Who Should Bear the Burden of Experimental Medical Device Testing: The Preemptive Scope of the Medical Device Amendments under Slater v. Optical Radiation Corp.

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WHO SHOULD BEAR THE BURDEN OF EXPERIMENTAL MEDICAL DEVICE TESTING: THE PREEMPTIVE SCOPE OF THE MEDICAL DEVICE AMENDMENTS UNDER SLATER v. OPTICAL RADIATION CORP.

INTRODUCTION

In 1984, Albert Slater had a cataract removed from his left eye, and rather than face potential blindness, he chose to undergo an experimental procedure in which his natural lens was replaced with an intraocular lens implant. The implant, manufactured by Optical Radiation Corporation ("ORC"), was inserted into Mr. Slater's eye as part of a clinical investigation conducted pursuant to the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act of 1938 and the regulations pertaining to intraocular lenses. Prior to the procedure, Mr. Slater signed a consent form indicating that he recognized that he was taking part in a clinical investigation.

Over the next several years, the vision in Mr. Slater's left eye deteriorated and he was in continuous pain. After he was diagnosed as suffering from cystoid macular edema, Mr. Slater's doctors recommended that his intraocular lens implant be taken out. The lens was subsequently removed, leaving Mr. Slater with permanent damage to his left eye, damage greater than that done by the cataract.

2. See DAVID J. APPLE ET AL., INTRAOCULAR LENSES: EVOLUTION, DESIGNS, COMPLICATIONS, AND PATHOLOGY 4-5 (1989) (stating that international and federal studies show that between twelve to fifteen million people worldwide are blind due to cataracts).
3. Slater, 961 F.2d at 1332.
6. Slater, 961 F.2d at 1332.
7. Id.
9. Slater, 961 F.2d at 1332.
itself.10

In 1989, Mr. Slater filed a product liability action against ORC in the federal district court for the Northern District of Illinois.11 On a motion for summary judgment, the district court held that Mr. Slater's state law claims were preempted by the Investigational Device Exemption for intraocular lenses contained in the Medical Device Amendments.12 Mr. Slater appealed the decision, and in Slater v. Optical Radiation Corp.,13 a case of first impression at the appellate level, the Seventh Circuit affirmed the district court's decision.14

Like Albert Slater, many people agree to participate in clinical investigation programs involving experimental medical devices, some of which result in injuries to the participants.15 According to the Slater decision, plaintiffs do not have a cause of action against the manufacturer of a defective experimental medical device based on the safety and effectiveness of the device, and therefore are divested of any state tort remedies which would otherwise be available to them.16 Moreover, the court found that no federal damages remedy exists, either.17

Congress's intention in enacting the Medical Device Amendments was not to leave plaintiffs like Mr. Slater to bear the burdens of experimental medical device testing on their own. Rather, the purpose of the Medical Device Amendments was to vest the Food and Drug Administration ("FDA") with the increased responsibility of ensuring that medical devices marketed in the United States are safe and effective.18 The effect of allowing a decision like Slater to

10. Id.
12. Id. at 374.
14. Slater, 961 F.2d at 1334.
15. Jennifer S. R. Lynn, Implantable Medical Devices: A Survey of Products Liability Case
Law, 38 MED. TRIAL TECH. Q. 44, 44 (1992). According to one writer:
There are nearly 200 body parts that can either be replaced by an implant or their function taken over by an installed device. Some of the implantable devices are life-saving, others facilitate recovery and restore function, and still others make life more productive physically and/or emotionally. As with natural organs and systems, implants fail. Some wear out and some are failures due to defects. Some failures can be catastrophic, and other failures can result in a return of disability. Some implants have adverse effects which may result in deleterious effects — adding to the person's problems.

16. Slater, 961 F.2d at 1333-34.
17. Id. at 1333 (emphasis added).
stand is that if a manufacturer defectively designs an experimental product, injured plaintiffs like Mr. Slater have no remedy.

This Note discusses the alleged preemptive effect of the Medical Device Amendments on state tort claims based on the safety and effectiveness of experimental intraocular lenses. Specifically, it addresses the Seventh Circuit's finding of express preemption and concludes that such a finding is erroneous. It also examines the legislative history of the Medical Device Amendments and discusses whether state tort claims against experimental intraocular lens manufacturers are impliedly preempted. In addition, this Note analyzes the difference between judicial and state regulation treatment of tort claims in the preemption arena. This Note concludes that a finding of preemption is inconsistent with the rationale behind holding manufacturers like ORC liable for defects in their products.

I. BACKGROUND

To fully comprehend the Seventh Circuit's holding in *Slater*, one must understand the doctrine of preemption generally as well as how it specifically occurs under the Medical Device Amendments.

A. The Doctrine of Federal Preemption

It is a well-established principle that the Supremacy Clause invalidates state laws that interfere with, or are contrary to, federal law;\(^\text{19}\) this includes not only the United States Constitution, treaties, and statutes, but also regulations promulgated by federal agencies.\(^\text{20}\) The doctrine of federal preemption preserves the federal government's authority in areas that Congress has deemed to be national in scope.\(^\text{21}\) In addition to national interest concerns, the federal gov-

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19. U.S. CONST. art. VI, cl. 2. The Supremacy Clause provides:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, under the Authority of the United States, shall be the supreme law of the Land; and the Judges in every State shall be bound thereby; any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

*Id.*

20. For cases holding that the federal regulations preempt state law as effectively as federal statutes, see Hillsborough County v. Automated Medical Labs., 471 U.S. 707 (1985); Fidelity Fed. Sav. & Loan Assoc. v. De La Cuesta, 458 U.S. 141, 153 (1982).

21. *De La Cuesta*, 458 U.S. at 153-54; see also Susan Bartlett Foote, *Administrative Preemp-
ernment also retains the power to regulate areas where it believes state laws are inadequate or inconsistent. For instance, Congress, believing that state and local regulation of consumer products was inadequate, created the federal Consumer Product Safety Commission.\textsuperscript{22} Inconsistent protection by the states also led to the enactment of the Occupational Health and Safety Act ("OSHA").\textsuperscript{23}

Even though the Constitution vests supreme legislative power in Congress, the Framers were equally concerned with preserving state autonomy.\textsuperscript{24} In The Federalist No. 45, James Madison stated that the powers delegated by the Constitution to the federal government are "few and defined," and that those preserved for the states are "numerous and indefinite."\textsuperscript{25} Madison believed that the states should govern "all of the objects, which, in the ordinary course of affairs, concern the lives, liberties and properties of the people . . . ."\textsuperscript{26} Consequently, the states have traditionally managed those areas that concern the lives of their citizens, most notably the areas of health and safety.\textsuperscript{27} For this reason, federal courts defer to the states on these issues in the face of federal preemption.\textsuperscript{28}

\footnotesize{\textit{Notes:} An Experiment in Regulatory Federalism, 70 Va. L. Rev. 1429, 1432 (1984) [hereinafter Foote, \textit{Experiment}] ("The Framers of the Constitution understood that supreme federal power was essential to coherent national government.").


23. 29 U.S.C. §§ 651-78 (1988); see also S. REP. No. 1282, 91st Cong., 2d Sess. 4 (1970), reprinted in 1970 U.S.C.C.A.N. 5177, 5180 ("[O]nly a relatively few states have modern laws relating to occupational health and safety and have devoted adequate resources to their administration and enforcement. Moreover, in a state-by-state approach, the efforts of the more vigorous states are inevitably undermined by the shortsightedness of others.").


25. \textit{Id.}

26. \textit{Id.} at 293.


28. Raymond Motor Transp., Inc. v. Rice, 434 U.S. 429, 443 (1978) (noting that "the Court has been most reluctant to invalidate under the Commerce Clause 'state legislation in the field of safety where the propriety of local regulation has long been recognized' ") (citations omitted).}
1. Types of Federal Preemption

There are two general types of federal preemption: express and implied. Express preemption occurs when Congress explicitly prohibits state regulation of a certain area. Implied preemption, on the other hand, can occur in one of three situations: (1) when the federal regulations involved are so comprehensive that state law is displaced; (2) when there is a dominant federal interest in the subject matter to be regulated; or (3) when there is a direct conflict between the federal and state laws at issue.

a. Express Preemption

Congress must explicitly declare that state law on a certain issue is preempted for express preemption to occur. When Congress expressly states such an intention, the results are clear and unambiguous.

For example, the Cigarette Labeling and Advertising Act ("Cigarette Act") provides: "No statement relating to smoking and health, other than the statement required by section 1333 of this title, shall be required on any cigarette package." This provision of the Cigarette Act was interpreted in Cipollone v. Liggett Group, Inc., where a smoker sued a cigarette manufacturer after she contracted lung cancer. The plaintiff asserted, inter alia, that the manufacturer had failed to warn her of the dangers of cigarette smoking. The cigarette manufacturer maintained that the plain-

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30. See, e.g., Cipollone v. Liggett Group, Inc., 112 S. Ct. 2608 (1992) (holding that the plaintiff's "failure to warn" claim was expressly preempted by a federal statute setting forth the warning label to be placed on cigarette packages); Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977) (holding that a state labeling requirement which used a different formula for determining the net weight to be reported on the label of packaged bacon was expressly preempted by a congressional prohibition on labeling, packaging, or ingredient requirements different from or in addition to those required by the federal statute).
31. Hillsborough, 471 U.S. at 713. See generally NOWAK & ROTUNDA, supra note 29, 311-30 (discussing federal regulation and state authority).
32. See supra note 30 and accompanying text (explaining and giving examples of express preemption).
34. Id. § 1334.
36. Id. at 2613.
37. Id.
tiff's claim was expressly preempted by the Cigarette Act. The Supreme Court agreed with the manufacturer and held that because the Cigarette Act clearly stated that no warning label other than that mandated by the Cigarette Act was required, the plaintiff's claim was expressly preempted.

