.S.C. § 360k (1976).

\textsuperscript{207}21 C.F.R. § 884.5460 (1992).

\textsuperscript{208}21 C.F.R. § 801.430 (1992).


Therefore, design defect claims were not preempted. In 1989, however, the FDA promulgated additional regulations applicable to tampons which impose requirements related to the manufacture and design of tampons. Therefore, as long as the manufacturer complies with these regulations, design defect claims related to tampons should also be preempted after the effective date of the additional regulations.

**Class III Devices**

Class III products present additional considerations with respect to the preemption analysis under section 521(a) of the Medical Devices Act. Class III devices, the most dangerous of the devices, are generally governed by the premarket approval process. The procedure for premarket approval, as required under section 515 of the MDA, is established in the Code of Federal Regulations, Part 814.

The premarket approval process is a review process requiring a manufacturer to submit an application for approval of his device before marketing. The FDA may require the manufacturer to submit safety and effectiveness data, protocols for tests and studies, and a list of product components. Furthermore, the manufacturer may be required to submit all proposed labeling for the device. Compliance with specific performance standards may also be required. After a formal review process by a selected panel, a premarket application may be approved or denied by the FDA.

If the device is approved for marketing under the premarket approval process, the manufacturer must file a supplement to its premarket approval application prior to making any changes affecting the safety and effectiveness of the device. Furthermore, the manufacturer is under a continuing duty to determine whether the device, including its labeling, is safe and effective.

The question presented by claims arising from Class III devices is whether a litigant's product liability claims are preempted by the fact that a device has been subjected to the premarket approval process. To resolve this question, it is necessary to consider whether the premarket approval process constitutes a specific requirement applicable to the device under the Medical Devices Act. In this respect, the legislative history of the original 1973 Amendments, introduced as S. 2368, indicates that a state requirement would be preempted.

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215 Id. § 814.
216 Id. § 814.20.
217 Id. § 814.20(b)(10).
218 21 C.F.R. § 814.
219 Id. § 814.39.
220 Id. § 814.39.
for any device which is "subject to an official Federal standard or scientific review, unless the state requirement is identical to the Federal requirement." Since the premarket approval process includes scientific review by a panel of experts, the premarket approval process should be deemed to be a specific "requirement" applicable to the device under the MDA. Therefore, if a device has been subjected to the premarket review process, a tort claim relating to the safety and effectiveness of a device is preempted to the extent that it imposes requirements in addition to or different from the premarket approval process.

For example, two federal district courts have considered the issue of whether a consumer's product liability claims for injuries related to implantable collagen, a Class III device, were preempted by the MDA. In *Stamps v. Collagen Corp.*, the plaintiff alleged that the collagen implants were defective as manufactured, that the defendant failed to provide adequate labeling or other warning of the defects, and that the use of the defective implants caused her injury. Based on the fact that collagen was a Class III device, the District Court for the Southern District of Texas concluded that all of the plaintiff's claims were preempted. The court based its decision on the fact that collagen was a Class III device subject to premarket approval procedures. As such, the court stated, the manufacturer was "required to provide comprehensive information to the FDA, including information regarding design, manufacturing methods, proposed packaging and labeling, and data from premarketing laboratory tests and clinical investigations." Furthermore, the court concluded that the premarket approval process was a specific "requirement" applicable to the device under the Act.

The Court of Appeals for the Fifth Circuit affirmed the district court's holding in *Stamps*, and concluded that the premarket approval process for

221 Medical Devices Amendments: *Hearings on S. 2368 Before the Subcomm. on Labor and Public Welfare of the United States Senate, 93d Cong., 1st Sess. 1114 (1973) (comparison of Medical Device legislation).


