Federal Preemption of State Products Liability Doctrines

Richard C. Ausness

University of Kentucky

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FEDERAL PREEMPTION OF STATE PRODUCTS LIABILITY DOCTRINES

RICHARD C. AUSNESS*

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* Ashland Oil Professor of Law, University of Kentucky. B.A. 1966, J.D. 1968, University of Florida; LL.M. 1973, Yale University.
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I. INTRODUCTION

Federal agencies now regulate the manufacture, design, and labeling of hundreds of consumer products.1 For example, the Consumer Product Safety Commission promulgates "consumer product safety standards" for a number of consumer products.2 Likewise, the National Traffic and Motor Vehicle Safety Act of 19663 authorizes the National Highway Transportation Safety Administration to develop safety standards for automobiles and other motor vehicles.4 Additionally, the Food and Drug Administration (FDA) exercises extensive control over prescription drugs, biologics, medical devices, and over-the-counter drugs.5 The FDA also regulates food


labeling. Finally, Congress has established statutory labeling requirements for cigarettes, smokeless tobacco products, and alcoholic beverages.

Many federal product safety statutes expressly prohibit states and localities from imposing on manufacturers product safety requirements that differ from those established by federal law. These statutes obviously preempt nonconforming state and local statutes, ordinances, and administrative regulations. However, it is less clear whether they should be construed also to preempt state tort-law damage claims against manufacturers whose products meet applicable federal standards. Despite the numerous product preemption cases decided over the past five years, federal courts remain hopelessly divided on this issue.

Part II of this Article analyzes the concept of preemption and discusses the various preemption categories. Part III surveys the preemption litigation


The United States Department of Agriculture (USDA) also exercises some regulatory authority over food production and marketing. For example, the USDA operates inspection programs for meat, eggs, and poultry products under the authority of the Federal Meat Inspection Act, 21 U.S.C. §§ 601-695 (1988 & Supp. III 1991), the Egg Products Inspection Act, 21 U.S.C. §§ 1031-1056, and the Poultry Products Inspection Act, 21 U.S.C. §§ 451-470. In addition, the USDA has promulgated labeling standards for each of these products. 21 U.S.C. § 611 (1988) (meat); id. § 1036(b) (eggs); id. § 457 (poultry products).


11. See discussion infra Part III.
involving cigarettes, airbags, pesticides, pharmaceuticals, and medical devices. A survey of these cases suggests that most courts ignore important policy issues by applying a one-dimensional approach to preemption issues.

Part IV describes a model of statutory interpretation based on the "practical reasoning" approach developed by Eskridge and Frickey. This model treats statutory interpretation as a dynamic process in which the interpreter constructs a meaning from considerations of statutory text, legislative history, and contemporary values and policies. The author of the present Article concludes that an interpretive approach based on the Eskridge-Frickey model may lead to better results in product preemption cases than those achieved by the interpretive approaches currently employed.

In Part V, the Eskridge-Frickey practical reasoning model is applied to each of the product preemption categories mentioned above. After an evaluation of text, legislative history, and contemporary values, the author concludes that the interpretive evidence generally does not support a finding of preemption in product preemption cases.

II. THE PREEMPTION DOCTRINE

The Supremacy Clause of the United States Constitution provides that the laws of the United States shall be the supreme law of the land. Therefore, Congress may enact laws that supersede state statutes or local ordinances. State common-law doctrines that conflict with federal law may also be preempted. However, the Supreme Court has often refused


13. Id. at 354-62.

14. U.S. CONST. art. VI, cl. 2. ("This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; . . . 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.").


to find preemption when Congress has not made its intent to supersede state law "clear and manifest."18 Furthermore, the Court is reluctant to preempt state common-law doctrines that represent many generations of judicial development and concern in areas that traditionally have been reserved to the states.19

Preemption can occur in a variety of ways.20 First, Congress can declare its intention to preempt state law by express language.21 Second, preemption may be implied when a federal regulatory scheme effectively occupies the field and leaves no room for state regulation.22 Finally, state law may be preempted when it conflicts with federal regulatory objectives.23

A. Express Preemption

Express preemption occurs when a federal statute specifically excludes state regulation in a particular area.24 For example, in Rice v. Santa Fe


20. See Pacific Gas & Elec., 461 U.S. at 203-04 (listing ways in which preemption can occur).

21. Id. at 203.

22. Id. at 203-04.

23. Id. at 204. Some commentators distinguish between express and implied preemption. The latter category includes preemption based on either occupation of the field or actual conflict. See Elaine M. Martin, Note, The Burger Court and Preemption Doctrine: Federalism in the Balance, 60 NOTRE DAME L. REV. 1233, 1235-36 (1985) (distinguishing express, conflict, and occupation-of-the-field preemption). However, as Justice Black observed, no classification scheme is applied consistently: "[N]one of these expressions provides an infallible constitutional test or an exclusive constitutional yardstick. In the final analysis, there can be no one crystal clear distinctly marked formula." Hines v. Davidowitz, 312 U.S. 52, 67 (1941).

Elevator Corp. the Court concluded that preemptive language in the federal Warehouse Act indicated that Congress intended to displace state jurisdiction over federally licensed warehouse operators. Consequently, the Court quashed proceedings brought against a federal licensee for violating state laws against rate discrimination.

Regulations promulgated by a federal agency acting within the scope of its delegated authority may also preempt state law. Fidelity Federal Savings & Loan Ass'n v. de la Cuesta involved a conflict between a regulation adopted by the Federal Loan Bank Board concerning "due-on-sale" clauses in home mortgage contracts and a state common-law doctrine that limited the use of due-on-sale provisions. The Court observed that the Home Owners' Loan Act of 1933 gave the Board broad authority over federal savings and loan associations. Because the Board clearly indicated its intent to displace state law concerning due-on-sale clauses, the Court ruled that the Board's regulation expressly preempted state law.

B. Federal Occupation of the Field

Federal and state regulatory schemes coexist in many areas. Even when

27. Rice, 331 U.S. at 233-34.
28. Id. at 235-36.
32. The California Supreme Court recognized this common-law doctrine in Wellenkamp v. Bank of America, 582 P.2d 970 (Cal. 1978) (en banc). The Wellenkamp court held that due-on-sale clauses constitute an unreasonable restraint on alienation unless the lender can show that such a clause is necessary to protect against impairment of its security interest or the risk of default. Id. at 976-77.
34. Fidelity, 458 U.S. at 159-67.
35. Id. at 158.
36. Id. at 170.
the federal government plays a dominant role in an area, the states often retain significant residual power.37 However, federal involvement in an area may become so pervasive that it displaces all forms of state regulation in the same regulatory field.38

1. Dominant Federal Interest

The dominant nature of a federal regulatory interest may justify federal occupation of a field.39 San Diego Building Trades Council v. Garmon40 provides a good example of this principle. Garmon involved a labor dispute between a lumber supply company and a number of labor unions. A state court awarded damages against a union for engaging in unfair labor practices.41 On appeal, the Supreme Court observed that Congress had placed primary responsibility for the administration of national labor policy within a single federal agency “armed with its own procedures, and equipped with its specialized knowledge and cumulative experience.”42 Congress took this action to ensure the application of uniform procedures and principles of substantive law.43

The Court noted that the National Labor Relations Act44 vests in the National Labor Relations Board (NLRB) the power to determine which union activities are protected and which acts constitute unfair labor practices.45 If the NLRB determines that a particular activity is either protected or prohibited, the states are ousted from any jurisdiction over the


Federal regulatory standards will also preempt state standards if federal standards are intended to be uniform. See, e.g., Ray v. Atlantic Richfield Co., 435 U.S. 151, 163 (1978); Campbell v. Hussey, 368 U.S. 297, 300-01 (1961).
41. Id. at 237-38.
42. Id. at 242.
43. Id. at 242-43 (quoting Garner v. Teamsters Local Union No. 776, 346 U.S. 485, 490-91 (1953)).

https://scholarcommons.sc.edu/sclr/vol44/iss2/2
activity. More importantly, because the NLRB has primary jurisdiction over this aspect of labor relations, the Court concluded that state jurisdiction is also displaced when the NLRB fails to make any determination concerning union activities. Accordingly, the Court held that the state court was without authority to award damages to the company for injuries caused by the unions' activities.

2. Pervasive Federal Regulation

A federal regulatory scheme may be so pervasive that it completely occupies a particular field, thereby excluding even supplementary or parallel state regulations. Schneidewind v. ANR Pipeline Co. illustrates this point. In Schneidewind a public utility company challenged the validity of a Michigan statute that requires companies to obtain approval of the state public service commission before issuing long-term securities. The utility company claimed that the federal Natural Gas Act preempted the Michigan statute. The Court agreed that federal regulation of natural gas distribution is so extensive that state regulation of this field must be precluded.

The Schneidewind Court observed that the Federal Energy Regulatory Commission (FERC) exercised substantial authority over the financing activities of natural gas companies to ensure that pipelines and other facilities were financed in accordance with the public interest. The Court concluded that, because the Michigan statute constituted an attempt to regulate natural gas company rates and facilities, the provisions invaded a regulatory area already fully occupied by the FERC. Consequently, the Court held that the state statute was preempted by the Natural Gas Act.