It is presumed that state law is not expressly preempted unless Congress explicitly states that such preemption is to occur. Therefore, absent a clear expression of intent from Congress, state law will not be displaced by federal law.

b. Implied Preemption

In the absence of express preemption, courts are left to decide whether a state law is impliedly preempted. The United States Supreme Court, in Hillsborough County v. Automated Medical Laboratories, outlined the ways in which implied preemption can arise: (1) when federal regulations are so comprehensive that state law is displaced; (2) when there is a dominant federal interest in the subject matter to be regulated; or (3) when there is direct conflict between the federal and state laws at issue. When any of these situations exist, courts will find implied preemption of state law. Congressional intent, however, must be considered when determining whether any of these tests are satisfied.

38. Id. at 2614.
39. Id. at 2621.
40. E.g., Graham v. Wyeth Labs., 666 F. Supp. 1483, 1489 (D. Kan. 1987) ("In the absence of express preemption, there is a strong presumption that Congress did not intend to displace state law."); later proceeding, 906 F.2d 1399 (10th Cir.), later proceeding, 906 F.2d 1419 (10th Cir.), cert. denied, 498 U.S. 981 (1990); see also Nowak & Rotunda, supra note 29, at 315 (noting that "[t]he Supreme Court presumes that Congress does not intend to preempt state legislation unless there is a clear indication from the language or purposes of the federal action or regulation").
44. Id. at 713.
45. Id. at 714.
i. Comprehensive Federal Regulations

State law may be displaced when the federal regulations involved are deemed so comprehensive that there is no room for the states to regulate the subject and it is reasonable to infer that Congress intended to preempt state law. For example, in Schneidewind v. ANR Pipeline Co., the Supreme Court was faced with a Michigan statute that required public utilities transporting natural gas in Michigan to obtain approval from the Michigan Public Service Commission ("MPSC") before issuing long-term securities. Several natural gas companies, which served customers in Michigan as well as in other states, filed suit seeking a declaratory judgment that the MPSC lacked jurisdiction over their securities issues because the Michigan statute was preempted by the Natural Gas Act of 1938. Relying on the fact that the federal government — through the Natural Gas Act — comprehensively regulates the natural gas industry, the Court held that the Michigan statute was impliedly preempted.

ii. Dominant Federal Interest

State law may also be displaced under the implied preemption doctrine when there is a dominant federal interest in the subject matter. The Supreme Court discussed this type of implied preemption in Hines v. Davidowitz. In Hines, the Court was called upon to determine the validity of a Pennsylvania alien registration statute in light of the federal Alien Registration Act of 1940. Pennsylvania characterized its statute as a local police measure designed to protect the citizens and property of the state.

In holding that the Pennsylvania statute was impliedly preempted by the federal statute, the Court focused on the fact that the federal

46. Id. at 713.
48. Id. at 296-97.
49. Id. at 298.
50. Id. at 300-09. With respect to the Natural Gas Act, the Court said that it has "long been recognized as a 'comprehensive scheme of federal regulation of 'all wholesales of natural gas in interstate commerce.'" Id. at 300 (quoting Northern Natural Gas Co. v. State Corp. Comm'n, 372 U.S. 84, 91 (1963)).
52. 312 U.S. 52 (1941).
53. Id. at 59-60.
54. Id. at 55.
government has a dominant interest in foreign affairs, specifically the power to regulate immigration. The Court stated: "Experience has shown that international controversies of the gravest moment sometimes even leading to war, may arise from real or imagined wrongs to another's subjects inflicted, or permitted, by a government." Because the federal statute was designed to protect the personal liberties of all aliens through one uniform system, thus protecting them from the possibility of inquisitorial practices that might affect international relations, the Pennsylvania statute was preempted. The Hines decision illustrates how an act of Congress in a field in which the federal government has a dominant interest precludes enforcement of state laws on the same subject.

iii. Direct Conflict Between State and Federal Law

Finally, state law may be displaced when it directly conflicts with federal law. Direct conflict can occur in two different situations. First, direct conflict can arise when compliance with both a state law and the federal regulatory scheme is not possible. Direct conflict may also occur when state law frustrates Congress's purpose in enacting the federal law.

When it is impossible to obey state and federal regulations simultaneously, the state statute will be held invalid. The Supreme Court addressed this type of direct conflict implied preemption in McDermott v. Wisconsin. In McDermott, the Court examined Wisconsin's syrup labeling regulations, under which an out-of-state syrup labeled in accordance with relevant federal regulations was considered to be mislabeled under Wisconsin law. Because joint compliance was impossible, the Court barred enforcement of

55. Id. at 62.
56. Id. at 64.
57. Id. at 74.
59. E.g., Hillsborough, 471 U.S. at 713; Capital Cities, 467 U.S. at 699; Hines v. Davidowitz, 312 U.S. 52, 67 (1941); see also Nowak & Rotunda, supra note 29, at 312 (discussing the preemption test created by the Hines Court).
60. Hill v. Florida, 325 U.S. 538, 542 (1945); see infra notes 66-70 and accompanying text (discussing the Hill decision).
61. Hillsborough, 471 U.S. at 713.
62. 228 U.S. 115 (1913).
63. Id. at 133.
64. Id. at 125-27.
the Wisconsin regulations.\textsuperscript{68}

A second type of implied preemption involving direct conflict was addressed in \textit{Hill v. Florida},\textsuperscript{66} which involved a Florida statute which placed certain restrictions on labor union bargaining activities.\textsuperscript{67} At issue in the case was the question of whether or not the state statute was preempted by the National Labor Relations Act.\textsuperscript{68} The Court held that the Florida statute conflicted with the workers' free bargaining rights provided by the Act;\textsuperscript{69} since the state statute "[stood] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," it was preempted.\textsuperscript{70}

In order to find implied preemption, however, courts must first overcome certain presumptions against preemption. First, courts assume that in the absence of express preemption, Congress does not intend to displace state law.\textsuperscript{71} Second, courts are reluctant to find a state law impliedly preempted when the state law deals with areas traditionally occupied by the states, such as regulation of matters related to health and safety.\textsuperscript{72} Finally, there is a presumption operating against preemption when the preemption of state tort claims would leave plaintiffs without a remedy.\textsuperscript{73} Despite these presump-

\textsuperscript{65} Id. at 134.
\textsuperscript{66} 325 U.S. 538 (1945).
\textsuperscript{67} Id. at 539.
\textsuperscript{68} Id.
\textsuperscript{69} Id. at 541.
\textsuperscript{70} Id. at 542.
\textsuperscript{71} Maryland v. Louisiana, 451 U.S. 725, 746 (1981) (noting that the preemption inquiry "starts with the basic assumption that Congress did not intend to displace state law"); see also Graham v. Wyeth Labs., 666 F. Supp. 1483, 1489 (D. Kan. 1987) ("In the absence of express preemption, there is a strong presumption that Congress did not intend to displace state law."); later proceeding, 906 F.2d 1399 (10th Cir.), later proceeding, 906 F.2d 1419 (10th Cir.), cert. denied, 498 U.S. 981 (1990); NOWAK & ROTUNDA, supra note 29, at 315 (noting that the Supreme Court presumes that Congress does not intend to preempt state law without clear language or federal purpose).
\textsuperscript{72} Hillsborough County v. Automated Medical Labs., 471 U.S. 707 (1985) (holding that the intent to preempt may not be inferred merely from the comprehensiveness of federal regulation); Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977) (holding that state law must yield to federal law only when there is clear congressional intent that federal law control); see also Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 236 (1947) (holding that when such historic police powers are at issue, preemption will not occur "unless that was the clear and manifest purpose of Congress").

This silence [regarding the preemption of state remedies] takes on added significance in light of Congress' failure to provide any federal remedy for persons injured by such conduct. It is difficult to believe that Congress would, without comment, remove all
tions, however, state law may be found to be impliedly preempted.

2. Preemption of State Regulation v. State Common Law Claims

Once federal preemption is found to exist, the courts must determine exactly what is preempted by the federal enactment. Specifically, courts must determine whether only state regulatory law is preempted or whether the preemption also includes state common law. It is clear that state regulation and state tort law claims have been treated differently in the preemption arena, although some courts do not subscribe to such a distinction.

Some courts are more likely to displace state-mandated regulations than to displace traditional state common law causes of action. The distinction between state regulation and state common law was explained in Ferebee v. Chevron Chemical Co. Ferebee involved the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). which prescribes labeling requirements for paraquat, a toxic agricultural herbicide. In Ferebee, an agricultural worker at a government research center brought an action against Chevron means of judicial recourse to those injured by illegal conduct.

Id. at 251. Maybe even more significant was Justice Harry Blackmun's dissenting opinion in Silkwood. Justice Blackmun believed that only punitive damage awards were preempted and that there was no congressional intent to preempt compensatory state tort claims, and he stressed the important role that states play in compensating their injured citizens. Id. at 263 (Blackmun, J., dissenting); see also Abbot v. American Cyanamid Co., 844 F.2d 1108, 1112 (4th Cir. 1988) (holding that the lack of a federal remedy works against a finding of implied preemption). But see Lister v. Stark, 890 F.2d 941, 946 (7th Cir. 1989) ("[T]he availability of a federal remedy is not a prerequisite for federal preemption."). It should be noted that although the Lister court held that the provision of a federal remedy is not required, the court found that while ERISA provided some form of a federal remedy, the federal system did not provide the exact remedy the plaintiff sought. Id.