223 Collagen is a product made from processed cow tissue and used for medical wrinkle treatments. The tort actions brought against the manufacturer of this product alleged that women injected with the collagen developed a rare autoimmune disease, dermatomyositis/polymyositis after being injected with the product. See *King v. Collagen Corp., No. Civ.A.90-12718-MA, 1992 WL 98292 (D. Mass. Feb. 2, 1992), aff'd 983 F.2d 1130 (1st Cir. 1993), cert. denied 114 S. Ct. 86 (1993).*


225 *Stamps, 1191 WL 351421 at 2.*

226 *Id. at 1.*

227 *Stamps, 984 F.2d at 1421.*
Class III medical devices preempts state tort causes of action to the extent they related to the safety, effectiveness, or other MDA requirements.228

Subsequently, in King v. Collagen Corp.,229 the Massachusetts District Court adopted the reasoning set forth in Stamps, supra. In that case, the plaintiff, Jane King alleged that she suffered from an autoimmune disease as a result of injections of the implantable collagen, Zyderm. She alleged seven claims. She alleged that the Zyderm was not safe for its intended purpose, and was unreasonably dangerous to its users. Second, she alleged that the Zyderm was sold in breach of the warranty of merchantability. In addition, she alleged negligence in the design, manufacture, marketing and design of Zyderm. Her fourth claim asserted that the Zyderm was misbranded or mislabeled. She further alleged that Collagen had failed to warn her of the defective condition of the product, had made misrepresentations of material fact, and had fraudulently obtained FDA approval to market the product. The district court found that all of the plaintiff’s claims were preempted under the MDA.230

King appealed the decision to the First Circuit Court of Appeals.231 She argued that her claims were allowed under the United States Supreme Court’s ruling in Cipollone v. Liggett Group, Inc.232 King also claimed that the FDA has repeatedly stated that state tort laws are not "requirements ... with respect to a device."233 Furthermore, King asserted that, "[a]t the time she received the implant, there were no FDA requirements governing collagen warning."234 Collagen maintained, however, that the petitioner’s claims for negligence, breach of warranty, and sale of personal property by deceit or fraud were all based on failure to warn, and were therefore preempted.235

The Court of Appeals for the First Circuit, applying the Cipollone analysis, concluded that all of King’s claims were preempted by section 521 of the MDA.236 First, the court analyzed the specific language of section 521(a) of the MDA, noting that "[t]he language of subsection (a) and the definition of state requirement promulgated under it demonstrate a field of preemption which is broad, but limited."237 The court concluded that the plaintiff’s tort claims were

228Id. at 1423-24.
229King, 1992 WL 98292 at *1.
230Id.
231King, 983 F.2d at 1130.
233Id.
234Id.
235Id.
236King, 983 F.2d at 1130.
237Id. at 1134.
preempted because "[a]ny state requirement which, in effect, establishes a new substantive requirement for the device in a regulated area . . . is preempted."\textsuperscript{238} With respect to King's strict liability claims, the court concluded that "[t]he entire MDA scheme for . . . Class III devices . . . is aimed at determining and regulating the intended purpose of the device, and at ensuring a reasonable level of safety for its users."\textsuperscript{239} Since the claims based on strict liability would require the court to conclude that collagen was unsafe and dangerous, despite a contrary determination by the FDA, the court concluded that the strict liability claims were preempted.\textsuperscript{240}

With respect to the breach of warranty claims, the court distinguished \textit{Cipollone} from the preemption analysis under the MDA on the basis that "the MDA imposed much more extensive regulation on class III device manufacturers" than the warning requirement which was in issue in \textit{Cipollone}.\textsuperscript{241} The court reasoned that "[t]he FDA retains rigid control over the entirety of the labeling and packaging of class III products, largely displacing the ability of manufacturers to make additional claims."\textsuperscript{242} Therefore, it concluded that the breach of warranty claims were preempted.\textsuperscript{243} Similarly, King's claims based on negligent design, manufacture, marketing, and sale were found to be preempted on the basis that the MDA regulates these aspects of Class III medical devices in an extensive way.\textsuperscript{244}