46. Id. at 245.
47. Id. at 245-46. The Court suggested, without deciding, that the states might retain the power to regulate an activity if the NLRB concludes that the activity is neither protected nor prohibited by the National Labor Relations Act. Id. at 245.
48. Id. at 246-48.
53. Schneidewind, 485 U.S. at 300.
54. Id. at 302-03.
55. Id. at 306-09.
56. Id. at 310.
57. Id.
However, as *Hillsborough County v. Automated Medical Laboratories, Inc.* evidences, pervasive federal regulation, standing alone, does not always result in preemption of state law. The plaintiff in *Hillsborough County* operated a blood plasma center in Tampa, Florida. As a vendor of blood products, the plaintiff was licensed by the Secretary of Health and Human Services (HHS) and regulated by the Food and Drug Administration (FDA). After Hillsborough County adopted an ordinance for blood vendors that was more stringent than the federal regulations, the plaintiff claimed that the FDA regulations preempted the local law.

The Court disagreed, observing that neither Congress nor the FDA has expressly preempted state or local regulation of blood plasma collection. Furthermore, the Court rejected the argument that an intent to preempt may be inferred merely from the comprehensiveness of the FDA’s regulations. Because federal agencies typically deal with problems in more detail than does Congress, the Court believed that inferring preemption from comprehensive regulation alone would exclude state regulation whenever a federal agency stepped into a field—a result that would conflict with states’ rights. Furthermore, the Court noted that agencies are expected to make clear their intentions about exclusivity.

### C. Actual Conflict Between State and Federal Law

In cases of conflict, federal statutes or regulations will override state law. A conflict may occur when state law requires action that federal law forbids, or vice versa. A conflict may also arise when state law impairs the exercise of federally created rights. Finally, state law may frustrate

59. Id. at 709-10. The Public Health Service Act authorizes the Secretary to license vendors of blood products. 42 U.S.C. § 262(a) (1988). The federal statute also requires that licensed vendors meet safety, purity, and potency standards established by the Secretary. Id. § 262(d). The FDA, as the delegate of the Secretary of HHS, has promulgated extensive regulations concerning donor protection and product labeling. See 21 C.F.R. §§ 640.60-.76 (1992).
60. Hillsborough County, 471 U.S. at 714.
61. Id. at 716-18.
62. Id. at 717.
63. Id. at 718.
64. E.g., Fidelity Fed. Sav. & Loan Ass’n v. de la Cuesta, 458 U.S. 141, 153 (1982).
federal regulatory goals by hindering conduct that federal law intends to encourage, or by promoting conduct that federal law seeks to discourage.

1. Impossibility of Compliance with Both State and Federal Law

McDermott v. Wisconsin illustrates a situation in which compliance with both state and federal law is impossible. In McDermott the Court ruled that the labeling provisions of the Federal Food and Drug Act preempted a Wisconsin labeling statute. The defendant, who sold syrup imported from another state, showed that syrup which met the federal labeling standards would be considered mislabeled under a Wisconsin statute. Furthermore, as the defendant asserted, compliance with the state statute would result in liability under the federal act. Because satisfying the requirements of both the state and federal statutes was impossible, the Court invalidated the state statute.

2. Impairment of Rights Created by Federal Law

A direct conflict may also occur when state law diminishes or interferes with the exercise of a right created by federal law. For example, in Wissner v. Wissner a married serviceman obtained a National Life Insurance policy and named his mother as the principal beneficiary. The serviceman's widow claimed that under California community-property law she was entitled to a share of the insurance policy proceeds. However,
the federal statute provided that the insured had the exclusive right to designate a beneficiary. According to the Court, application of state community-property law to military insurance policies would diminish the rights of military policyholders, thereby potentially impairing morale within the armed services. Consequently, the Court held that federal law controlled the disposition of the insurance proceeds.

3. Frustration of Federal Regulatory Objectives

Sometimes provisions of federal law and state law do not openly conflict, but their regulatory objectives are incompatible nonetheless. For example, *Michigan Canners & Freezers Ass'n v. Agricultural Marketing & Bargaining Board* concerned the Michigan Agricultural Marketing and Bargaining Act, which established a state-administered system under which growers' associations were organized and certified as exclusive bargaining agents for all producers of a particular agricultural commodity. The Michigan Agricultural Cooperative Marketing Association, Inc. (MACMA) was accredited as the sole sales and bargaining agent for asparagus producers in the state. A group of asparagus farmers and processors challenged the Michigan statute because it required nonmember growers to pay service fees or adhere to contracts negotiated by MACMA. The plaintiffs argued that these provisions conflicted with the federal Agricultural Fair Practices Act of 1967 (AFPA) and thus should be preempted.

The Court noted that both the AFPA and the Michigan statute were intended to facilitate collective action among producers and to protect producers from coercive action by processors. However, unlike the state statute, the federal act also protected individual producers against coercive action by associations of producers. According to the Court, Congress

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78. *Id.* at 658.
79. *Id.* at 660.
80. *Id.* at 659.
85. *Id.*
88. *Id.* at 464-66.
89. *Id.* at 464-65. The federal act makes it unlawful for "handlers," defined to include associations of producers as well as associations of processors, *see* 7 U.S.C. § 2302(a) (1988), to "coerce any producer in the exercise of his right to join and belong to or https://scholarcommons.sc.edu/sclr/vol44/iss2/2
enacted the AFPA with the intent to safeguard the right of producers to choose the method of marketing their products. On the other hand, the Michigan statute empowers producers’ associations to do precisely what the federal act forbids them to do. Consequently, the Court concluded that the Michigan statute “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”

Even when state and federal law share the same regulatory goal, state law may be preempted on actual conflict grounds if it employs means different from federal law to achieve the same objective. International Paper Co. v. Ouellette is illustrative. In Ouellette property owners on the Vermont shore of Lake Champlain brought suit against a paper mill located on the New York side of the lake. Alleging that the defendant’s discharge of pollutants into Lake Champlain constituted a nuisance under Vermont common law, the plaintiffs sought damages and injunctive relief. The paper mill claimed that the federal Clean Water Act (CWA) preempted the plaintiffs’ state-law nuisance action because, as authorized by the CWA, the mill held a National Pollutant Discharge Elimination System (NPDES) permit that allowed the mill to discharge effluents into the lake.

The Court acknowledged that the ultimate goal of both Vermont nuisance law and the CWA was water pollution control. However, the Court warned that state law may still be preempted “if it interferes with the methods by which the federal statute was designed to reach this goal.” In this case, Congress chose the NPDES permit system as the method to reduce water pollution. The criteria under which the EPA or the source state issues discharge permits reflects the cost and availability of pollution technology and the competing needs of public and industrial uses. The

refrain from joining or belonging to an association of producers.” Id. § 2303(a). The federal act also makes it unlawful for handlers to “coerce or intimidate any producer to enter into, maintain, breach, cancel, or terminate a membership agreement or marketing contract with an association of producers or a contract with a handler.” Id. § 2303(c).

90. Michigan Canners & Freezers Ass’n, 467 U.S. at 470-72.
91. Id. at 477-78.
92. Id. at 478 (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)).
94. Id. at 483-84.
95. Id. at 484. The plaintiffs sought $20 million in compensatory damages, $100 million in punitive damages, and an injunction to require the defendant to restructure part of its water treatment system. Id.
97. Ouellette, 479 U.S. at 484.
98. Id. at 489, 490 n.10.
99. Id. at 494.
100. Id.
Court explained that the CWA allows a state to impose more stringent standards, yet limits to the source states and the EPA the right to administer the permit system.\textsuperscript{102} The Court further reasoned that the CWA does not grant the affected state the right to administer the permit system because to do so would disrupt the balance of interests inherent in a state's policy decision.\textsuperscript{103} For example, if a New York source were subject to damages under Vermont nuisance law, the law of Vermont would effectively override both the permit requirements and the source state's policy choices.\textsuperscript{104}

Notwithstanding the holdings in \textit{Michigan Canners} and \textit{Ouellette}, the Court has sometimes tolerated a considerable degree of tension between federal and state regulatory schemes. In \textit{Silkwood v. Kerr-McGee Corp.}\textsuperscript{105} the Court upheld a punitive damages award despite the defendant's contention that such awards would interfere with the ability of the Nuclear Regulatory Commission (NRC) to punish safety violations by a system of civil fines.\textsuperscript{106} In the Court's view, Congress had indicated a willingness to tolerate any tension that might arise between the NRC's system of civil penalties and the imposition of punitive damages by the states.\textsuperscript{107}

\section*{III. An Overview of Recent Product Preemption Cases}

Over the past five years, federal and state courts have considered the preemption issue in numerous products liability cases. Most of these decisions have involved either the Federal Cigarette Labeling and Advertising Act,\textsuperscript{108} the National Traffic and Motor Vehicle Safety Act of 1966 (NTMVSA),\textsuperscript{109} the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),\textsuperscript{110} the Federal Food, Drug, and Cosmetic Act (FDCA),\textsuperscript{111} or the Medical Device Amendments of 1976 (MDA)\textsuperscript{112} to the FDCA. This portion of the Article examines each of these statutes and discusses product preemption cases that have arisen under them:

\begin{itemize}
  \item \textsuperscript{102} \textit{Ouellette}, 479 U.S. at 495.
  \item \textsuperscript{103} Id.
  \item \textsuperscript{104} Id.
  \item \textsuperscript{105} Id.
  \item \textsuperscript{106} 464 U.S. 238 (1984).
  \item \textsuperscript{107} Id. at 257.
\end{itemize}
A. The Federal Cigarette Labeling and Advertising Act

1. Structure and Purpose

In 1964 a committee appointed by the Surgeon General concluded that smoking was a potential cause of lung cancer, chronic bronchitis, and emphysema. The public's response to the report was "immediate and vocal." One year later, Congress passed the Federal Cigarette Labeling and Advertising Act. The Act required all cigarette packages to contain the following language: "Caution: Cigarette Smoking May Be Hazardous to Your Health." Congress strengthened the required language in 1969 and again in 1984. The Labeling Act also declared the intent of Congress to establish a comprehensive federal program of cigarette labeling and advertising related to smoking and health. The program's goals are to inform the public about the health hazards of smoking, to protect commerce and the national economy to the extent consistent with informing the public and to prevent commerce and the economy from being "impeded by diverse, nonuniform, and confusing cigarette labeling . . . regulations with respect to any relationship between smoking and health.