Chemical, the manufacturer of paraquat, alleging that his lung disease and subsequent death resulted from Chevron's failure to place adequate warning labels on its product.\textsuperscript{79} FIFRA precludes a state from imposing any requirements for the labeling of paraquat in addition to or different from those required by FIFRA,\textsuperscript{80} so in determining whether FIFRA preempted the relevant state tort claims, the court examined whether the statute specifically addresses state tort claims and found that it did not.\textsuperscript{81} Consequently, the court held that FIFRA does not preempt state damage actions, but merely precludes states from directly ordering changes in labels approved by the federal statute.\textsuperscript{82}

Although some courts distinguish between state regulation and state common law tort claims, other courts have held that state tort compensation is akin to state regulation. For example, \textit{Palmer v. Liggett Group, Inc.}\textsuperscript{83} involved a cigarette smoker's claim against a cigarette manufacturer based on its failure to warn consumers of the dangers of cigarette smoking.\textsuperscript{84} In finding that the plaintiff's claims were preempted by the Cigarette Act,\textsuperscript{85} the court rejected the characterization of compensatory awards based on a failure to warn of the dangers of cigarette smoking as indirect rather than regulatory.\textsuperscript{86} The court reasoned that since a jury verdict effectively compels a manufacturer to alter its cigarette labels, it has the same effect as a state regulation ordering the manufacturer to conform to state law requirements different from or in addition to the federal requirements.\textsuperscript{87}

\textsuperscript{79} \textit{Ferebee}, 736 F.2d at 1533. His estate continued the action after his death. \textit{Id.} at 1529.
\textsuperscript{80} \textit{Id.} at 1540; 7 U.S.C. § 136 (1988).
\textsuperscript{81} \textit{Ferebee}, 736 F.2d at 1540.
\textsuperscript{82} \textit{Id.} at 1542. In determining that the plaintiff's common law claims were not preempted, the court also considered whether or not the statute provided a federal remedy and found that it did not. \textit{Id.} In addition, the court assumed that health and safety issues are not to be preempted absent a clear manifestation of Congress's intent. \textit{Id.} at 1542-43.
\textsuperscript{83} 825 F.2d 620 (1st Cir. 1987).
\textsuperscript{84} \textit{Id.} at 622.
\textsuperscript{86} \textit{Palmer}, 825 F.2d at 627.
\textsuperscript{87} \textit{Id.} at 627-28. It should be noted that the \textit{Palmer} court relied on San Diego Bldg. Trades Council v. Garmon, 359 U.S. 236 (1959), a decision in which the Supreme Court stated: "Regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy." \textit{Id.} at 247 (quoted in \textit{Palmer}, 825 F.2d at 628). Justice John Harlan authored a concurring opinion in \textit{Garmon} which discussed the decision's limited applicability and stated that preemption of state tort law remedies would only occur to the
In summary, even though the federal government has the power under the Supremacy Clause to displace state law, the Framers of the Constitution were equally concerned with preserving the power of the states. Issues relating to health and safety are generally reserved for the states, although the federal government does step in where state protection is inadequate or disparate. When the federal government decides to preempt state law, it may do so either expressly or impliedly. Express preemption occurs when Congress clearly states an intent to preempt state law on a certain subject; implied preemption occurs when Congress indirectly indicates its intent to preempt. However, certain presumptions must be overcome before courts will find that a state law has been impliedly preempted. Finally, state common law, as opposed to state or local regulation, is more likely to be preserved in the face of federal preemption.

B. Preemption Under the Medical Device Amendments

In 1976, Congress enacted the Medical Device Amendments ("MDA" or "Amendments") to the Federal Food, Drug, and Cosmetic Act of 1938. The purpose behind the MDA was to bolster the FDA's authority over the regulation of medical devices. With the enactment of the Amendments, the FDA assumed the increased responsibility of ensuring that all drugs and devices marketed in the extent that they had been displaced by federal law. Garmon, 359 U.S. at 252 (Harlan, J., concurring). Because Palmer did not involve preemption of a state remedy to the extent that it was being replaced by a federal remedy, some scholars have argued that the Palmer court's reliance on Garmon was clearly misplaced. Edell & Walters, supra note 74, at 607-13.

88. See supra notes 24-28 and accompanying text (discussing how the Framers were not only concerned with preserving state autonomy, but also with having the states manage the areas which concern people's lives).
89. See supra notes 22-23 and accompanying text (noting that inadequate state protection of consumers led to the enactment of the Consumer Product Safety Commission and OSHA).
90. See supra notes 32-41 and accompanying text (discussing express preemption).
91. See supra notes 42-70 and accompanying text (explaining implied preemption and the three instances in which it occurs).
92. See supra notes 71-73 and accompanying text (delineating the presumptions that courts make in determining whether state law is preempted).
93. See supra notes 74-87 and accompanying text (discussing the preservation of state common law as opposed to the preservation of regulatory law).
United States are safe and effective. Prior to 1976, manufacturers were not required to establish the safety and efficacy of a device before marketing it. Under the current federal legislation, however, a medical device must satisfy rigorous safety standards and obtain FDA approval before it can be marketed.

1. Experimental Medical Devices Under the MDA

The federal regulatory scheme governing medical devices includes experimental medical devices. Intraocular lenses, like the one at issue in Slater, are classified as "investigational devices" and are thus subject to the Investigational Device Exemption, which exempts them from the customary safety and efficacy requirements of the MDA. Specifically, an investigational device does not have to comply with the pre-market approval procedures under section 360e,
the good manufacturing practice requirements described at section 360j(f), or the performance standards under section 360d. Instead, intraocular lenses must comply with other rules established by the FDA for investigational devices.

The rules governing investigational devices require, among other things, the submission of an application to the FDA describing the device and setting forth a plan for studying the device's use on human subjects. After approval by the FDA, the clinical investigation is monitored to assure that its continuation is justified. The stated purpose of the Investigational Device Exemption is to encourage innovation consistent with the protection of public health and safety.

To take part in an experimental project under the FDA's regulations, a participant must consent to the procedure. The FDA's regulations provide general requirements for informed consent, under which a participant cannot be made to waive his legal rights or to release the investigator, the sponsor, the institution, or its agents from liability.

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102. Id.; see also 21 U.S.C. §§ 360d, 360e, 360j(f) (1988) (codifying these respective provisions).
103. 21 C.F.R. §§ 813.1-.170 (1992). Section 813.1(a) outlines the scope of the Investigational Device Exemption for intraocular lenses:

(a) General. This part provides that intraocular lenses may be exempted from any of the requirements of the act enumerated in paragraph (b) of this section that would otherwise be applicable to the device, to permit investigational studies of the device by experts who are qualified by scientific training and experience to investigate the safety and effectiveness of the lenses.

104. Id. §§ 813.20-.39.
105. Id. § 813.66(a)(5).
106. Id.; see also H.R. Rep. No. 853, 94th Cong., 2d Sess. 12 (1976), which provides:

The Committee recognizes the necessity to encourage the discovery and development of medical devices intended for human use and the need for scientific investigators to maintain freedom to do so. On the other hand, research on medical devices in the developmental stage must not endanger the public health and must assure the highest ethical standards . . . .

107. Id. at 42.
108. The regulations provide that:

No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appear to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

109. Id.
EXPERIMENTAL MEDICAL DEVICES

a. The “Preemption” Provision of the MDA

As part of the MDA, Congress enacted a preemption provision which provides:

Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement — (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to a device under this chapter.110

Thus, a state is prohibited from adopting any requirement that conflicts with a stated provision of the MDA. A state may, however, request an exemption from the preemption provision if its regulations are “more stringent” than the federal requirements or if its regulations are “required by compelling local conditions.”111

As in other contexts, two types of preemption may occur under the MDA: express and implied preemption.112 For express preemption to occur under the MDA, a two-pronged test must be satisfied.113 First, it must be determined whether the state requirement in question relates to a matter included in the federal regulations.114 If it does, then it must be determined whether the state law requirement is different from or in addition to the specific requirement found in the federal regulations.115 Express preemption under the MDA, then, is limited to situations where specific counterpart regulations exist.116 Where the two-pronged test is not satisfied, it must

111. Id. § 360k(b). The exemption requirements codified in this section provide:

Upon application of a State or political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from [preemption] . . . a requirement of such State or political subdivision applicable to a device intended for human use if — (1) the requirement is more stringent than [the federal requirement] . . . 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.

Id.

112. See supra note 29-31 and accompanying text (describing the two different types of federal preemption).
114. Id.
115. Id.
116. The regulations provide: “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 . . . .” 21 C.F.R. § 808.1(d) (1993); see also 43 Fed. Reg. 18,661 (May 2, 1978), in which the FDA explains:
then be considered whether the state requirement is impliedly preempted. As in other contexts, legislative intent is a key factor in ascertaining whether implied preemption exists.\textsuperscript{117}

b. The Legislative History of the MDA

Two general purposes have been advanced as reasons for the enactment of the MDA. One goal was to ensure that Americans are not put at risk from using unsafe or ineffective medical devices.\textsuperscript{118} The MDA was also intended to prevent the undue burden on interstate commerce caused by varying state requirements for medical devices.\textsuperscript{119}

i. Health and Safety

The report of the Senate Committee on Labor and Public Welfare indicates that the medical device legislation was prompted by the Dalkon Shield litigation.\textsuperscript{120} The Report explains that the Health Subcommittee believed that medical device legislation was urgently needed because of the health hazards posed by unregulated intrauterine devices ("IUDs").\textsuperscript{121} The witnesses before the Health Subcommittee urged that the deaths and illnesses caused by the Dalkon Shield could have been prevented had medical device legislation been in place at the time IUDs were developed.\textsuperscript{122} As a result,

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\textsuperscript{117} See supra notes 42-45 and accompanying text (discussing the role of congressional intent in determining the existence of implied preemption).


\textsuperscript{121} Id.