The court then turned to the claims based on product misbranding, misrepresentation, and failure to warn. Since the FDA must reject product labeling that is "false or misleading in any particular," these claims were preempted.\textsuperscript{245} The court concluded that the "MDA forecloses these claims because Collagen cannot be forced to change zyderm's . . . labeling by virtue of these state law damage claims."\textsuperscript{246}

Finally, the court considered the appellant's claim that Collagen had fraudulently obtained premarket approval for marketing of the device. The fraud claim was based on a Massachusetts statute which required privity with the seller.\textsuperscript{247} The court rejected the fraud claim on the basis that King was not

\textsuperscript{238}Id. at 1134-35.
\textsuperscript{239}Id. at 1135.
\textsuperscript{240}King, 983 F.2d at 1135.
\textsuperscript{241}Id.
\textsuperscript{242}Id.
\textsuperscript{243}Id.
\textsuperscript{244}King, 983 F.2d at 1136.
\textsuperscript{245}Id.
\textsuperscript{246}Id.
\textsuperscript{247}Id. (citing Mass. Gen. ch. 231 § 85J as construed Kourouvacilis v. General Motors Corp., 410 Mass., 706, 575 N.E.2d 734 (1991)).
in privity with the seller. In addition, the court noted that the fraud claim was basically a failure to warn claim, which sought to impose additional packaging and labeling requirements on the manufacturer, and was therefore, preempted by the MDA.

Although the court's conclusion that King's claims based on strict liability, negligence, and failure to warn are consistent with the preemption analysis in Cipollone, its analysis of the breach of warranty claims and fraud claims is difficult to reconcile with Cipollone. First, the court in King v. Collagen acknowledged that the Supreme Court's holding in Cipollone seems to require a finding of no preemption with respect to King's claims based on breach of express and implied warranties. In Cipollone, the Court specifically found that the petitioner's claims based on express warranty were not preempted because a manufacturer's breach of express warranty derives from the terms of the warranty, and are not imposed under state law. In reaching this conclusion, the Court stated that, "a common law remedy for a contractual commitment voluntarily undertaken should not be regarded as a 'requirement' imposed under state law." Applying this same reasoning to the preemption analysis under the MDA would seem to require a conclusion that King's express warranty claim was not preempted.

In addition, the court's finding of preemption with respect to King's claim that the product was not fit for its intended purpose, is difficult to reconcile with the FDA's own specific regulations governing the preemptive scope of section 521(a) which states that, "[s]ection 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness))."

The First Circuit did not discuss the significance of this regulation in reaching its conclusion that the petitioner's warranty claims were preempted.

Furthermore, the First Circuit's conclusion that the petitioner's claims based on fraud were preempted is surprising, in light of Cipollone. In Cipollone, the Court concluded that the petitioner's claims that Ligget concealed material

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248 King, 983 F.2d at 1136.
249 Id.
251 983 F.2d 1130 (1st Cir. 1993).
253 King, 983 F.2d at 1135.
254 112 S. Ct. at 2622.
255 Id. at 2622.
257 King v. Collagen Corp., 983 F.2d 1130 (1st Cir. 1993).
information were not preempted because the claims were not based on a duty related to smoking and health, but instead, were predicated on the more general duty not to deceive.\textsuperscript{258} Similarly, in the Collagen cases, it would seem that the petitioner’s claims based on fraudulent misrepresentation should not be preempted. This is because the state law claim based on fraud arises out of a general state law duty not to deceive, and not a requirement based on the safety or effectiveness of a device. The First Circuit, however, rejected this application of Cipollone, and held that all of the appellant’s state law claims including warranty and fraud claims, were preempted by the MDA.\textsuperscript{259}

In summary, most state tort law claims arising out of Class III devices which have undergone premarket approval are preempted by the MDA. Claims based on failure to warn, defective design, and inadequate testing, are preempted. Although breach of warranty claims may also be preempted under the First Circuit’s analysis in King v. Collagen Corp.,\textsuperscript{260} the FDA regulations indicate that Uniform Commercial Code claims based on breach of warranty of fitness for a particular purpose are not preempted.\textsuperscript{261} In addition, although the court in King v. Collagen\textsuperscript{262} held that the plaintiff’s fraud claims were preempted, this result is inconsistent with the Supreme Court’s ruling in Cipollone v. Liggett Group, Inc.\textsuperscript{263}