The Act's preemption provision, codified in section 1334, declares: "No statement relating to smoking and health, other than the statement required by section 1333 of this title, shall be required on any cigarette

120. Id. § 1331(1).
121. Id. § 1331(2)(A).
122. Id. § 1331(2)(B).
package."\(^\text{123}\) Furthermore, section 1334(b) provides: "No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter."\(^\text{124}\) Thus, section 1334 expressly prohibits states from requiring additional health-related statements on cigarette packages and from imposing any requirement or prohibition concerning the advertising or promotion of cigarettes with properly labeled packages.\(^\text{125}\)

2. Caselaw prior to Cipollone

In recent years, many plaintiffs have filed lawsuits against cigarette companies alleging that the companies failed to provide adequate warnings about the health risks of smoking.\(^\text{126}\) In response, tobacco companies have

123. Id. § 1334(a).
124. Id. § 1334(b).
argued that such claims are precluded by the Federal Labeling Act. Prior to the Supreme Court’s recent decision in Cipollone v. Ligget Group, Inc.,127 most courts agreed with the tobacco companies,128 although a few found in favor of consumers.129

Moreover, until the Cipollone decision, no court had decided a cigarette case on express preemption grounds.130 In addition, courts generally refused to find preemption based on federal occupation of the field.131 Instead, most courts attempted to resolve preemption questions by engaging in an actual conflict analysis.132

One of the most popular theories provided that holding cigarette manufacturers liable for inadequate warnings would conflict with federal regulatory policy by upsetting the Act’s “balance” between health concerns and commercial interests.133 Palmer v. Ligget Group, Inc.134 illustrates

Cigarette Manufacturers Liable for Failing to Provide Adequate Warnings of the Hazards of Smoking, 27 B.C. L. REV. 1033, 1064 (1986) (claiming cigarette manufacturers’ warnings are “woefully inadequate” when measured against principles of modern tort law). Finally, cigarette companies have offset the effect of statutory warnings by positive advertising strategies. See Bryan D. McElvaine, Note, Liability of Cigarette Manufacturers for Smoking Induced Illnesses and Deaths, 18 RUTGERS L.J. 165, 183 (1986) (“The strong positive images in the advertising overpower and neutralize the dry warnings which are now required to be placed in the ads.”). Therefore, the argument concludes, cigarette manufacturers should be held strictly liable in tort for failing adequately to warn consumers about the health risks of smoking.

130. See, e.g., Pennington, 876 F.2d at 418; Roysdon, 849 F.2d at 234; Palmer, 825 F.2d at 625; Cipollone v. Ligget Group, Inc., 789 F.2d 811, 185 (3d Cir. 1986); Palmer, 633 F. Supp. at 1174; Dewey, 577 A.2d at 1247; Forster, 437 N.W.2d at 658; Forster v. R.J. Reynolds Tobacco Co., 423 N.W.2d 691, 696 (Minn. Ct. App. 1988), aff’d in part and rev’d in part, 437 N.W.2d 655 (Minn. 1989).
132. See, e.g., Pennington, 876 F.2d at 421; Roysdon, 849 F.2d at 234-35; Palmer, 825 F.2d at 626; Cipollone, 789 F.2d at 187; Forster, 437 N.W.2d at 659.
133. See, e.g., Pennington, 876 F.2d at 421; Roysdon, 849 F.2d at 234-35; Cipollone,
this approach. Relying on the Labeling Act’s declaration of policy, the court of appeals concluded that the Act was a response to two distinct legislative concerns: (1) the need to warn consumers about the health risks of smoking; and (2) the protection of commerce from the effects of “diverse, nonuniform and confusing” state cigarette labeling regulations. In the Palmer court’s view, the Act represented a carefully drawn balance between these two potentially conflicting objectives. The court further determined that state tort actions would upset this “carefully wrought balance of national interests.”

3. The Cipollone Decision

In Cipollone v. Ligget Group, Inc. the United States Supreme Court held that the Federal Cigarette Labeling and Advertising Act, as amended in 1969, expressly preempts tort claims against cigarette manufacturers for improper health warnings with respect to advertising or promotion. However, the Court also concluded that the amended Act does not necessarily preempt claims against cigarette manufacturers for breach of express warranty, misrepresentation, or conspiracy.

The Cipollone decision marks the culmination of the Cipollone family’s eight-year effort to obtain compensation for the death of Rose Cipollone, who died of lung cancer in 1984. The complaint alleged that the respondents failed to provide adequate warnings about the health risks of smoking, that they expressly warranted their products were not dangerous to the health of consumers, that they attempted to neutralize the effects of statutory warnings, that they ignored medical evidence about the dangers of smoking, and that they conspired to prevent such medical evidence from

789 F.2d at 187; Forster, 437 N.W.2d at 658.
134. 825 F.2d 620 (1st Cir. 1987), called into doubt by Cipollone, 112 S. Ct. 2608 (1992).
135. Id. at 626.
136. Id.
137. Id.
141. Cipollone, 112 S. Ct. at 2621-22 (plurality opinion).
142. Id. at 2622-24.
143. Rose Cipollone and her husband brought suit against respondent tobacco companies in 1983 to recover damages for her smoking-related injuries. After Rose’s death, her husband filed an amended complaint and continued the lawsuit. When he died, the Cipollone’s son was substituted as the plaintiff both individually and in his capacity as executor of his parents’ estates. Id. at 2613-14.
reaching the general public.\footnote{144} The cigarette companies countered by arguing that the petitioner's claims were preempted by the Federal Cigarette Labeling Act.\footnote{145}

On review, Justice Stevens, joined by Chief Justice Rehnquist and Justices White and O'Connor, proposed two rules of statutory construction.\footnote{146} First, Justice Stevens suggested that the Court should not rely on implied preemption theories when the statute in question contains an express preemption provision.\footnote{147} This rule assumes that when Congress defines a specific area as preempted, it impliedly intends to exclude all other areas from the preemptive reach of the statute.\footnote{148} Since the cigarette labeling statute contains no other preemptive language, Justice Stevens limited the Court's examination to the statute's preemption provisions.\footnote{149}

Second, Justice Stevens contended that express preemption provisions should be interpreted narrowly.\footnote{150} He derived this narrow construction, or

\footnote{144. \textit{Id.} at 2614. The complaint also contained claims based on a theory of design defect, but the Court was not presented with any question concerning those claims. \textit{Id.} at 2614, 2615 n.6.}

\footnote{145. \textit{Id.} at 2615. The trial court initially rejected the respondents' preemption defense, Cipollone v. Liggett Group, Inc., 593 F. Supp. 1146, 1148 (D.N.J. 1984), rev'd, 789 F.2d 181 (3d Cir. 1986), but this ruling was reversed on appeal, \textit{Cipollone}, 789 F.2d at 187-88. On remand, the trial court determined that the petitioner's claims were preempted insofar as they relied on advertising after the effective date of the Act. Cipollone v. Liggett Group, Inc., 649 F. Supp. 664, 668 (D.N.J. 1986). At trial, the jury found that the respondents had breached both their duty to warn and express warranties made prior to the effective date of the Act. The jury refused to award any damages to Rose Cipollone's estate, concluding that she voluntarily and unreasonably encountered a known danger by smoking cigarettes. However, the jury did award $400,000 to her husband's estate as compensation for losses caused by the respondents' conduct. Cipollone v. Liggett Group, Inc., 693 F. Supp. 208, 210 (D.N.J. 1988), \textit{aff'd in part and rev'd in part}, 893 F.2d 541 (3d Cir. 1990), \textit{aff'd in part and rev'd in part}, 112 S. Ct. 2608. Both parties appealed. The court of appeals upheld the trial court's ruling on preemption, but ordered a new trial on other grounds. \textit{Cipollone}, 893 F.2d at 582-83. The United States Supreme Court then granted a petition for certiorari. Cipollone v. Liggett Group, Inc., 111 S. Ct. 1386 (1991).}

\footnote{146. Justice Blackmun, joined by Justices Kennedy and Souter, concurred in this part of the Court's analysis. \textit{Cipollone}, 112 S. Ct. at 2625-26 (Blackmun, J., concurring in part, concurring in the judgment in part, and dissenting in part).}

\footnote{147. \textit{Id.} at 2618.}

\footnote{148. \textit{Id.} Justice Blackmun agreed that the Court should resort to implied preemption only when Congress is silent about the preemptive scope of the statute. \textit{Id.} at 2625 (Blackmun, J., concurring in part, concurring in the judgment in part, and dissenting in part). On the other hand, Justice Scalia maintained that this approach would be appropriate when occupation of the field was alleged, but that it should not be used in conflict cases. \textit{Id.} at 2633 (Scalia, J., concurring in the judgment in part and dissenting in part).}

\footnote{149. \textit{Id.} at 2618.}

\footnote{150. \textit{Id.} Justice Scalia, however, argued that the Court should interpret Congress's
“clear meaning,” rule from the Court’s longstanding presumption against preemption of state police-power regulations. Accordingly, he declared that the 1965 Act’s preemption provision, section 5(b), did not bar state-law damage claims against cigarette companies.