\textsuperscript{122} One witness noted:

Today the Food and Drug Administration only has limited authority to act with respect to a medical device in the market place which has been proven dangerous and patients have been injured. Medical device legislation is intended to assure that medical devices such as these IUD's meet the requirements of safety and effectiveness
consumer health and safety seem to have been the primary concerns in introducing the Amendments. As Senator Ted Kennedy, the bill's sponsor, stated: "The legislation [was] written so that the benefit of the doubt is always given to the consumer. After all it is the consumer who pays with his health and his life for medical device malfunctions."\(^{123}\)

ii. Protection of Interstate Commerce

The legislative history of the Amendments also shows that Congress was concerned with the issue of interstate commerce, as the House Committee on Interstate and Foreign Commerce debated the effects that differing state regulations would have on such commerce.\(^{124}\) The House Report indicates "[t]he Committee recognize[d] that if a substantial number of differing requirements applicable to a medical device [were] imposed by jurisdictions other than the federal government, interstate commerce would be unduly burdened."\(^{125}\)

One of the drafts of the medical device legislation spoke directly to the issue of interstate commerce. That draft contained a provision which mandated that in order to avoid preemption, a more stringent state requirement\(^{126}\) must not interfere with interstate commerce.\(^{127}\)

before they are put in widespread use throughout the United States.

\(^{123}\) Id. at 2 (statement of Sen. Kennedy).


\(^{125}\) H.R. REP. No. 853, 94th Cong., 2d Sess. 12, 45 (1976); see also S. REP. No. 33, 94th Cong., 2d Sess. 2 (1975), reprinted in 1976 U.S.C.C.A.N. 1070, 1107 (stating that one of the purposes for the MDA's enactment was to prevent an undue burden on interstate commerce through the proliferation of varying state regulations.).

\(^{126}\) Id. 126. See supra note 111 and accompanying text (describing how states can supplement the federal regulations with more stringent requirements).

\(^{127}\) H.R. 5545, 94th Cong., 2d Sess. 75 (1975). The bill provided that:

(2) 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), 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 — (A) the requirement is required by compelling local conditions, (B)
The legislation that was ultimately passed, however, did not contain any requirements compelling a state to show the absence of a burden on interstate commerce, although nothing in the MDA's legislative history refers to the reason for this deletion.

2. Preemption Cases Under the Investigational Device Exemption For Intraocular Lenses

To date, only two preemption cases have specifically construed the investigational intraocular lens provision of the MDA. Other than Slater, the only preemption case dealing with the intraocular lens provision of the MDA is Mitchell v. IOLAB Corp., which has a fact pattern very similar to that of Slater.

In Mitchell, the plaintiff sued the manufacturer of his intraocular lens implant, alleging that he suffered injuries as a result of a defect in the lens. The defendant, IOLAB, filed a motion for summary judgment claiming that Mitchell's state law claims were preempted by the MDA, and particularly by the federal regulations governing intraocular lenses. Focusing on the consent provision in the federal regulations, the Mitchell court declined to hold that state common law claims were preempted. The court reasoned that the federal regulations clearly provide that informed consent is required; thus, a consent form cannot include any exculpatory language through which test subjects are forced to waive or release their legal rights. The court noted that the informed consent provision is incorporated by reference in the regulations exempting investigational devices. Therefore, the court held that Mitchell's legal rights were preserved since they were not "different from, or in addition to, any requirement applicable under this Act . . . which relates to the

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130. Id. at 877-78.
131. Id. at 878.
132. Id.
133. Id.
134. Id.
135. Id. at 879; see supra notes 99-109 and accompanying text (discussing experimental medical devices and their exempt status).
safety and effectiveness of the device . . . ."\textsuperscript{136}

Although there have been other suits against intraocular lens manufacturers, these cases have been settled and therefore have not resulted in the development of any substantive law on the issue of preemption under the intraocular lens provision of the MDA. Nonetheless, the existence of these cases suggests that manufacturers are being held accountable for the injuries caused by their defective products. For example, in \textit{Donnelly v. Copeland Intra Lenses, Inc.},\textsuperscript{137} the plaintiff filed a suit against a lens manufacturer claiming that the defendant’s lens had caused an infection that led to the loss of sight in her left eye and the loss of muscle control in part of her face.\textsuperscript{138} The suit was ultimately settled for $50,000.\textsuperscript{139}

\textbf{C. Policy Reasons For and Against Holding Manufacturers Liable for Product Defects in the Experimental Medical Device Context}

While some policy reasons support holding manufacturers liable for defects in their products, there are other arguments which oppose the imposition of liability in the experimental medical device context.\textsuperscript{140}

\textbf{1. Policy Reasons for Imposing Liability}

There are two major policy reasons for imposing liability on manufacturers of defective products. First, liability provides an incentive for manufacturers to produce safer products. Second, holding manufacturers liable spreads the loss caused by defective products among all of those who benefit from such products.

\footnotesize{\textsuperscript{136} Mitchell, 700 F. Supp. at 879.  
\textsuperscript{137} 87 F.R.D. 80 (E.D.N.Y. 1980).  
\textsuperscript{138} Id. at 82.  
\textsuperscript{139} Id. The United States District Court for the District of Minnesota entered a default judgment against Torrigan Laboratories, Inc., a third-party defendant who had sterilized and packaged the lens. The United States District Court for the Eastern District of New York, however, held that the Minnesota judgment was void because the court never acquired personal jurisdiction over Torrigan Laboratories. \textit{Id.} at 85-86; see also \textit{Kennedy v. IOLAB Corp.}, No. 51261 (Ohio Ct. App. Nov. 6, 1986) (dismissing a suit against an intraocular lens manufacturer without prejudice).  
\textsuperscript{140} Even though liability claims relating to experimental medical devices may present some practical problems on the merits, that subject is beyond the scope of this Note because if preemption occurs, the merits of the case are never reached.}
a. Promotion of Product Safety

One reason for holding manufacturers liable for product defects is that the imposition of liability promotes product safety.¹⁴¹ Many courts subscribe to this product safety theory of liability.¹⁴² Since a manufacturer’s goal is to maximize profits, there is less incentive to spend the extra time and money to make a product safer if the manufacturer will not be held liable for product-related injuries.¹⁴³ By holding manufacturers liable, the courts force manufacturers to choose between making their products safer and compensating injured plaintiffs.¹⁴⁴

¹⁴¹. *Escola v. Coca Cola Bottling Co.*, 150 P.2d 436, 440-41 (Cal. 1944) (Traynor, J., concurring) (“[P]ublic policy demands that responsibility be fixed wherever it will most effectively reduce the hazards to life and health inherent in defective products that reach the market. It is evident that the manufacturer can anticipate some hazards and guard against the occurrence of others, as the public cannot.”). See David G. Owen, *Rethinking the Policies of Strict Product Liability*, 33 VAND. L. REV. 681, 684 (1980) (arguing that since manufacturers advertise their products to the public and thereby cause consumers to rely on their safety, manufacturers must bear the burden of safety); Rosemary Kelley, Comment, *Prescription Drugs and Strict Liability: The Flaw in the Ointment*, 19 PAC. L.J. 193, 198 (1987) (stating that strict liability creates an incentive for manufacturers to make safer products).

¹⁴². See, e.g., *Lewis v. Timco, Inc.*, 716 F.2d 1425, 1429 (5th Cir. 1983) (stating that manufacturer liability encourages the production of safe products); *Salt River Project Agric. Improvement & Power Dist. v. Westinghouse Elec. Corp.*, 694 P.2d 198, 205-06 (Ariz. 1984) (“When . . . defendants realize that they may be held liable, there is of course a strong incentive to prevent the occurrence of the harm. Not infrequently one reason for imposing liability is the deliberate purpose of providing that incentive . . . . [T]he manufacturer who is made liable to the consumer for defects in a product will do what can be done to see that there are no such defects.”) (quoting William L. Prosser & W. Page Keeton, *The Law of Torts* § 24, at 25-26 (5th ed. 1984)); *Daly v. General Motors Corp.*, 575 P.2d 1162, 1169 (Cal. 1978) (reasoning that strict liability gives manufacturers an “incentive to produce safe products, . . . to avoid and correct product defects . . . [, and an] incentive toward safety both in design and production”); *Palmer v. A.H. Robbins Co., Inc.*, 684 P.2d 187, 218 (Colo. 1984) (stating that the principles of modern product liability law evolved in part to motivate manufacturers to combat the massive problem of product accidents); *Star Furniture Co. v. Pulaski Furniture Co.*, 297 S.E.2d 854, 860-61 (W.Va. 1982) (allowing a claim based on product liability because “strict liability places an obligation on manufacturers . . . to market safe products”).


¹⁴⁴. This rationale presupposes that manufacturers will only increase product safety where it is cost-effective to do so. See William R. Hadley, Comment, *Strict Liability — The Medical Malpractice Citadel Still Stands*, 11 CREIGHTON L. REV. 1357, 1360 (1978) (discussing a manufacturer’s choice between making a product safer or compensating injured consumers); John Riper, Note, *Strict Liability in Hybrid Cases*, 32 STAN. L. REV. 391, 394 (1980) (criticizing the product safety rationale of product liability law). Thus, when it is cheaper to pay tort judgments than it is to improve the safety of a product, a manufacturer will be inclined to choose the former course of action.
b. Spreading the Loss

Another public policy reason for holding manufacturers liable for defects in their products involves the spreading of losses.\textsuperscript{145} Loss-spreading allows a victim to deflect the costs of her injuries onto those individuals who benefit from the product: the consuming public. Loss-spreading is justified in part by the fact that future consumers benefit from information gathered during the period prior to their own use of the product.\textsuperscript{146} Placing the loss on the product seller through manufacturer liability is the easiest way in which the cost of product losses can be shifted to the consuming public, since the manufacturer can include the cost of the loss in the price of the product.\textsuperscript{147}