\textbf{Substantially Equivalent Devices}

Few devices currently being marketed have been subjected to the scrutiny of the premarket approval process. According to the legislative history of the Safe Medical Devices Act of 1990, 98\% of an estimated 5,000 marketed devices have entered the market on the basis of a claim by the manufacturer of substantial equivalence to a pre-1976 device.\textsuperscript{264} Over 80\% of Class III devices have entered the market on a claim of “substantial equivalence.”\textsuperscript{265} This means that many devices have entered the market through an abbreviated premarket notification process under section 510k of the Act, thereby avoiding the more rigorous premarket approval process.\textsuperscript{266}

The issue of whether product liability claims based on a Class III device which entered the market without being subjected to premarket approval are preempted by the MDA has recently been addressed by the Supreme Court of

\textsuperscript{258}112 S. Ct. at 2624.
\textsuperscript{259}King, 983 F.2d at 1131.
\textsuperscript{260}Id. at 1130.
\textsuperscript{261}See 21 C.F.R. § 808.1(d)(l).
\textsuperscript{262}983 F.2d 1130 (1993).
\textsuperscript{263}112 S. Ct. 2608 (1992).
\textsuperscript{265}Id.
\textsuperscript{266}Id.
In *Larsen v. Pacesetter Systems, Inc.*, the plaintiff brought an action alleging that a pacemaker which had been implanted was defectively designed. The pacemaker had been tested at normal body temperature during the product testing and development, and had been found to malfunction at elevated body temperatures.

Because the statute of limitations had run on the plaintiff's tort claim, the plaintiff's cause of action was based on breach of warranty. However, the court stated that, in order for the plaintiff to bring an action in implied warranty for personal injury, he must "show product unmerchantability sufficient to avoid summary judgment on the issue of defectiveness in a tort strict products liability suit." The court rejected the manufacturer's argument that the pacemaker was an unavoidably unsafe product under comment k of section 402 of the Restatement of Torts.

The court analyzed Pacesetter's defense of federal preemption in light of section 521 of the MDA, § 808.1 of regulations promulgated by the FDA, and the United States Supreme Court's decision in *Cipollone*. The court began its analysis by acknowledging that both section 521 (§ 360k) and § 808.1(d) govern the scope of preemption under the MDA. The *Larsen* court also acknowledged that, in the absence of sufficiently specific FDA regulations pertaining to device design and construction, "state law claims of defective design, composition and construction... have been found to fall outside the preemptive scope of section 808.1(d)."

The defendant Pacesetter claimed that the plaintiff's claim was preempted because the pacemaker was a Class III device subject to premarket approval under the MDA. However, the court rejected this argument, stating that the "statutes and regulations governing premarket approval set forth general procedural requirements... [which] do not trigger a preemption analysis under § 808.1(b)." Therefore, the court found that there were no specific statutes or regulations applicable to the pacemaker in this case.

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268 *Id.* at 1273.
269 *Id.* at 1277.
270 *Id.* at 1280.
271 *Larsen*, 837 P.2d at 1273.
272 *Id.* See *Restatement (Second) of Torts* § 402A(k) (1990).
273 *Larsen*, 837 P.2d at 1280-81.
274 *Id.*
276 *Id.* This construction of the preemptive scope of the MDA was rejected by the Fifth Circuit in *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1423 (5th Cir. 1993). The court in *Stamps* distinguished *Larsen* on the basis that the Class III product in *Larsen* entered the market
Furthermore, the court stated that, although the pacemaker was a Class III device under the Act, it had entered the market on a claim that it was "substantially equivalent" to a device already on the market, and therefore, had not been subjected to the premarket approval process. The court noted that the FDA’s acceptance of a claim of substantial equivalence does not in any way denote official approval of the device. Furthermore, the court indicated that "meritorious claims ... would not contravene FDA ‘approval’ of the device and would further Congressional intent by providing pacemaker manufacturers a product safety incentive in those areas where the premarket approval process has failed adequately to protect the consumer." Therefore, the court rejected Pacesetter’s claim of preemption and upheld the jury’s finding in favor of the plaintiff on the breach of implied warranty claim.