Justice Stevens determined, however, that the reach of the 1969 Act’s preemption provision was much broader than that of the 1965 Act’s preemption provision. As the Court observed, section 5(b) of the 1969 Act expressly prohibits any “‘requirement or prohibition based on smoking and health . . . imposed under State law with respect to . . . advertising or promotion.’” Applying this analysis, Justice Stevens concluded that the duty to warn is “a state law ‘requirement . . . with respect to . . . advertising or promotion’”, therefore, claims based on that duty are preempted to the extent that they penalize the respondents for failing to provide additional or more specific warnings than those required by the federal statute.

However, Justice Stevens found that Cipollone’s claims for breach of express warranty are not preempted by the Act. The petitioner argued that the respondents made express warranties when they suggested in their advertising that cigarette smoking was safe. Justice Stevens reasoned that the respondents’ duty under express warranty arose from the terms of the warranty itself, not from some independent state-law requirement or prohibition related to health and smoking. Therefore, he concluded that the petitioner could sue for breach of express warranty even if the warranty was communicated by the respondents’ advertising or promotional activities.

Justice Stevens also upheld the petitioner’s claim for fraudulent misrepresentation. The petitioner alleged that the respondents falsely represented in their advertising that smoking was safe, and that they

preemption decrees “neither narrowly nor broadly, but in accordance with their apparent meaning.” Id. at 2632 (Scalia, J., concurring in the judgment in part and dissenting in part).

151. Id. at 2618.
152. Id. at 2619.
153. Id. at 2619-21 (plurality opinion).
155. Id.
156. Id. at 2621-22. Significantly, Justice Stevens suggested that claims based on failure to discover and disclose risks because of inadequate testing or research would not be preempted because they are not directly related to advertising or promotional activities. Id.
157. Id. at 2622-23.
158. Id. at 2622.
159. Id.
160. Id. at 2622-23.
161. Id. at 2624.
fraudulently concealed evidence about the health risks of smoking.\textsuperscript{162} According to Justice Stevens, section 5(b) preempts only state requirements with respect to \textit{advertising} or \textit{promotion}, but does not bar claims based on failure to disclose material facts through other forms of communication.\textsuperscript{163} Furthermore, claims arising from false or misleading statements in the respondents' advertising are not preempted because these claims are based not on a duty relating to smoking and health, but rather on a broader duty not to deceive.\textsuperscript{164}

Using the same analysis, Justice Stevens also upheld Cipollone's claim of conspiracy to misrepresent or conceal material facts concerning the health risks of smoking.\textsuperscript{165} Justice Stevens reasoned that this claim was based on a general duty "not to conspire to commit fraud," instead of on a specific state requirement relating to health warnings.\textsuperscript{166}

Justice Blackmun, joined by Justices Kennedy and Souter, maintained that none of Cipollone's claims should be preempted by section 5(b) of the 1969 Act.\textsuperscript{167} Justice Blackmun argued that the phrase "requirement or prohibition imposed under State law" was ambiguous. He observed that the dictionary definitions of "requirement" and "prohibition" suggest "specific actions mandated or disallowed by a formal governing authority," but do not necessarily include duties imposed by common-law doctrines.\textsuperscript{168} According to Justice Blackmun, common-law damage awards do not have the same impact on product manufacturers as do statutory or administrative regulations.\textsuperscript{169} A product manufacturer can respond to its common-law duty to warn in a variety of ways, including payment of damage awards.\textsuperscript{170} In addition, Justice Blackmun noted that tort law differs from statutes or administrative regulations because tort law is primarily concerned with compensating injured parties.\textsuperscript{171}

Justice Scalia, joined by Justice Thomas, asserted that the 1965 Act preempted Cipollone's failure-to-warn claims and the 1969 Act preempted all of Cipollone's common-law claims.\textsuperscript{172} Justice Scalia argued that both

\textsuperscript{162} Id. at 2623-24. The petitioner also maintained that the respondents' advertising has neutralized the effect of federally mandated health warnings. Justice Stevens ruled that this claim was preempted because it was nothing more than the converse of Cipollone's preempted failure to warn claim. \textit{Id.} at 2623.

\textsuperscript{163} Id. at 2623.

\textsuperscript{164} Id. at 2624.

\textsuperscript{165} Id. at 2624-25.

\textsuperscript{166} Id. at 2624.

\textsuperscript{167} Id. at 2631 (Blackmun, J., concurring in part, concurring in the judgment in part, and dissenting in part).

\textsuperscript{168} Id. at 2627.

\textsuperscript{169} Id. at 2627-28.

\textsuperscript{170} Id. at 2628.

\textsuperscript{171} Id.

\textsuperscript{172} Id. at 2632-37 (Scalia, J., concurring in part in the judgment and dissenting in
Acts expressly preempt any legal rule that imposes liability upon cigarette companies based on the failure to include, in their advertising or promotional material, information concerning the health risks of smoking.173 Under this analysis, the petitioner's failure-to-warn claim is obviously preempted.174 In addition, Justice Scalia reasoned that Cipollone's express warranty claim should be preempted because background legal principles, not voluntary actions by the respondents, impose liability for promises or representations about smoking and health.175 This reasoning also led Justice Scalia to conclude that Cipollone's fraudulent misrepresentation claims should also be preempted.176 According to Justice Scalia, there is no difference between an affirmative duty to warn about a smoking-related health risk and a duty not to deceive the public about the existence of such a risk.177

B. The National Traffic and Motor Vehicle Safety Act

1. Structure and Purpose

Motor vehicle design is regulated under the National Traffic and Motor Vehicle Safety Act of 1966.178 The Act directs the Secretary of Transportation to promulgate federal motor vehicle safety standards.179 This authority has been delegated to the National Highway Traffic Safety Administration (NHTSA).180 Safety standards address vehicle defects that cause accidents, and may also apply to design characteristics that aggravate occupants' injuries from automobile accidents.181 Federal standards

part).

173. Id. at 2635.
174. Id.
175. Id.
176. Id. at 2636-37.
177. Id. at 2636.
179. Id. § 1392.

https://scholarcommons.sc.edu/sclr/vol44/iss2/2
currently govern safety glass, door strength and latch design, fuel system integrity, occupant protection, and numerous other areas.\(^{182}\)

The Act contains a preemption provision that prohibits nonidentical state regulations when a federal standard addresses the same aspect of performance.\(^{183}\) However, states may enforce safety standards that are identical to federal standards and may also regulate aspects of performance that federal safety standards do not specifically cover.\(^{184}\) Finally, the Act contains a "savings clause" that purports to preserve common-law remedies against automobile manufacturers.\(^{185}\)

Federal Motor Vehicle Safety Standard (FMVSS) 208 specifies equipment requirements for active and passive restraint systems.\(^{186}\) When FMVSS 208 was first promulgated in 1967, it merely required automakers

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183. 15 U.S.C. § 1392(d) (1988). This subsection provides in part:

"Whenever a Federal motor vehicle safety standard established under this subchapter is in effect, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, with respect to any motor vehicle or item of motor vehicle equipment any safety standard applicable to the same aspect of performance of such vehicle or item of equipment which is not identical to the Federal standard."

Id.

184. Id. The subsection continues:

"Nothing in this section shall be construed as preventing any State from enforcing any safety standard which is identical to a Federal safety standard. Nothing in this section shall be construed to prevent the Federal Government or the government of any State or political subdivision thereof from establishing a safety requirement applicable to motor vehicles or motor vehicle equipment procured for its own use if such requirement imposes a higher standard of performance than that required to comply with the otherwise applicable Federal standard."

Id.

185. Id. § 1397(k). This subsection of the Act states: "Compliance with any Federal motor vehicle safety standard issued under this subchapter does not exempt any person from any liability under common law." Id.

to install seat belts in their motor vehicles.\textsuperscript{187} In 1972, NHTSA issued a new version of FMVSS 208 that required all vehicles produced after August 15, 1975 to have full passive restraint protection for front-seat occupants.\textsuperscript{188} Since 1972, FMVSS 208 has undergone a number of transformations.\textsuperscript{189} Presently, the regulation allows manufacturers to comply by meeting one of three options: (1) a passive restraint system, such as airbags, in conjunction with seatbelts; (2) a combination of passive restraints, detachable shoulder harnesses, lap belts, and warning systems; or (3) a combination of nondetachable shoulder harnesses, lap belts, and warning systems.\textsuperscript{190}

In recent years, numerous injured parties have brought design defect claims against automobile manufacturers who failed to equip their vehicles with airbags.\textsuperscript{191} For the most part, however, courts have ruled against plaintiffs on preemption grounds.\textsuperscript{192}


\textsuperscript{190} 49 C.F.R. \S 571.208, S4.1.2.1 to S4.1.2.3 (1991).

\textsuperscript{191} Injured parties have generally relied on the "crashworthiness" doctrine. This doctrine requires automakers to design vehicles that provide reasonable protection against injuries that may occur during a collision. For a discussion of the crashworthiness doctrine, see Werber, \textit{supra} note 182, at 3-5; Ellen L. Theroff, Note, \textit{Preemption of Airbag Litigation: Just a Lot of Hot Air?}, 76 VA. L. REV. 577, 587-88 (1990).