2. Policy Reasons Against Imposing Liability

There are also some public policy reasons that cut against holding manufacturers liable for defective products in the experimental medical device context. First, holding manufacturers liable may discourage manufacturers from developing new products.\textsuperscript{148} Second,

\begin{itemize}
  \item \textsuperscript{145} See generally William C. Powers, Jr., Distinguishing Between Products and Services in Strict Liability, 62 N.C. L. REV. 415, 423-28 (1984) (noting that a common rationale for strict product liability is that it internalizes accident costs by incorporating them into the price of the product, thus spreading a victim's loss among an entire group of consumers).
  \item \textsuperscript{146} See George C. Pratt & Fred W. Parnon, Diagnosis of a Legal Headache: Liability for Unforeseeable Defects in Drugs, 53 ST. JOHN'S L. REV. 517, 538 (1979) (discussing the possibility that manufacturers will use the first injured parties as "guinea pigs").
  \item \textsuperscript{147} As Judge Roger Traynor stated in his concurring opinion in \textit{Escola v. Coca Cola Bottling Co.}: "The cost of an injury and the loss of time or health may be an overwhelming misfortune to the person injured, and a needless one, for the risk of injury can be insured by the manufacturer and distributed among the public as a cost of doing business." \textit{Escola v. Coca Cola Bottling Co.}, 150 P.2d 436, 441 (Cal. 1944) (Traynor, J., concurring); \textit{see also} Becker v. IRM Corp., 698 P.2d 116, 123 (Cal. 1985) (declaring that the paramount policy of the strict liability rule remains spreading the cost of compensating otherwise defenseless victims of manufacturing defects throughout society); Immerguck v. Ridgeview House, Inc., 368 N.E.2d 803, 804 (Ill. App. Ct. 1977) ("It is also widely held that another policy consideration to be considered is that the commercial enterprise distributing the product is in the best position to distribute the risk of injury proximately caused by a defective condition of its product, by passing the loss on to the public as an additional cost of doing business."); Berry v. Beech Aircraft Corp., 717 P.2d 670, 673 (Utah 1985) (stating that the doctrine of product liability was premised on the proposition that the cost of injuries caused by defective products which are sold for a profit should be considered a cost of doing business to be borne by manufacturers, through insurance if necessary, rather than by injured individuals who could not have effectively protected themselves through insurance or other means); Fleming James, General Products — Should Manufacturers Be Liable Without Negligence?, 24 TENN. L. REV. 923, 924 (1957) (arguing that "it is both just and expedient that the enterprise which causes losses should lift them from the individual victims and distribute them widely among those who benefit from the activities of the enterprise").
  \item \textsuperscript{148} See, e.g., Pennington P. Landen, Federal Preemption and the Drug Industry: Can Courts
holding manufacturers liable forces both the states and the courts to second-guess the FDA.\textsuperscript{149}

a. Discouraging Innovation

Allowing state tort claims against manufacturers may in fact chill a manufacturer's desire to produce new products because of potential liability costs.\textsuperscript{150} This argument has been forcefully advanced in the context of drug manufacturer liability.\textsuperscript{151} As one scholar writes:

\begin{quote}
Drug manufacturers on the whole produce valuable, sometimes life-saving products. The specter of liability . . . chills the manufacturer's incentive to develop new products, making it prefer instead the tried and true remedies which appear safer from a liability standpoint. Because it is the nature of medical science to advance and progress, a pharmaceutical industry that lags woefully behind scientific advances prevents the public from partaking in new remedies for illness.\textsuperscript{152}
\end{quote}

In addition, tort liability may even force manufacturers to take existing products off the market.\textsuperscript{153} It is the public then that suffers from the current liability system, because "[w]hen it is not cost-benefit effective to produce approved drugs or develop new drugs, the public pays the price in unnecessary and unrelieved suffering."\textsuperscript{154}

b. Improper Second-Guessing of the FDA

Another policy reason opposing manufacturer liability in the medical device context is that states and courts should not second-guess the FDA. The FDA is considered to be the governing body in medical device regulation; under the MDA, medical devices must comply with FDA standards and receive approval before they can be mar-

\textit{Co-Regulate?}, 43 \textit{Food Drug Cosm.} L.J. 85, 118 (1988) (noting that "[t]he spectre of liability — despite FDA approval — chills the manufacturer's incentive to develop new products").

149. See Charles J. Walsh & Marc S. Klein, \textit{The Conflicting Objectives of Federal and State Tort Law Drug Regulation}, 41 \textit{Food Drug Cosm.} L.J. 171, 193 (1986) ("In view of the comprehensiveness and rigor of the federal scheme, courts should defer to the specific scientific and policy judgments made by the FDA.").

150. Landen, supra note 148, at 118.

151. Id.

152. Id. at 118-19.

153. Id. at 119.

154. Id.; see also Peter W. Huber, \textit{Liability: The Legal Revolution and Its Consequences} 4 (1988) (discussing how America's tort system costs manufacturers more than $80 billion a year in direct payments and insurance costs and thus has prevented new and possibly safer products from entering the marketplace).
Holding a manufacturer liable after it has complied with FDA standards effectively second-guesses the FDA’s judgment. Because the FDA is considered to be the expert in the medical device context, states and courts should defer to the FDA’s judgment.156

While the policy reasons for holding manufacturers liable for defects in their products are consistent with the preservation of statute tort claims in the face of preemption, there are some arguments that cut against holding manufacturers liable in the experimental medical device context. Despite the policy rationales for preserving tort claims, the Seventh Circuit in Slater held that common law tort claims are preempted by the Medical Device Amendments.157

II. SUBJECT OPINION — SLATER V. OPTICAL RADIATION CORP.

A. Facts and Procedural History

On July 19, 1984, Albert Slater was admitted to Hinsdale Hospital to have a cataract removed from his left eye.158 Cataract removal procedures destroy the eye’s natural lens,159 so rather than face potential blindness, Mr. Slater chose to undergo an experimental procedure in which his natural lens was replaced with an intraocular lens implant.160 Mr. Slater used the Stableflex Model #UV-11-H lens implant manufactured by ORC.161 The implant was inserted into Mr. Slater’s eye as part of a clinical investigation con-

155. See supra notes 94-98 and accompanying text (discussing the purpose of the MDA).
156. See Walsh & Klein, supra note 149, at 193 (arguing that “[i]n view of the comprehensiveness and rigor of the federal scheme, courts should defer to the specific scientific and policy judgments made by the FDA”). Moreover, others argue that courts and juries are incapable of making the determinations that are generally left to the FDA. See Premo Pharmaceutical Labs., Inc. v. United States, 629 F.2d 795, 804 (2d Cir. 1980) (opining that the FDA, by reason of its expertise, is usually better-equipped to make such a determination than the courts); United States v. 1,048,000 Capsules, 494 F.2d 1158, 1160 (5th Cir. 1974) (stating that under the Food, Drug, and Cosmetic Act, the ultimate determination of the safety of a drug is not a matter given to the courts, but one to be determined by the FDA); United States v. Articles of Drug, 498 F. Supp. 424, 431 (D.N.J. 1980) (holding that “[a] district court is not empowered to evaluate the actual safety and effectiveness of a drug product” and that the “determination is committed to the FDA due to its superior access to technical expertise”). But see Graham v. Wyeth Labs., 666 F. Supp. 1483, 1499 (D. Kan. 1987) (rejecting the defendant’s argument that it would be improper for a lay jury to decide issues delegated to the expertise of a federal agency), later proceeding, 906 F.2d 1399 (10th Cir.), later proceeding, 906 F.2d 1419 (10th Cir.), cert. denied, 498 U.S. 981 (1990).
158. Id. at 1332.
159. See supra notes 1-2 and accompanying text (noting the effects of cataract removal).
160. Slater, 961 F.2d at 1332.
161. Id.
ducted pursuant to the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA") and the regulations pertaining to intraocular lenses. Prior to the implantation of the lens, Mr. Slater signed a consent form indicating that he recognized that he was taking part in a clinical investigation program.

Over the next several years, the vision in Mr. Slater's left eye deteriorated, leaving him in continuous pain. On January 8, 1986, Mr. Slater was diagnosed with cystoid macular edema, and his doctors recommended that his intraocular lens implant be removed. Subsequent removal of the lens left Mr. Slater with permanent damage to his left eye, damage greater than what he would have suffered had he not had the implant.

The doctor performing the lens removal noticed that the lens was difficult to remove because of its awkward design. Based on his findings, the doctor wrote a letter to the FDA urging that the Stableflex Model #UV-11-H lens be removed from the market; ORC acquiesced and subsequently halted manufacture of its lens. Mr. Slater then brought a cause of action against ORC, the manufacturer of the intraocular lens, seeking recovery under Illinois law in negligence, strict liability, breach of implied warranty, and willful and wanton misconduct. All of Mr. Slater's claims were essentially based on the safety and effectiveness of the lens. The district court granted summary judgment for ORC. Mr. Slater appealed the decision, but the Seventh Circuit affirmed the district court's finding that preemption existed.

164. Slater, 961 F.2d at 1332.
165. Id.
166. See supra note 8 and accompanying text (defining cystoid macular edema).
167. Slater, 961 F.2d at 1332.
168. Id.
169. Id.
170. Appellant's Brief at 4, Slater (No. 91-1544).
171. Apple et al., supra note 2, at 88.
173. Slater, 756 F.Supp at 373.
174. Id. at 374.
176. Slater, 961 F.2d at 1334.
B. The District Court’s Reasoning

In holding that Mr. Slater’s claims were expressly preempted by the MDA, the district court specifically analyzed the preemption provision of the Amendments. As the court noted, the MDA only preempts “any state tort standard which would impose requirements on producers of medical devices which are different from or in addition to the specific counterpart regulations or other specific requirements promulgated by the FDA.”

Searching for such specific “counterpart regulations,” the court focused on the Investigational Device Exemption for intraocular lenses. The Investigational Device Exemption sets forth the procedures and conditions under which intraocular lens manufacturers, during the investigational stage, may be granted an exemption from the otherwise required safety and effectiveness provisions for medical devices. The district court believed that this exemption constituted the necessary specific counterpart requirement and thus held that all of the plaintiff’s claims were preempted. Without clearly articulating its reasoning, the court stated that “[t]he imposition of state tort requirements in this case would clearly be ‘different from, or in addition to’ both the terms of the [Food, Drug, and Cosmetic Act] and the requirements of the [Investigational Device Exemption] promulgated by the FDA for safety and effectiveness.”