The Hawaii Supreme Court’s determination that the premarket approval process is not a specific requirement under the MDA and does not trigger a claim of preemption conflicts with the First Circuit’s finding to the contrary King v. Collagen. In light of the legislative history of the original version of the Amendments, if the device has been subject to the scientific review process, tort claims imposing additional requirements would be preempted.

The Hawaii Supreme Court in Larsen appropriately recognized, however, that devices which enter the market on a claim of substantial equivalence should not be preempted under the section 521(a) of the MDA. Since devices which are placed on the market based upon a claim of "substantial equivalence" to a device already on the market have not been subjected to the strict scrutiny which the premarket approval entails, the potential for dangerous and defective devices causing injury to consumers is greatly enhanced. In addition, although the Larsens’ claim was based on warranty, it would seem that additional tort claims should not be preempted in these circumstances.

The distinction recognized in Larsen between devices which have undergone full premarket and devices which are claimed to be "substantially equivalent" is appropriate, in light of the injuries which may result from a Class III device on a claim of "substantial equivalence," and therefore, had not been subjected to the full rigor of the premarket approval process. Stamps, 984 F.2d at 1423, n.6.

277Larsen, 837 P.2d at 1282.


279Larsen, 837 P.2d at 1282.

280Id. at 1287.

281983 F.2d. 1130 (1st Cir. 1993).


283837 P.2d at 1273.
which enters the market without appropriate testing or scientific review. If a device has not undergone premarket approval, the FDA has not made a determination sufficient to provide a reasonable assurance of safety with respect to that device. Furthermore, the FDA has not promulgated any specific requirement applicable to the device under the MDA. Therefore, a claim of preemption by the manufacturer of the product should not survive.

Transitional Devices

Prior to the enactment of the MDA, some devices were regulated as drugs so that the FDA could exert its regulatory powers over the device. This category of devices is called "transitional devices." Under the MDA, transitional devices should be reclassified as Class III devices under the MDA.

The MDA of 1976 were enacted largely in response to the IUD crisis. Prior to the enactment of the MDA, intrauterine devices were classified as drugs so that the FDA could exert its regulatory powers over the device. The FD&C Act of 1938 does not contain a preemptive provision similar to section 521(a) of the MDA. Therefore, courts which have considered whether claims arising from IUDs, which were regulated as drugs prior to enactment of the MDA, have generally held that a plaintiff's tort law claims based on inadequate warning and design defects are not preempted.

Some IUDs, however, are now regulated under the MDA as Class III devices. Since the regulations prescribe specific performance standards and design requirements, a claim arising from an IUD regulated under the MDA and the specific regulations promulgated thereunder would most likely be preempted.

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284Id.


286"Transitional devices are those products now known as Medical Devices which were regulated as drugs prior to the passage of the Amendments." Boguslaski, supra note 3, at 426.


292Id.
Investigational Devices

In addition to the foregoing analysis of Class I, II, and III claims, the categorization of a device as an investigational device, a custom device, or a transitional device may affect the preemption analysis. Recently, the Seventh Circuit has considered a claim of preemption with respect to a claim arising from a defective intraocular implant. Intraocular implants are exempted from the premarket approval process under the MDA because they are investigational devices under the MDA. The intraocular lens investigational device exemption is the subject of a specific regulation promulgated by the FDA under the MDA.