2. Express Preemption

A few courts have held that the NTMVSA's preemption section expressly preempts tort claims based on failure to provide airbags. For example, in Vanover v. Ford Motor Co. the court ruled that a damage award would effectively impose a safety standard on a manufacturer since an award would penalize the manufacturer for failing to install airbags. The court reasoned that section 1392(d) expressly preempts tort claims because the standard imposed by state common-law is inconsistent with the federal standard.

On the other hand, most courts have declined to find express preemption in airbag cases. These courts have based their conclusions either on the absence of any specific reference to common-law claims in the Act's preemption section, or on the Act's savings clause that expressly preserves common-law claims.

3. Occupation of the Field

Although the federal government is primarily responsible for regulating automobile safety, Congress has given some regulatory authority to the states. For example, states may enforce safety standards that are identical to federal standards. States may also establish more stringent standards for their own procurement purposes. Moreover, the Act encourages
states to enforce inspection programs for used cars.202 These provisions militate against any preemption argument based on federal occupation of the entire field of motor vehicle safety.203 Consequently, courts have firmly rejected the occupation-of-the-field theory in this area.204

4. Actual Conflict

State law may be preempted on actual conflict grounds when compliance with both state and federal law is impossible, or when state law stands as an obstacle to the accomplishment of the full purposes and objectives of Congress.205 Automobile manufacturers cannot claim “physical impossibility” as a basis for federal preemption because they can install airbags in their vehicles and still comply with the requirements of FMVSS 208.206 Accordingly, courts have tended to focus on whether damage awards frustrate the Act’s regulatory purpose.

In automobile safety cases, as in the cigarette cases, courts have disagreed about the coercive effect of damage awards. Some courts have reasoned that tort liability does not compel carmakers to install airbags because carmakers can accept the risk of having to pay damages instead of changing their conduct.207 Hence, a number of courts have concluded that damage awards do not constitute a form of state regulation.208 Other courts, however, have held that damage awards are inherently coercive and thus would have a regulatory effect on automobile manufacturers.209

A number of courts have also invoked the reasoning of International

202. Id. § 1397(b)(1).
203. See Theroff, supra note 191, at 615 (“[I]t is clear that Congress did not intend to establish a federal presence in the field of motor vehicle safety sufficient to eliminate all corresponding state action.”).
204. See Garrett v. Ford Motor Co., 684 F. Supp. 407, 409 (D. Md. 1987); see also Miller, supra note 186, at 911 (“[T]he language of section 1392(d) demonstrates that Congress did not mean to occupy the field of automobile safety completely.”).
206. See Miller, supra note 186, at 914; Theroff, supra note 191, at 611-12.
"Paper Co. v. Ouellette" to conclude that common-law damage claims interfere with the method that Congress and the Department of Transportation have chosen to regulate motor vehicle design. As discussed previously, carmakers can satisfy the requirements of FMVSS 208 by employing any one of three passenger restraint systems. According to some courts, imposing tort liability on automakers who fail to install airbags would frustrate the Act's regulatory policy by removing two of the three options FMVSS 208 allows.

C. The Federal Insecticide, Fungicide, and Rodenticide Act

1. Structure and Purpose

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes the Environmental Protection Agency (EPA) to regulate most aspects of the development, manufacture, sale, and use of pesticides. All pesticides must be registered with the EPA before they are distributed for sale in the United States. To register a pesticide under FIFRA, the manufacturer must submit to the EPA the pesticide's names, labeling information, and directions for use. The EPA then determines what supporting data will be required. Supporting data may include chemical composition, physical and chemical characteristics, and studies of tetragenicity, mutagenicity, and effects on metabolism. The EPA will approve a registration request only if the product can perform its intended function without unreasonable adverse effects on the environment.

211. See, e.g., Wood, 865 F.2d at 408; Kolbeck, 702 F. Supp. at 541.
212. 49 C.F.R. § 571.208, S4.1.2.1 to S4.1.2.3 (1991), discussed supra text accompanying note 190. The apparent purpose of this provision is to encourage manufacturers to develop new and more effective passenger restraint systems instead of limiting carmakers to a single restraint technology. See Miller, supra note 186, at 936; Wilton, supra note 186, at 27.
218. Id. §§ 158.150, 158.202 (1992). Also, the EPA may independently collect information about the proposed pesticide. See 7 U.S.C. §§ 136a(c)(2)(A), 136s.
The EPA also exercises strict control over product labeling. When a pesticide is registered, the manufacturer must submit the proposed label to the EPA for approval.\(^{220}\) The Act requires the label to be "adequate to protect health and the environment"\(^{221}\) and "likely to be read and understood."\(^{222}\) The EPA also determines whether the product will be classified for general use, restricted use, or both.\(^{223}\) "General use pesticides" are less hazardous and are ordinarily available for public use.\(^{224}\) "Restricted use pesticides" are those which, without additional regulatory restrictions, "may generally cause . . . unreasonable adverse effects on the environment, including injury to the applicator."\(^{225}\) Restricted use pesticides may only be used under the direct supervision of a "Certified Applicator."\(^{226}\)

The states are authorized to regulate the sale and use of pesticides to the extent that such regulation does not conflict with FIFRA.\(^{227}\) However, Congress has granted to the EPA exclusive control over labeling and packaging.\(^{228}\) Nevertheless, it is unclear whether FIFRA's preemptive language also precludes damage awards against pesticide manufacturers for failure to provide adequate warnings.\(^{229}\) A number of courts have allowed injured parties to allege that manufacturers breached their duty to warn.\(^{230}\)

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222. Id. § 136(q)(1)(E). Regulations promulgated under FIFRA not only require particular warning language, 40 C.F.R. § 156.10(a)(1) (1992), but also specify the type size, color, and placement of the warning, id. § 156.10(a)(2), (4).

223. 7 U.S.C. § 136a(d).

224. Id. § 136a(d)(1)(B).

225. Id. § 136a(d)(1)(C).

226. Id. § 136a(d)(1)(C)(i)-(ii).

227. Id. § 136v(a) ("A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.").

228. See id. § 136v(b) ("Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.").


However, other courts have concluded that FIFRA preempts such claims.\(^{231}\)

2. **Express Preemption**

Most courts have rejected the argument that FIFRA expressly preempts common-law claims.\(^{232}\) This reluctance to find express preemption is based, at least in part, on the failure of Congress to mention common-law damage awards in the Act’s preemption section.\(^{233}\) However, the court in *Kennan v. Dow Chemical Co.*\(^{234}\) apparently concluded that the language in FIFRA’s preemption section manifests an express intent to exclude all forms of state regulation over labeling, including common-law damage awards.\(^{235}\)

3. **Occupation of the Field**

Although FIFRA gives the EPA extensive regulatory control over pesticides,\(^{236}\) few courts have concluded that this authority occupies the entire field.\(^{237}\) Most courts have refused to preempt on occupation-of-the-field grounds because section 136v(a) reserves a certain amount of

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233. *Fisher*, 716 F. Supp. at 1286-87. At least one court seems to have excluded express preemption on the theory that damage awards do not constitute “requirements for labeling” and, therefore, do not fall within the literal language of § 136v(b). *See* *Ferebee*, 736 F.2d at 1541.


235. *Id.* at 805.


One federal circuit court, however, has found preemption based on occupation of the field. *Papas v. Upjohn Co.* concerned a failure-to-warn claim against two pesticide manufacturers. The lower court granted the defendants partial summary judgment on preemption grounds, and the plaintiff appealed. In affirming the lower court's ruling, the federal appellate court declared that FIFRA gives the EPA the exclusive right to regulate pesticide labels. After reviewing the labeling regulations adopted by the EPA, the court concluded that "the federal government has occupied the entire field of labeling regulation, leaving no room for the states to supplement federal law, even by means of state common law tort actions." However, the Supreme Court vacated the *Papas* ruling in light of *Cipollone v. Ligget Group, Inc.*

4. Actual Conflict

As in the cigarette and airbag cases, courts in pesticide cases have resolved preemption issues based on whether damage awards frustrate the regulatory objectives of federal law. Again, the courts have devoted much attention to the question of whether damage awards are sufficiently coercive to serve as a surrogate for direct state regulation of product labeling. *Ferebee v. Chevron Chemical Co.* is the leading case on this issue. In *Ferebee* an agricultural worker brought suit against a herbicide manufac-
turer, alleging injury from long-term occupational exposure to paraquat.245 The plaintiff claimed that the labeling on the defendant's product was defective because it failed to warn that long-term exposure to paraquat could cause serious lung disease.246 The defendant contended that FIFRA preempts damage claims based on inadequate product labeling. The defendant argued that section 136v(b) preempts state regulation of product labeling and that damage awards based on label inadequacy have a regulatory aim that is necessarily preempted.247

The court refused, however, to characterize damage awards as purely regulatory, noting that the manufacturer could elect to retain the existing label and simply pay damages.248 The court also recognized that tort recovery may promote regulatory aims by inducing manufacturers to request the EPA to allow more detailed labeling.249 Furthermore, the court reasoned that damage awards do not frustrate federal regulatory objectives because Congress intended EPA labeling standards to prescribe a floor on acceptable conduct, not a ceiling.250 The Ferebee court concluded that absent a clear expression of congressional intent, federal courts should not deprive the states of the power to compensate injured citizens.251