C. The Seventh Circuit’s Reasoning

In affirming the district court’s holding, the Seventh Circuit agreed that Mr. Slater’s claims were preempted by the Medical Device Amendments. Speaking for the Seventh Circuit, Judge Richard Posner characterized Mr. Slater’s “real gripe” as a defective

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179. Id.
180. Id., see also supra notes 99-109 and accounting text (discussing the terms and scope of the Investigational Device Exemption).
182. Id. Evidently the court believed that the imposition of state tort claims would require the defendant manufacturer to do more with respect to the “safety and effectiveness” of the lens than was required under the Investigational Device Exemption, since manufacturers are exempt from the safety and effectiveness requirements under the regulations.
design claim, summing up the plaintiff's design defect theory as a claim that since the exemption regulations do not specify a design for investigational devices, there are no specific federal counterpart regulations based on design which trigger the preemption provision.

After considering the Investigational Device Exemption, the Seventh Circuit agreed that the regulations do not impose any requirements concerning the design of intraocular lenses. However, the court stated that the plaintiff's argument assumed that the only way to avoid preemption would be to actually specify the design. Judge Posner found this to be a "cramped" interpretation of the preemption provision, and cautioned that allowing such an interpretation would "cripple the exemption for investigational devices" altogether. The court stated that since the devices are experimental during the time in which the exemption is in effect, the FDA can hardly be expected to specify a safe and effective design.

The court further stated that the regulations at the experimental stage are procedural as opposed to substantive. Rather than specifying an actual safe and effective design, the regulations specify procedures for determining whether a device is safe and effective. The appellate court stated that procedural requirements pertaining to safety and effectiveness can and do have a preemptive effect over any state requirements relating to safety and effectiveness. Allowing a state common law recovery would essentially require the manufacturer to take actions greater than or different from those required by the FDA regulations; namely, they would be required to have different design characteristics. The court stated that "this

184. Id. at 1333.
185. Id.
186. Id.
187. Id.
188. Id.
189. Id.
190. Id. The court further stated: "If there were a known safe and effective design, the device would no longer be experimental. The point of the experiment is to find out whether it is safe and effective." Id.
191. Id.
192. Id.
193. Id. The court stated that although an investigational exemption "is different from a certification that the design of the device is safe and effective, it is a certification that the design is sufficiently safe and effective to allow experimental use on human beings" and therefore is a safety and effectiveness requirement. Id.
194. Id.
engrafting of additional requirements relating to safety or effectiveness is forbidden by the preemption provision in the Medical Devices Amendments."\(^{195}\)

The Seventh Circuit did acknowledge that the district court had disagreed with *Mitchell*,\(^{196}\) the only other case concerning the preemptive force of the exemption provision for investigational devices.\(^{197}\) The court then proceeded to criticize the *Mitchell* decision, stating that *Mitchell* effectively repealed the preemption provision by allowing the plaintiff's claims based on safety and effectiveness.\(^{198}\) According to the Seventh Circuit, only claims not based on the safety and effectiveness of the lens are preserved by the consent provision in the federal regulations governing intraocular lenses.\(^ {199}\)

### III. Analysis

Determining whether preemption exists and exactly what is preempted is not an easy task. Perhaps that is why the Seventh Circuit failed when it reached its decision in *Slater*. First, the Seventh Circuit erroneously held that Mr. Slater's claims were expressly preempted. Although it was questionable whether express preemption existed in this case, the Seventh Circuit also failed to consider whether Mr. Slater's claims were impliedly preempted. Third, the court gave no attention to the distinction between state regulation and state common law tort actions. Finally, the court failed because the result in *Slater* is inconsistent with policy reasons favoring the imposition of liability on manufacturers for defects in their products.

#### A. The Seventh Circuit Erroneously Found Express Preemption

In *Slater*, the Seventh Circuit held that the preemption provision of the MDA expressly preempts product liability claims against intraocular lens manufacturers.\(^{200}\) This finding is erroneous for three reasons. First, the broad preemption provision of the MDA is not specific enough to trigger express preemption. Second, allowing claims similar to those of Mr. Slater would not impose requirements

\(^{195}\) Id.
\(^{196}\) See supra notes 129-36 and accompanying text (discussing the *Mitchell* case).
\(^{197}\) *Slater*, 961 F.2d at 1331.
\(^{198}\) Id. at 1334.
\(^{199}\) Id.
\(^{200}\) Id.
different from or in addition to a provision found in the federal statute. Third, under a finding of express preemption, it is not possible to reconcile the reasoning of Slater with that of Mitchell.

1. The Language of the MDA Preemption Provision is Not Specific

For express preemption to occur, Congress must explicitly declare that state law on a certain subject is preempted. The preemption provision of the MDA does not explicitly state that experimental medical device manufacturers will be immune from tort liability; indeed, the Investigational Device Exemption for intraocular lenses does not contain any preemption language at all. As has been previously mentioned, however, specific preemption language is needed for express preemption to occur.

One example of the necessary express preemption language is found in the Cigarette Act, which expressly provides that states may not impose any advertising or labeling requirements that are inconsistent with those required by the federal statute. But while the language of the Cigarette Act is very specific as to what is preempted, the preemption language in the MDA is quite different. The preemption provision of the MDA prohibits a state from imposing any requirement on producers of medical devices which is different from or in addition to any other regulation promulgated by the FDA. This is a blanket approach to preemption which clearly conflicts with the entire basis of the express preemption doctrine.

The essence of express preemption is that where Congress unambiguously states that preemption is to occur, there is no need to look beyond the specific language at issue because the results of the preemptive language are clear and unambiguous. In other words, because express preemption language is used, it is certain that Con-

201. See supra notes 32-41 and accompanying text (describing when express preemption occurs).
202. See supra notes 110-11 and accompanying text (noting the language of the MDA's preemption provision).
205. This language was interpreted as expressly preempting further labeling requirements in Cipollone v. Ligget Group, Inc., 112 S. Ct. 2608 (1992). See supra notes 35-39 and accompanying text (discussing the Cipollone decision).
206. See supra notes 110-11 and accompanying text (noting the text of the preemption provision of the Medical Device Amendments).
gress intended the exact results. With respect to the preemption language used in the Cigarette Act, such is the case; by stating that state labeling and warning requirements on cigarette packages are preempted, Congress was apparently aware of the effects preemption would have. Such is not the case, however, with respect to the preemption language of the MDA, as Congress did not consider the effects of such a broad preemption provision. Thus, the broad preemption language found in the Amendments is not the type of specific statement necessary for express preemption to occur.

2. A State Court Judgment Would Not Impose Requirements Different From or in Addition to a Provision Found in the Federal Statute

Assuming the broad preemption provision of the MDA applies, allowing Mr. Slater's claim would not necessarily impose requirements different from or in addition to a provision found in the MDA. Express preemption under the Amendments requires that a two-pronged test be satisfied. First, it must be determined whether the state requirement in question relates to a matter included in the federal regulations. If so, it must then be determined whether the state law requirement is different from or in addition to the specific requirement found in the regulations. In other words, a court must determine whether the state requirement conflicts with the federal requirement.

In Slater, the Seventh Circuit held that the Investigational Device Exemption for intraocular lenses — specifically the exemption from having to specify a safe and effective design before marketing an experimental device — constitutes the specific counterpart regulation necessary to invoke the preemption provision. While the court was correct in holding that a state tort judgment based on the safety and effectiveness of a device relates to the exemption provision, the court erred in summarily assuming that a state tort judgment conflicts with the federal exemption. Simply requiring a manu-

208. Congress would have had to consider the effects of preemption with respect to each and every regulation promulgated by the FDA.
209. Smith v. Pingree, 651 F.2d 1021, 1023 (5th Cir. 1981); see supra notes 113-17 and accompanying text (describing the two-pronged test).
210. Pingree, 651 F.2d at 1023.
211. Id.
facturer to pay a state tort judgment does not necessarily require the manufacturer to do more than is required by the federal statute. 213 Rather than specify a safe and effective design before marketing an experimental product, the manufacturer could simply treat a tort judgment as a cost of doing business and pass the cost on to the consumer. 214 Because the state regulation at issue in Slater did not conflict with a requirement found in the federal statute, express preemption did not occur.

3. Express Preemption Prevents Reconciliation of Slater and Mitchell

Under a finding of express preemption, it is not possible to reconcile the reasoning of Slater with that of Mitchell, the only other case directly on point. The two decisions clash over the actual meaning and scope of the consent provision in the federal statute. 215 The consent provision concerns the type of informed consent that must be given to patients who take part in investigational device programs; 216 the provision clearly states that patients cannot be made to waive any legal claims, including those against the manufacturer. 217

The Mitchell court held that the consent provision clearly preserves a patient’s legal rights, even against the manufacturer. 218 That court stated that since the consent provision is incorporated by reference into the regulations governing intraocular lenses, state law claims are not preempted. 219 On the other hand, the court in Slater found that the consent provision merely preserves the plaintiff’s common law rights outside of the preemption provision. 220

While both courts acknowledged the validity of the informed con-

213. A state tort judgment is akin to neither a state regulation nor an injunction that clearly prohibits a manufacturer from selling a product until it proves that it is safe and effective, and thus does not require more than is required under the federal statute.

214. This approach furthers the risk-spreading policy for imposing liability on manufacturers for product defects. See supra notes 145-47 and accompanying text (discussing the policy of loss-spreading).

215. 21 C.F.R. § 50.20 (1992); see supra note 108 (providing the text of the consent provision).


217. Id.


219. Id.

sent provision, they differed as to the meaning and effect the provision is to have. Under *Slater* a patient's legal rights against the manufacturer, which are supposedly preserved under the MDA's consent provision, were stripped away. Since the federal statute does not state that the consent provision is limited by other provisions of the MDA, it should not be given the limited effect that the *Slater* court gave it; the decision in *Slater* effectively repealed the consent provision. The MDA's consent provision, which preserves a patient's legal rights against a manufacturer, directly conflicts with the *Slater* court's finding of express preemption.