The specific regulations applicable to investigational devices require a local institutional review board to review and approve any experimental protocol applicable to a medical device used in clinical investigational trials. The regulations require that all participants in investigational studies be fully informed of all risks associated with the device or the procedure for implantation.

In *Slater v. Optical Radiation Corp.*, the plaintiff consented to the implantation of an experimental intraocular lens. Subsequently, the intraocular implant had to be removed because of a defect which caused it to cocoon in the eye. The plaintiff sustained permanent eye injury as the result of the

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293 See FD&C Act, § 520(g), as codified at 21 U.S.C. § 360j(g); see also 21 C.F.R. § 812 - Investigation Device Exemptions.

294 "Custom device" means a device that:

1. Necessarily deviates from devices generally available or from an applicable performance standard on premarket approval requirement in order to comply with the order of an individual physician or dentist;
2. Is not generally available to or generally used by, other physicians or dentists;
3. Is not generally available in finished form for purchase or for dispensing upon prescription;
4. Is not offered for commercial distribution through labeling or advertising, and
5. Is intended for use by an individual patient named in the order of a physician or dentist, and is to be made in a specific form for that patient, or is intended to meet the special needs of the physician or dentist in the course of professional practice.

21 C.F.R. § 812(3) (1993); FD&C Act, 520(b), as codified at 21 U.S.C. § 360j(b).

295 See supra note 287.


298 *Id.*

299 *Id.* § 812.62.


301 961 F.2d. 1330 (7th Cir. 1992).
implantation and removal of the device. The intraocular lens was ultimately withdrawn from the market because of the defect.\textsuperscript{302}

The plaintiff asserted a cause of action against the manufacturer under state law based on negligence, strict liability, and breach of implied warranty.\textsuperscript{303} Specifically, the plaintiff alleged that the manufacturer had performed inadequate clinical testing of the product, failed to warn the public of the dangers of the product, and defectively designed the product. Optical Radiation claimed that the plaintiff's claims were preempted under section 521(a) of the MDA.\textsuperscript{304}

The plaintiff conceded that "insofar as the complaint might be construed to allege that Illinois tort law required the defendant to do more or different clinical testing of [the device] than required by the FDA's regulations," the claim was preempted.\textsuperscript{305} With respect to the design defect claim, the plaintiff argued that since the FDA's regulations applicable to investigational devices "impose no requirements concerning the design of the intraocular lens," the claim of defective design was not preempted.\textsuperscript{306} Furthermore, the plaintiff argued that a finding of preemption would leave the plaintiff remediless.\textsuperscript{307}

The court rejected both arguments, stating that:

The argument assumes that the only federal requirement that might relate to the safety or effectiveness of the design of a medical device would be an actual specification of that design . . . In the experimental phase the appropriate regulations of safety and effectiveness are procedural rather than substantive ones. They do not specify the safe and effective design; they specify the procedures for determining whether the experimental design is safe and effective. These are requirements relating to safety and effectiveness and they can therefore have preemptive effect.\textsuperscript{308}

Furthermore, the court rejected the plaintiff's claim that preemption in these circumstances would leave the consuming public remediless.\textsuperscript{309} The court stated that the scope of preemption under the Act is "limited to efforts by states to impose sanctions for compliance with federal regulations relating to the safety and efficacy of experimental lenses."\textsuperscript{310} The Act would not affect cases
charging negligence in the implantation of the lens, bacterial contamination of
the lens, or failure to obtain informed consent to the implantation or removal
of the lens. Therefore, a patient who does not receive informed consent could
recover damages on this basis.

Under Judge Posner's analysis in *Slater*, a plaintiff who has consented to
participate in a clinical investigation of a device under the guidelines set forth
in the regulations will not be able to recover for injuries related to the device
on the basis of failure to warn, negligent testing, or design defects. However,
a patient's common law rights arising out of medical battery, informed consent,
or negligent insertion of a medical device are preserved outside the scope of
preemption of section 521(a) of the MDA.