Other federal courts have agreed with Ferebee that damage awards are not regulatory because product manufacturers can choose to pay damages instead of changing product labeling.252 However, a number of other courts have concluded that damage awards are coercive and, therefore, conflict with FIFRA.253 Judicial support also exists for the Ferebee court's

245. Id. at 1531-32.
246. Id. at 1532.
247. Id. at 1540.
248. Id. at 1541.
249. Id.
250. Id. at 1543.
251. Id.
conclusion that EPA labeling standards are merely minimum standards;\(^\text{254}\) although some courts have disagreed with *Ferebee* and characterized EPA standards as uniform, rather than minimum, standards.\(^\text{255}\)

### D. The Federal Food, Drug, and Cosmetic Act

#### 1. Structure and Purpose

Pursuant to the Federal Food, Drug, and Cosmetic Act (FDCA)\(^\text{256}\) and certain provisions of the Public Health Service Act (PHS),\(^\text{257}\) the Food and Drug Administration (FDA) oversees the manufacture and marketing of virtually all pharmaceutical products.\(^\text{258}\) The FDA requires manufacturers of pharmaceutical products to produce, package, and store all products in conformity with Good Manufacturing Practice (GMP).\(^\text{259}\) Pharmaceutical products that do not comply with GMP are considered "adulterated."\(^\text{260}\) The FDA also regulates drug labeling and specifies the information that must be supplied on package inserts and other labeling.\(^\text{261}\) If a manufacturer fails to comply with FDA labeling requirements, its product will be deemed misbranded.\(^\text{262}\)

In addition, the FDA must license any new drug before the drug is marketed.\(^\text{263}\) The approval process begins with the submission of an Investigational New Drug (IND) application.\(^\text{264}\) If the IND is approved,


\(^{255}\) See, e.g., *Arkansas-Platte*, 959 F.2d at 162; *Papas*, 926 F.2d at 1025-26; *Fisher*, 716 F. Supp. at 1289; *Fitzgerald*, 681 F. Supp. at 407.


\(^{258}\) See generally Ann N. James, Comment, *Warnings and the Pharmaceutical Companies: Legal Status of the Package Insert*, 16 HOUS. L. REV. 140, 143 (1978) (stating that the entire industrial process of drug manufacture and sale is closely regulated by the FDA).


\(^{262}\) Landen, *supra* note 259, at 104.

\(^{263}\) 21 U.S.C. § 355(a). The definition of "new drug" is provided in 21 C.F.R. § 310.3(h) (1992). In general, the FDA regulating process for biologics is similar to that for chemical drugs. See Gibbs & Mackler, *supra* note 5, at 205-06.

the manufacturer may gather data needed for the formal application, a New Drug Application (NDA). The NDA is a comprehensive compilation of all information known about the drug at the time of the application. Experts then review the NDA to determine whether the evidence shows the drug to be safe and effective for its intended purpose. Only after this review process is completed will the FDA license a new drug for marketing.

2. Pharmaceutical Products in General

Despite the comprehensiveness of federal regulation in the drug industry, courts have resisted preemption arguments made by manufacturers of pharmaceutical products. MacDonald v. Ortho Pharmaceutical Corp. illustrates this resistance. In MacDonald, a consumer sued a manufacturer of oral contraceptives, alleging that the package insert failed to provide an adequate warning of the risk of stroke associated with the drug's use. The manufacturer claimed that its warning complied with FDA labeling requirements and that those requirements preempted any duty to warn under state tort law. The court declared, however, that "[t]he regulatory history of the FDA requirements belies any objective to cloak them with preemptive effect." The court then concluded that the adequacy of the warning was a question of fact for the jury. Most courts

Judicial Role in the Regulation of Pharmaceuticals, 103 Harv. L. Rev. 773, 776 (1990) ("The IND contains information about the proposed drug's chemistry, manufacturing, pharmacology, and toxicology.").


267. Landen, supra note 259, at 100.


269. See Del Giorno, supra note 266, at 640-44 (discussing courts' reasons for rejecting federal preemption).


271. Id. at 67-68. However, the warning did warn of "abnormal blood clotting which can be fatal." Id. at 66 (quoting drug warning).

272. Id. at 70.

273. Id.

274. Id. at 71-72. Some commentators have criticized the MacDonald decision. E.g.,
have employed the same approach used by the MacDonald court.\textsuperscript{275}

3. DPT Vaccine

During the 1980s, numerous injured parties brought lawsuits against manufacturers of the diphtheria, pertussis, and tetanus (DPT) vaccine.\textsuperscript{276} Plaintiffs' claims were based on both inadequate warning and defective design theories.\textsuperscript{277} Vaccine manufacturers maintained that federal law preempts common-law damage awards.\textsuperscript{278} However, the courts have generally rejected the manufacturers' arguments.

a. Inadequate Warning Claims

In many cases, plaintiffs have alleged that manufacturers failed to provide adequate information about the risks of DPT vaccine,\textsuperscript{279} or that manufacturers failed to communicate this information to vaccine recipients.\textsuperscript{280} Although courts have rejected some of these claims on the merits,\textsuperscript{281} they have generally declined to find preemption on grounds of either express preemption,\textsuperscript{282} occupation of the field,\textsuperscript{283} or actual conflict.\textsuperscript{284}

Walsh & Klein, supra note 268, at 192 (stating that MacDonald conflicts with the federal regulatory scheme).


\textsuperscript{277} Dark, supra note 276, at 820.


\textsuperscript{281} E.g., Jones, 695 F. Supp. at 708; Foyle, 674 F. Supp. at 536; White v. Wyeth Lab., Inc., 533 N.E.2d 748, 755 (Ohio 1988).

\textsuperscript{282} See, e.g., Abbot, 844 F.2d at 1111; Foyle, 674 F. Supp. at 532; Wack v. Lederle Lab., Inc., 533 N.E.2d 748, 755 (Ohio 1988).
Hurley v. Lederle Laboratories285 (Hurley I) represents an exception to this trend. The plaintiff in Hurley I sued Lederle, alleging that the product was defectively designed and that the manufacturer had failed to provide an adequate warning about the possibility of an adverse reaction from whole-cell pertussis vaccine.286 The district court considered four factors to determine whether to imply preemption in a regulatory field: (1) the intent of Congress as revealed by the statute's text or legislative history; (2) the pervasiveness of the federal regulatory scheme; (3) whether the subject matter of the regulation demands exclusive federal regulation to achieve uniformity; and (4) whether state law stands as an obstacle to the accomplishment of federal objectives.287

The court concluded that the first factor was not present.288 Regarding the second factor, the Hurley I court did find that the comprehensiveness of FDA regulation over DPT labeling evidenced an intent to occupy the field, thereby precluding state regulation.289 The court observed that the FDA strictly controls the contents and wording of product inserts, including information about potential adverse reactions. Furthermore, once the FDA approves particular language, the manufacturer cannot change the language without the FDA's permission.290

Although in Hurley I the court found preemption on the basis of the second factor, it evaluated DPT labeling in light of the remaining factors as well. Examining the third factor, the court concluded that a dominant federal interest exists with respect to drug labeling because of the need to achieve uniformity in this area.291 The court supported this conclusion by quoting from an FDA regulation that declared the "'FDA has a well established policy of promoting uniformity in the area of labeling.'"292

The court also ruled that the fourth factor supported a finding of

283. See, e.g., Abbot, 844 F.2d at 1112; Foyle, 674 F. Supp. at 533; Graham, 666 F. Supp. at 1491-93; Martinkovic, 669 F. Supp. at 214.
284. See, e.g., Abbot, 844 F.2d at 1113-14; Martinkovic, 669 F. Supp. at 215.
286. Id. at 994-95.
289. Id. at 999.
290. Id.
291. Id.
292. Id. (alteration in original) (quoting 30 Fed. Reg. 51,403 (1985)).
preemption.\footnote{Id. at 999-1000.} According to the court, the FDA had an express regulatory policy of restricting material on package inserts, including statements about adverse effects, to information that was supported by clear scientific evidence.\footnote{Id. at 1000 (citing 44 Fed. Reg. 37,441 (1979)).} Therefore, the FDA disapproved of warning about risks that were still in dispute within the scientific community.\footnote{Id. (citing 39 Fed. Reg. 33,230, at 33,230-32 (1974)).} The court noted that the FDA had examined the risk of encephalopathy, the plaintiff’s injury, and had specifically addressed this risk by requiring certain statements about it in DPT labeling.\footnote{Id. at 1001.} Permitting a state to determine that an FDA-mandated warning was inadequate “would obviously undermine or overrule the FDA’s duty to establish a uniform nation-wide system of useful product information as to the drug’s effectiveness and its risks.”\footnote{Id. at 1001.} (citing 44 Fed. Reg. 37,436. The court in \textit{Hurley I} also rejected the conventional view that FDA labeling regulations imposed only minimum requirements on drug manufacturers. Instead, the court declared that FDA regulations should be treated as exclusive, thus preempting any inadequate-warning claim against a drug manufacturer when the manufacturer has complied with FDA labeling requirements. \textit{See id.}}

In \textit{Hurley II}\footnote{Hurley v. Lederle Lab., 851 F.2d 1536 (5th Cir.), \textit{superseded by} 863 F.2d 1173 (5th Cir. 1988).} the Fifth Circuit reversed the lower court’s decision with respect to labeling.\footnote{Id. at 1543.} Relying on the reasoning in \textit{Hillsborough County v. Automated Medical Laboratories, Inc.},\footnote{471 U.S. 707 (1985).} the court in \textit{Hurley II} declared that FDA regulations do not ordinarily preempt stricter state-law standards.\footnote{Hurley II, 851 F.2d at 1539-40.} The court also rejected the claim that the PHSA and its regulations are pervasive enough to exclude state regulation.\footnote{Id. at 1540.} Finally, the court concluded that the National Childhood Vaccine Injury Act of 1986,\footnote{42 U.S.C. §§ 300aa-1 to -34 (1988 & Supp. II 1990).} passed after the case was filed, indicated that Congress did not intend to preempt common-law claims.\footnote{Hurley II, 851 F.2d at 1540-41. However, the court suggested that compliance with FDA-approved labeling would immunize drug manufacturers from tort liability if they provided the FDA with all appropriate information about product risks before the agency approved the product’s labeling. \textit{See id.} at 1542.}

\textit{b. Design Defect Claims}

The design defect claims are based on the assumption that whole-cell
DPT vaccine is more dangerous than split-cell or acellular vaccine. Plaintiffs have alleged that vaccine manufacturers continued to produce whole-cell DPT vaccine even though less-toxic alternatives were available. Vaccine manufacturers have replied that because FDA regulations only allow them to produce whole-cell vaccine, they cannot be held liable for injuries resulting from the use of this approved technology.