**B. The Seventh Circuit's Failure to Consider Implied Preemption**

Because it is questionable whether Mr. Slater's state tort claims were expressly preempted by the MDA, the Seventh Circuit should have considered whether those claims were impliedly preempted. If the court had considered implied preemption, it would have concluded that state common law claims were not preempted.

Implied preemption analysis starts with the premise that there is a strong presumption against preemption, particularly where the state law deals with areas that have been traditionally occupied by the states, such as the local regulation of matters related to health and safety. Implied preemption occurs when federal regulations are so comprehensive that state law is displaced, when there is a dominant federal interest in the subject matter, or when there is a direct conflict between the federal and state laws at issue. Congressional intent must be considered in determining whether any of these tests are satisfied.

1. **Comprehensive Federal Regulations**

Where Congress comprehensively deals with a subject, implied preemption occurs. Implied preemption under such circumstances

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221. See *supra* notes 71-73 and accompanying text (noting the presumptions courts make in determining if implied preemption exists).

222. See *supra* notes 42-73 and accompanying text (discussing the three types of implied preemption).

223. See *supra* note 45 and accompanying text (noting that congressional intent is part of the determination of implied preemption).

224. See *supra* note 46-50 and accompanying text (discussing how comprehensive federal regulations displace state law).
is based on the assumption that because Congress left no room for state regulation, Congress intended to preempt state law.

Notwithstanding the extensive nature of the federal system governing medical devices, the legislation is not exclusive enough to warrant a finding of implied preemption. The legislative history of the MDA reveals that Congress knew that the FDA would not be able to eliminate all injuries arising from medical devices, and thus the FDA was not intended to be the only source of regulation on the subject. To this end, the MDA provides a mechanism whereby a state may supplement the federal regulations, provided that the state's regulations are "more stringent" than the federal regulations or are "required by compelling local conditions." Because the medical device legislation permits the states to play a supplementary role in the context of medical device regulation, it cannot be assumed that Congress intentionally proscribed state regulation of this area. Thus, a finding of implied preemption on this basis must fail.

2. Dominant Federal Interest

An act of Congress in a field in which the federal government has a dominant interest will be assumed to preclude enforcement of state laws on the same subject. For implied preemption to occur based on the federal government's dominant interest, that interest must indeed be superior to the state's interest. The Supreme Court has held that the federal government holds such a requisite interest

225. See H.R. Rep. No. 853, 94th Cong., 2d Sess., 15-16 (1976), which provides in pertinent part:

Contained in various provisions throughout the proposed legislation is the requirement that regulatory action be taken to provide reasonable assurance of the safety and effectiveness of medical devices. This requirement is predicated upon the recognition that no regulatory mechanism can guarantee that a product will never cause injury, or will always produce effective results. Rather, the objective of the legislation is to establish a mechanism in which the public is afforded reasonable assurance that medical devices are safe and effective.

Id. Congress apparently intended this legislation to be only a reasonable assurance that medical devices were safe and effective, because Congress knew that the FDA would not be able to eliminate all injuries resulting from medical devices. Clearly, the FDA was not intended to be the only source of regulation on the subject.

226. See supra note 111 and accompanying text (citing the Medical Device Amendments' exception provisions).

227. See supra note 51-57 and accompanying text (discussing the dominant federal interest basis for implied preemption).
in issues involving foreign affairs and national security. The same can hardly be said about the subject matter governed by the Amendments. Although the federal government does have an interest in protecting the health and safety of the nation's citizens, its interest is not superior to that of the states in this area.

Historically, the states have governed the ordinary affairs of people's lives; consequently, issues relating to health and safety have traditionally been preserved for the states. Deference to the states on this issue is actually reflected in the MDA; the fact that the federal regulatory scheme allows the states to supplement the federal regulations relating to medical devices evidences the fact that Congress recognized the overlapping federal and state interests involved in the health and safety area. Because the federal government does not have a dominant federal interest in the health and safety arena, implied preemption on this basis cannot succeed.

3. Direct Conflict Between State and Federal Law

State law is also impliedly preempted when it directly conflicts with federal law on the same subject. Direct conflict occurs in two different situations: when compliance with both state law and the federal regulatory scheme is not possible, and when state law frustrates Congress's purpose for enacting a particular federal law.

The first type of direct conflict implied preemption is not present in the instant situation. For this type of preemption to occur, an intraocular lens manufacturer would have to find it impossible to simultaneously comply with both the requirements of the Amendments and the paying of state tort judgments. Under the MDA, a

228. See supra notes 52-57 and accompanying text (describing the Supreme Court's decision in Hines.

229. See supra note 24-28 and accompanying text (noting the Framers' concerns with preserving state autonomy).

230. See supra note 27-28 and accompanying text (citing cases supporting the proposition that issues relating to health and safety have traditionally been within the competence of the states).

231. See supra note 58-73 and accompanying text (discussing implied preemption based on direct conflicts between state and federal law).

232. E.g., Hillsborough County v. Automatic Medical Labs., 471 U.S. 707, 713 (1985); Capital Cities Cable, Inc. v. Crisp, 467 U.S. 691, 699 (1984); Hines v. Davidowitz, 312 U.S. 52, 67 (1941); see also NOWAK & ROTUNDA, supra note 29, at 312 (discussing the preemption test created by the Hines Court).

233. See supra notes 66-70 and accompanying text (discussing a second type of direct conflict implied preemption and the Court's decision in Hill).

234. For example, direct conflict occurs where the federal statute requires a manufacturer to do
manufacturer does not have to prove that its products are safe and
effective before they are used in an investigational setting.\textsuperscript{238} Although paying state tort judgments would require a manufacturer to
do more than is required under the federal statute, it does not force the
manufacturer to violate the federal statute. Thus, because it is possible to simultaneously comply with the MDA and still pay state
tort claims, implied preemption is not present.

The second type of direct conflict implied preemption is also not
present in the instant situation. For it to occur, the state regulation
at issue must conflict with the federal scheme so as to frustrate its
purpose.\textsuperscript{236} Because requiring manufacturers to pay state tort claims
is consistent with the purpose of the MDA, implied preemption does
not occur.

The legislative history of the Amendments indicates that the pur-
pose of the federal legislation was to protect consumer health and
safety.\textsuperscript{237} Allowing state tort claims actually advances this goal;
holding manufacturers liable for defects in their products gives them
an incentive to produce better and safer products, which results in
the protection of consumer health and safety.\textsuperscript{238} Because there is no
conflict when both the state and federal regulations are working to-
ward the same goal, implied preemption does not occur.

\section{The Slater Court Did Not Address the Distinction Between
State Regulation and State Tort Claims}

Without considering the language of the preemption provision of
the MDA, the Seventh Circuit held that Mr. Slater's common law

\begin{itemize}
\item X and the state requirement prohibits the manufacturer from doing X. Because compliance with
the state requirement forces the manufacturer to violate the federal standard, the state require-
ment is preempted.
\item See supra note 101 and accompanying text (setting forth the exemption for investigational
devices under the MDA).
\item See supra notes 66-70 and accompanying text (discussing the Hill decision, which dealt
with direct conflict implied preemption).
\item See supra notes 118-23 and accompanying text (setting forth and discussing the health
and safety concerns pervading the MDA's legislative history). To the extent that it is argued that
the purpose of the Investigational Device Exemption for intraocular lenses was to encourage inno-
vation, Congress has stated that innovation is only to be encouraged in accordance with the pro-
tection of public health and safety. See infra notes 252-53 and accompanying text (describing the
legislative history of the MDA, which illustrates Congress's intent to preserve health and safety
while encouraging innovation); see also supra notes 150-54 and accompanying text (discussing
how the policy of promoting innovation cuts against imposing manufacturer liability).
\item See supra notes 141-44 and accompanying text (discussing the product safety theory of
liability).
\end{itemize}
claims were preempted.\textsuperscript{239} This finding was erroneous because the preemption provision speaks only to conflicting requirements imposed by states or political subdivisions;\textsuperscript{240} the statute does not preempt common law tort actions.\textsuperscript{241}

This interpretation of the statute is supported by the legislative history of the MDA. A report by the House Committee on Interstate and Foreign Commerce indicates that Congress intended to abolish state regulation relating to the sale and distribution of medical devices.\textsuperscript{242} The report also indicates that Congress was concerned about the burden that would be placed on interstate commerce if the states were allowed to impose different regulations.\textsuperscript{243} In addition, the House Report never even hinted at the MDA's effect on state common law.\textsuperscript{244} Because the legislative history only dis-

\textsuperscript{239} Slater v. Optical Radiation Corp., 961 F.2d 1330, 1333 (7th Cir), cert. denied, 113 S. Ct. 327 (1992). The court stated that although "[t]he plaintiff wishes in the name of state tort law to impose additional requirements ... [, such] engrafting of additional requirements relating to safety or effectiveness is forbidden by the preemption provision in the Medical Devices Amendments." \textit{Id.}

\textsuperscript{240} For the text of the preemption provision of the Amendments, see \textit{supra} notes 110-111 and accompanying text.

\textsuperscript{241} The cases construing similar preemption language also support this statutory interpretation and hold that where common law claims are not mentioned in the statute, they are preserved. \textit{See supra} notes 77-82 and accompanying text (discussing the \textit{Ferebee} case, wherein the D.C. Circuit held that a federal statute which did not address state tort claims did not preempt state damage actions). It should be noted that although Congress did not refer to "court decisions" in the statute, the regulations at 21 C.F.R. § 808.1(b) (1992) do. The regulations provide:

Section 521(a) of the act [21 U.S.C. § 360k(a)] contains special provisions governing the regulation of devices by States and localities. That section prescribes a general rule that ... no State or political subdivision of a State may establish or continue [to] 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.