IV. CONCLUSION

The foregoing analysis demonstrates that the MDA presents a complex
scheme of federal regulation which defies a simple analysis of federal
preemption. An understanding of the classification scheme under the MDA is
necessary to predict whether a state tort law claim will be preempted under the
MDA. Courts may reach different results, depending on whether the device is
a Class I, II, or III device, or whether it has entered the market on a claim that
it was "substantially equivalent" to a device already on the market. In addition,
claims arising out of transitional devices may not be preempted under the
Medical Devices Act, whereas, most claims based on investigational devices
will be preempted unless the patient did not consent to the implantation of the
device.

After determining how the device has been classified under the MDA, it is
necessary to identify any specific regulations applicable to the device under
the MDA, such as performance standards, labeling, or warning requirements
imposed by the FDA. If a specific regulation such as a performance standard
has been promulgated, the scope of preemption must be determined by
referring to the scope of preemption as defined in the regulations under 21
C.F.R. § 808.1.

Once it has been determined that the state tort claim falls within the scope
of preemption of section 521(a), as defined in the interpretive regulations, the
*Cipollone* analysis must be used to compare each state tort claim to the
specific requirements applicable to the device under the MDA. To determine if
a specific tort claim is preempted by a particular requirement under the Act,
the central inquiry in each case is whether the legal duty of the common law

311 *Id.*

312 *Id.*

313 961 F.2d at 1330.

314 *Id.* at 1332.

315 *Id.* at 1334.

316 112 S. Ct. at 2608.
damages action constitutes a requirement that is different from or in addition to a specific requirement applicable to the device under the MDA and which relates to the safety or effectiveness of the device.

Claims of preemption must also be analyzed in light of the underlying policy considerations of the MDA. It is clear that the major concern of Congress in enacting the MDA was the protection of public health and safety from defective and dangerous devices. However, Congress was also concerned that the imposition of varying state and local requirements on device manufacturers would unduly burden commerce, and would impede the further research and development of new devices. The resolution of claims of preemption under section 521(a) of the MDA must be carefully analyzed to strike an appropriate balance between these competing concerns.

In situations where the FDA has promulgated specific requirements applicable to a particular device, a claim of preemption should be upheld, provided that the manufacturer has complied with all appropriate regulations and premarket approval requirements under the MDA. Under these circumstances, the imposition of additional state law requirements would impose conflicting requirements on device manufacturers which could impose an undue burden on the continued development and marketing of potentially lifesaving devices.

In situations where the manufacturer has failed to comply with applicable regulations under the MDA, however, a claim of preemption should be resolved against the manufacturer, and in favor of upholding the plaintiff's claims. In addition, in circumstances where the manufacturer has intentionally withheld information from the FDA which was necessary to obtain approval for marketing the device, or has intentionally misrepresented a material risk or side effect of a device, the manufacturer should not be afforded the protection of a defense of preemption under the MDA. In addition, in situations where the FDA has not promulgated any specific requirements applicable to the particular device under the MDA, tort claims arising from injury related to a device should not be preempted.

In light of the difficulty the FDA has encountered keeping defective and dangerous medical devices from entering the market, care must be taken not to preclude an injured person from all remedies arising from defective medical devices in circumstances where the regulatory scheme fails to detect defective devices prior to their introduction into the medical market. An injured person should be afforded an opportunity to recover his medical expenses and other damages resulting from the implantation of a device which is clearly defective.

In enacting the MDA, Congress did not create a private federal remedy for consumers who are injured by defective devices. Since the major goal of the MDA, as enacted in 1976, was to protect the public from defective and unsafe medical devices, it is unlikely that Congress intended to preclude injured persons from all recovery in the event that they sustain injuries related to a clearly defective device. Perhaps it is time that Congress clarify this issue by more clearly stating the effect of the Act on state tort law remedies. If Congress did intend to preempt state tort law remedies, then perhaps it is time to consider the creation of a private federal remedy under the MDA to ensure that injured consumers are compensated for medical expenses and other losses incurred as the result of a defective medical devices.