The courts are generally in agreement that neither the FDCA nor the PHSA expressly preempts state-law claims. Furthermore, most courts

305. DPT vaccine provides protection against diphtheria, pertussis (whooping cough), and tetanus (lockjaw). Adverse reactions to DPT are usually attributable to the pertussis antigens in the vaccine. These reactions range from swelling, fever, and irritability to encephalopathy, paralysis, and death. Graham ex rel. Graham v. Wyeth Lab., 666 F. Supp. 1483, 1485-86 (D. Kan. 1987). "The expected rate of severe reactions ranges between 1 in 100,000 and 1 in 310,000 doses." Toner ex rel. Toner v. Lederle Lab., 779 F.2d 1429, 1431 (9th Cir. 1986), amended by 831 F.2d 180 (9th Cir. 1987), cert. denied, 485 U.S. 942 (1988).

The organisms that cause diphtheria and tetanus excrete toxins that can be removed, inactivated with formaldehyde, and transformed into toxoids. A toxoid can immunize against disease by stimulating the production of antibodies in the recipient even though the toxoid is no longer poisonous. On the other hand, the pertussis component contains whole killed pertussis organisms. The whole-cell pertussis organism contains toxins that, if not removed from the vaccine, can cause adverse reactions. The whole organism must be used because the pertussis organism, Bordetella pertussis, contains fifteen or sixteen different antigens, and scientists have not yet identified the one that stimulates the production of antibodies. Id. at 1430; Jones ex rel. Jones v. Lederle Lab., 695 F. Supp. 700, 702 (E.D.N.Y. 1988).

306. The split- or fractionated-cell design was first marketed by Eli Lilly & Co. under the trade name Tri-Solgen between 1960 and 1976. The split-cell vaccine contains pertussis cells that have been chemically fragmented. Jones, 695 F. Supp. at 702. Because only part of the pertussis organism is used to make the split-cell vaccine, it contains fewer toxins than whole-cell vaccine. White v. Wyeth Lab., Inc., 553 N.E.2d 748, 749 (Ohio 1988).

Acellular vaccines, developed and used in Japan, contain antigens rather than cells of the Bordetella pertussis organism. They are less toxic than whole-cell vaccines, but it is not clear whether they are as effective. See Allison B. David & Ali Jalilian-Marian, DTaP: Drug Manufacturers' Liability in Vaccine-Related Injuries, 7 J. LEGAL MED. 187, 201-02 (1986).


308. See, e.g., Hurley II, 851 F.2d at 1540; see also Patten v. Lederle Lab., 655 F. Supp. 745, 749 (D. Utah 1987) ("[D]efendant argues that if tort actions for defective design and testing are to be recognized at all, they must be recognized only where a manufacturer fails to comply with some FDA rule or regulation related to design or testing.").

have rejected preemption arguments based on occupation of the field, refusing to imply preemption merely from the comprehensive FDA regulation of pharmaceutical products.\textsuperscript{310} Instead, these courts have reasoned that the FDA would have spoken clearly had it wished to preclude state regulation of DPT design.\textsuperscript{311}

Once again, Hurley I\textsuperscript{312} stands out as an exception to this approach. Applying the four-factor test previously discussed,\textsuperscript{313} the district court in Hurley I concluded that the stringent testing requirements for DPT mandated by the PHSA and the rules promulgated under the PHSA are sufficiently comprehensive and pervasive to occupy the field with respect to DPT design.\textsuperscript{314} Consequently, the court ruled that state courts are precluded from finding that the FDA-approved whole-cell vaccine was defectively designed.\textsuperscript{315} The federal appellate court held, however, that the comprehensive nature of FDA regulation of pharmaceutical products is not, in and of itself, enough to support a finding of preemption.\textsuperscript{316}

With the exception of Hurley I, the courts have also rejected the notion that damage awards based on defective design frustrate federal regulatory objectives.\textsuperscript{317} Vaccine manufacturers have suggested several rationales to support their actual conflict claim. According to one theory, damage awards would affect the cost and availability of DPT vaccine, thereby frustrating federal efforts to encourage immunization.\textsuperscript{318} Drug manufacturers have also contended that the FDA struck a balance between safety and availability


\textsuperscript{311} See MacGillivray, 667 F. Supp. at 745; Abbot, 844 F.2d at 1112; Wack, 666 F. Supp. at 127; Morris, 667 F. Supp. at 1337 (quoting Hillsborough County v. Automated Medical Lab., Inc., 471 U.S. 707, 717 (1985)).

\textsuperscript{312} Hurley v. Lederle Lab., 651 F. Supp. 993 (E.D. Tex. 1986), rev'd, 851 F.2d 1536 (5th Cir.), superseded by 863 F.2d 1173 (5th Cir. 1988).

\textsuperscript{313} See supra text accompanying note 287.

\textsuperscript{314} Hurley I, 651 F. Supp. at 1004.

\textsuperscript{315} Id. at 1003.

\textsuperscript{316} Hurley II, 851 F.2d at 1540.


\textsuperscript{318} See Jones, 695 F. Supp. at 711; Hurley I, 651 F. Supp. at 1005-06.
of vaccine by approving the whole-cell DPT vaccine, and that this balance would be upset if manufacturers were subjected to large damage awards for marketing whole-cell vaccine.\(^{319}\) However, courts have relied on the provisions of the National Childhood Vaccine Injury Act of 1986 (NCVIA)\(^ {320}\) to rebut these arguments.\(^ {321}\) This Act, which established a compensation program for those injured by vaccines, including DPT,\(^ {322}\) also allowed tort actions to be brought against vaccine manufacturers.\(^ {323}\)

Vaccine manufacturers have also claimed that because the FDA's decision to license whole-cell pertussis vaccine represents a considered judgment that the vaccine's design is safe, this decision should not be second-guessed by state-court juries.\(^ {324}\) The courts have responded by characterizing the FDA as a "passive agency," since the FDA can only license product designs that manufacturers submit. For this reason, product designs approved by the FDA may not always be the safest that are technologically achievable. Consequently, according to these courts, FDA approval should not preclude state courts from holding drug manufacturers to a higher standard of product safety.\(^ {325}\)

\(^{319}\) See Abbot, 844 F.2d at 1113; Morris, 667 F. Supp. at 1338-39.


\(^{323}\) Those who were injured more than eight years before the passage of the Act could not recover under the Act, 42 U.S.C. § 300aa-16(b)(2), but were free to pursue existing remedies under state law, see id. § 300aa-22(a), (e). Those who were injured within eight years of the passage of the Act could either seek compensation under the provisions of the Act or sue vaccine manufacturers under state tort-law doctrines. See id. §§ 300aa-11(a)(4), (5), 300aa-22(a), (e). Furthermore, persons who were injured after the enactment of the NCVIA had to complete the compensation proceeding, but reject the award and sue the manufacturer directly. Id. § 300aa-11(a)(2). Finally, the Act declared that no state may prevent an injured party from bringing a civil action against a vaccine manufacturer if such an action is not barred by the Act. Id. § 300aa-22(a).


\(^{325}\) See Hurley II, 851 F.2d at 1540; Jones ex rel. Jones v. Lederle Lab., 695 F.
E. The Medical Device Amendments of 1976

1. Structure and Purpose

The Medical Device Amendments of 1976 (MDA) to the FDCA authorize the FDA to approve the manufacture and sale of medical devices. Two methods exist by which medical devices can receive the necessary FDA approval. The first method is by premarket approval application (PMA). The PMA must contain clinical test results and other data sufficient to show that the device is safe and effective. No PMA will be approved until both FDA staff members and an outside panel of experts review the application. A second procedure is available for any new device that is "substantially equivalent" to a device that was in commercial distribution before passage of the Amendments in 1976. The FDA requires much less information under this procedure than under a PMA filing.

Section 360k(a) of the Amendments specifically limits the power of states and localities to impose requirements for medical devices.

Supp. 700, 711 (E.D.N.Y. 1988). A related argument is that FDA standards are intended to be "uniform" or exclusive. However, many courts have characterized FDA-mandated DPT design standards as "minimum," thereby leaving state courts free to impose higher standards on vaccine manufacturers. Graham, 666 F. Supp. at 1491; MacGillivray v. Lederle Lab., 667 F. Supp. 743, 746 (D.N.M. 1987).