\textit{Id.}

A district court, in \textit{Callan v. G.D. Searle & Co.}, 709 F. Supp. 662 (D. Md. 1989), addressed this inconsistency between the statute and the implementing regulations and stated: "To the extent that the FDA’s inclusion of the words 'court decision' in its implementing regulations suggests otherwise, the FDA regulation contradicts congressional intent and is not based on a permissible construction of the statute." \textit{Id.} at 668. The \textit{Callan} court went on to hold that the plain language of the MDA’s preemption provision indicates that Congress intended to preempt state and local legislation and administrative regulations governing devices, but not state tort law; the court, however, did not mention whether or not the common law was preempted. \textit{Id.}

\textsuperscript{242} 121 \textit{CONG. REC.} 10,688 (April 17, 1975) (statement of Sen. Kennedy).

\textsuperscript{243} \textit{See supra} note 125 and accompanying text (setting forth the Committee’s reservations about the effect of state regulations on interstate commerce).

\textsuperscript{244} \textit{See supra} notes 124-25 and accompanying text (discussing the House Report).
cusses the burden on interstate commerce in light of state and local regulation, it can be argued that the preemption provision was only intended to refer to legislative and administrative programs governing the sale and distribution of devices.

The fact that a federal remedy for those who have been injured by medical devices does not exist under the MDA also supports the contention that Congress intended to preserve state law claims.\footnote{In fact, the cases that have found the existence of preemption despite the fact that state tort claims were not specified in the statute have allowed preemption only to the extent that the state tort remedy was displaced by a federal remedy. \textit{See supra} notes 77-82 and accompanying text (discussing the \textit{Ferebee} decision, which held that a federal statute which did not address state tort claims did not preempt state damage actions).}

The absence of a federal remedy goes directly to whether Congress intended to preempt state common law tort claims, thus leaving plaintiffs with no remedy.\footnote{As the Supreme Court stated in \textit{Silkwood}: "[I]t is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct." \textit{Silkwood v. Kerr-McGee Corp.}, 464 U.S. 238, 251 (1984).}

Since the Amendments do not provide a federal remedy, the Seventh Circuit should not have been so quick to include state tort actions in the preemption provision.

In further support of the proposition that the preemption provision was only meant to apply to state regulation is the fact that states may impose more stringent requirements relating to medical devices, provided that they apply to the FDA for an exemption.\footnote{See supra notes 111 and accompanying text (noting and discussing the MDA's exemption requirements).}

State tort judgments can be viewed as more stringent state requirements. However, since a state cannot be required to apply for an exemption after each state tort judgment, it can be argued that the preemption provision was meant to apply only to state regulation.

The clear language of the preemption provision indicates that only state regulation was to be preempted. Supporting this interpretation is the legislative history of the MDA, the fact that no federal remedy exists under the MDA, and the fact that states cannot apply for an exemption each time they impose a more stringent state requirement in the form of a state tort judgment. Had the Seventh Circuit considered the distinction between state regulation and state common law claims, it would have found that Mr. Slater's claims were indeed preserved.
D. Slater is Inconsistent With Policy Reasons Favoring Manufacturer Liability

The decision in *Slater* is inconsistent with the policy reasons for holding manufacturers liable for defects in their products. While there are some policy arguments against imposing liability in the experimental medical device context, such arguments can be easily discounted.

Holding manufacturers liable for defects in their products gives them an incentive to produce better and safer products.\(^{248}\) This is extremely important in the experimental stage; since experimental devices are exempted from the usual requirements of establishing pre-market safety and effectiveness under the FDA guidelines, manufacturers need incentives to make their products safe enough to be tested on people. Allowing state tort claims advances this goal.

Imposing liability on manufacturers also allows the risks of products to be shifted from the injured plaintiff to everyone who benefits from the product.\(^{249}\) The risk-spreading rationale is also very important in the experimental medical device context. Because pre-market testing cannot reveal all the risks in a product, consumers act as "guinea pigs" during the first few years that a product is marketed. Since future consumers benefit from the information generated from use of the product during the experimental period, it is only fair to impose compensation costs on future consumers. Placing liability on the manufacturer is a way of passing this cost on to the consumer, since the cost of injuries can be reflected in the price of the product.\(^{250}\)

In opposition to the imposition of manufacturer liability in the experimental medical device context is the argument that allowing state tort claims chills a manufacturer's incentive to produce new products because of the potential liability costs.\(^{281}\) Although innovation is indeed a goal to be achieved with respect to experimental devices, it should not be realized at the expense of health and safety. Congress considered this very issue when it enacted the Amend-

\(^{248}\) See *supra* notes 141-44 and accompanying text (discussing the product safety theory of liability).

\(^{249}\) See *supra* notes 145-47 and accompanying text (discussing the spreading of losses theory of imposing liability).

\(^{250}\) See *supra* note 147 and accompanying text (discussing the theories of cost-shifting and cost-spreading).

\(^{251}\) See *supra* note 150-54 and accompanying text (discussing how the allowance of state tort claims may discourage a manufacturer's innovation).
ments. The legislative history of the MDA indicates that Congress did not intend for health and safety to be sacrificed in the name of new product development. The legislative history provides:

The Committee recognizes the necessity to encourage the discovery and development of medical devices intended for human use and the need for scientific investigators to maintain freedom to do so. On the other hand, research on medical devices in the developmental stage must not endanger the public health and must assure the highest ethical standards.

When health and safety concerns run up against the desire to encourage new product development, health and safety should prevail.

Second, the policy argument that imposing liability on manufacturers second-guesses the FDA is not supported in the experimental medical device context. The policy of not second-guessing the FDA is based on two assumptions: that the FDA is the authoritative body on the subject that is being regulated, and that the FDA is to be the sole source of regulation with respect to medical devices. Neither of these assumptions is valid in the experimental medical device context.

Because little is known about a product at the experimental stage, there is in reality no authority regarding that product, not even the FDA. In fact, to gain the necessary information about experimental products, the FDA grants exemptions for experimental medical device testing and use. Thus, while the FDA is generally considered the governing body with respect to drugs and devices, this is not the case in the context of experimental products because the FDA arguably does not have superior knowledge to which states and courts can defer.

The second assumption is that the sole source of regulation with respect to medical devices should be the FDA; this is also not the case with the MDA. The legislation clearly provides that the states may supplementally regulate medical devices as long as the state requirements are more stringent than the federal requirements. Thus, the argument that states and courts should defer to the FDA conflicts with the fact that supplemental state regulation is allowed.

In summary, the policy reasons for imposing liability on manufac-

253. Id. at 42.
254. See supra note 155 and accompanying text (discussing the role of the FDA in the medical device context).
255. See supra note 111 and accompanying text (setting forth and discussing the MDA's requirements for exemption from the federal preemption provision).
turers for product defects are in line with the goal of preserving tort claims in the face of preemption. The imposition of liability provides an incentive for manufacturers to produce safer products. It also spreads the risk of products to all who benefit from them. While there may be some policy arguments against imposing liability on manufacturers in the experimental medical device context, those arguments are easily rebutted.

IV. IMPACT

Like Albert Slater, many people agree to participate in clinical investigation programs involving experimental medical devices which sometimes result in injuries to the participants. According to the Seventh Circuit’s decision in *Slater*, injured participants are prevented from bringing a cause of action against the manufacturer of an experimental medical device based on the safety and effectiveness of the device, and they are therefore divested of any state tort remedies which would otherwise be available to them. Moreover, the Medical Device Amendments as they stand today do not provide any federal remedy for plaintiffs injured by experimental medical devices.

The most direct impact of this decision is that plaintiffs like Albert Slater are forced to bear the burden of experimental medical device testing on their own. Clearly, this is not what Congress intended when it enacted the MDA. Not only is this decision inequitable, it is also inappropriate from a policy perspective. Congress did not intend for the victims of experimental medical testing to bear the burden of potential injury on their own. This proposition is supported in the text of the MDA, which contains a consent provision that preserves a patient’s legal rights against a manufacturer. The fact that such a consent provision exists indicates that Congress did not intend for participants in the clinical testing context to be forced to solely bear the burden of experimental testing.

Furthermore, requiring patients to bear the burden of experimental medical testing is inappropriate from a policy perspective. Such a result requires an injured plaintiff to bear all of the cost when there are others who also benefit from the testing. Because future consumers will benefit from the information generated from use of the product during the experimental period, it is only fair that they should share in the cost of developing that information. Placing liability on the manufacturer is a way of passing this cost on to the
consumer, since the cost of injuries can be reflected in the price of the product. Moreover, it is also inappropriate to allow manufacturers to use this legislation to shield themselves from liability for the very group of people the legislation was designed to protect — consumers.

It seems that there are two possible alternatives to lifting the burden of experimental medical device testing that Slater imposes: either tort claims against manufacturers should be allowed, or a federal remedy should be provided. Allowing state tort claims would not only provide plaintiffs with compensation for their injuries but would also allow the cost of new products to be spread to all of those who benefit from them. Moreover, the imposition of liability on the manufacturer would give the manufacturer an incentive to produce safer products.

A federal compensation system may also be a viable alternative for dealing with this issue. Congress has enacted such a system in the past. Indeed, this may be the preferable solution since it would lower the cost of injuries as a whole by avoiding the litigation expenses that would otherwise be involved in tort claims. Providing injured plaintiffs with some type of compensation through a federal system would make the Slater court's finding of preemption a little easier to accept.

V. CONCLUSION

Under the decision in Slater v. Optical Radiation Corp., plaintiffs like Albert Slater are stripped of their state tort remedies for medical experiments gone awry. Furthermore, the Medical Device Amendments do not provide a federal remedy for the victims of experimental medical device mishaps. The MDA was not intended to insulate manufacturers from liability, thus leaving plaintiffs like Mr. Slater to bear the burden of experimental medical device testing on their own. The legislative history indicates that this was not the intended effect; rather, protection of the consumer was of utmost im-


portance. Nevertheless, the Seventh Circuit in *Slater* avoided following Congress's intent by erroneously concluding that Mr. Slater's state tort claims were expressly preempted by the Medical Device Amendments.

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