327. A PMA must be submitted for any new device that is not substantially equivalent to an "old" device, as well as for certain Class III devices. Medical devices are divided into three categories based on potential risk: Class I devices pose the least risk, while Class III pose the greatest degree of risk. Gibbs & Mackler, supra note 5, at 207-09.

328. Normally, the sponsor must conduct clinical investigations. However, under some circumstances, the sponsor can show effectiveness through "valid scientific evidence" other than clinical trials. See 21 U.S.C. § 360c(a)(3)(B) (1988).

329. See Gibbs & Mackler, supra note 5, at 208-09.


331. This premarket notification procedure merely requires the sponsor to submit proposed product labeling and evidence that the new device is substantially equivalent to a pre-Amendment device. See 21 C.F.R. § 807.87 (1992). However, the FDA may request additional information on the "substantially equivalent" issue. Id. § 807.87(h).

332. Section 360k(a) provides:

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

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.
Moreover, the FDA has stated that the preemptive language of section 360k(a) applies to court decisions as well as to state statutes and local ordinances. 333 For the most part, the courts have concluded that section 360k bars state damage claims against manufacturers of medical devices. 334

2. Tampons

A number of recent preemption decisions have involved claims against tampon manufacturers for failure to warn about the risk of toxic shock syndrome. 335 Tampons are classified as Class II medical devices 336 and are thus subject to FDA labeling requirements. 337 Although FDA regulations require tampon manufacturers to warn consumers about the risk of toxic shock syndrome, 338 these regulations do not prescribe specific language; they merely require that warning statements contain certain


333. 21 C.F.R. § 808.1(b) (1992). This regulation declares:

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 after May 28, 1976, no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for 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 . . . .

Id. (emphasis added).

334. However, not all state-law claims are preempted. Cf. Desmarais v. Dow Corning Corp., 712 F. Supp. 13, 16 (D. Conn. 1989) (ruling that failure-to-warn claim against manufacturer not preempted when silicone mammary implants were implanted prior to the enactment of § 360k); Mitchell v. Iolab Corp., 700 F. Supp. 877, 878-79 (E.D. La. 1988) (holding that claim based on lack of informed consent against manufacturer of intraocular eye lens not preempted by FDA regulations).


Several courts have noted that § 360k(a) does not preempt design or manufacturing defect claims against tampon manufacturers because the FDA has not established regulatory standards in these areas. E.g., Moore, 867 F.2d at 246; Rinehart, 688 F. Supp. at 478.


337. Id. § 801.430.

338. Id.
information in terms that are understandable to an ordinary person.\textsuperscript{339}

Many courts have agreed with the FDA that section 360k applies to court decisions.\textsuperscript{340} Consequently, these courts have determined that this provision expressly preempts inadequate-warning claims when a manufacturer's warning complies with FDA requirements.\textsuperscript{341} Other courts have applied a conflict analysis and have concluded that damage awards under state law interfere with FDA regulatory objectives. For example, in \textit{Lindquist v. Tambrands, Inc.}\textsuperscript{342} a federal district court declared that FDA labeling requirements, which establish a uniform standard, were intended to strike a balance between product safety and protecting interstate commerce from the undue burdens imposed by nonuniform standards.\textsuperscript{343} According to the \textit{Lindquist} court, damage awards would undermine this goal of uniformity.\textsuperscript{344} In \textit{Edmondson v. International Playtex, Inc.}\textsuperscript{345} another federal district court found that damage awards for inadequate warnings might frustrate the FDA's policy of clear and concise warnings.\textsuperscript{346}

3. \textit{Intrauterine Devices}

The FDA designates intrauterine devices (IUDs) as Class III medical devices and regulates them under the Medical Device Amendments.\textsuperscript{347} FDA regulations require IUD manufacturers to warn consumers that IUDs may cause pelvic inflammatory disease (PID) in some users.\textsuperscript{348} Nevertheless, some IUD users have brought suit against product manufacturers, arguing that the provided warnings were inadequate. Manufacturers of IUDs

\textsuperscript{339} \textit{Id.} \textsuperscript{Id.} § 801.430(d).


\textsuperscript{342} 721 F. Supp. 1058 (D. Minn. 1989).

\textsuperscript{343} \textit{Id.} at 1063.

\textsuperscript{344} \textit{Id.}

\textsuperscript{345} 678 F. Supp. 1571 (N.D. Ga. 1987).

\textsuperscript{346} \textit{Id.} at 1574-75.

\textsuperscript{347} 21 C.F.R. § 884.5360 (1992).

\textsuperscript{348} \textit{Id.} § 801.427 (device IUDs); \textit{Id.} § 310.502 (drug IUDs). Pelvic inflammatory disease is a bacterial infection of the upper genital tract, including the uterus, fallopian tubes, and ovaries. PID may cause adhesions to form along the walls of reproductive organs, which can damage the reproductive organs and lead to ectopic (tubal) pregnancy and infertility. \textit{Allen v. G.D. Searle & Co.}, 708 F. Supp. 1142, 1145 (D. Or. 1989).
have maintained that section 360k of the Amendments preempts such claims, however, the courts have uniformly rejected this argument.\(^{349}\)

Most of the IUD preemption cases have involved the Cu-7 IUD, developed and marketed by G.D. Searle & Co.\(^{350}\) The Cu-7 is a plastic and copper IUD that releases small amounts of copper into the uterus. The copper irritates the lining of the uterus, thus interfering with the implantation of the egg in the uterine wall.\(^{351}\) In 1974 the FDA approved the Cu-7 as a drug, not as a medical device.\(^{352}\)

Because the FDA approved the Cu-7 as a prescription drug, rather than as a medical device, many courts have concluded that the preemptive language of the Medical Device Amendments does not apply to the Cu-7. For example, in \textit{Allen v. G.D. Searle & Co.}\(^{353}\) the defendant argued that the Cu-7 should be characterized for preemption purposes as a medical device rather than as a drug. The defendant based this argument on the fact that the FDA has treated all IUDs alike for regulatory purposes, regardless of whether they were approved as drugs or as medical devices.\(^{354}\) However, the court cited FDA regulations to show that the FDA continued to make a distinction among IUDs based on their status as either drugs or devices.\(^{355}\) Consequently, the court concluded that section 360k does not expressly preempt failure-to-warn claims against the manufacturers of Cu-7 IUDs.\(^{356}\) In \textit{Callan v. G.D. Searle & Co.}\(^{357}\) a federal court also held that section 360k is inapplicable to the Cu-7 IUD. The \textit{Callan} court observed

\begin{footnotes}

350. One exception is \textit{Tetuan}, 738 P.2d 1210. In \textit{Tetuan} a plastic "Dalkon Shield" IUD caused the plaintiff's injuries. The court held that the Medical Device Amendments of 1976 did not preempt the plaintiff's failure-to-warn claim because the Dalkon Shield was marketed between 1970 and 1974, prior to the passage of the Amendments. \textit{Id.} at 1233.


352. \textit{Allen}, 708 F. Supp. at 1145. The manufacturer voluntarily withdrew the Cu-7 IUD from the market in 1986. \textit{Id.}


354. \textit{Id.} at 1151.

355. \textit{Id.} The \textit{Allen} court referred to FDA comments at 52 Fed. Reg. 23,772 (1977), which declared: "The agency's policy of treating some IUDs as drugs and others as devices is unaffected by the revised definition of device found in the federal Food, Drug and Cosmetics Act, as amended by the Medical Device Amendments of 1976." \textit{Allen}, 708 F. Supp. at 1151 (quoting 52 Fed. Reg. 23,772).


\end{footnotes}
that the Cu-7, unlike plastic IUDs, does not meet the statutory definition of a device because the Cu-7 relies in part on chemical means to achieve its contraceptive purpose.  

A few courts have suggested that section 360k would not preempt state-law claims even if the Medical Device Amendments applied to Cu-7 IUDs. For example, in Kociemba v. G.D. Searle & Co., the court flatly stated that Congress intended section 360k to apply only to state statutes, regulations, and local laws governing medical devices, but not to state tort claims. The Callan court agreed with this conclusion. Relying on a House Committee report concerning the proposed statute, the court declared that Congress understood the term "requirement," as used in section 360k, to refer to "legislative and administrative 'programs' governing the sale and distribution of devices, not to state common law." Despite the deference courts have shown to the FDA's interpretation of section 360k in the tampon cases, the Callan court summarily rejected the FDA's position on this issue.

IUD manufacturers have also claimed that FDA regulation of pharmaceutical products is sufficiently pervasive to occupy the entire field of drug labeling. Once again, however, the courts have disagreed. Finally, some defendants have suggested that damage awards in IUD cases conflict with federal regulatory goals. According to product manufacturers, damage awards based on a theory of inadequate warning implicitly challenge the FDA's determination that such warnings are adequate. Most courts have responded to this argument by characterizing FDA regulations as minimum standards. According to these courts, because FDA labeling require-

358. Id. at 666; accord Tarallo, 704 F. Supp. at 657-58. The Medical Device Amendments define "device" as an instrument "which does not achieve its primary intended purposes through chemical action within or on the body of man . . . and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes." 21 U.S.C. § 321(h) (1988 & Supp. III 1991).


360. Id. at 1298.


362. Id. at 668. The court declared: "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 permissable construction of the statute." Id.


366. See, e.g., Allen, 708 F. Supp. at 1152; Spychala, 705 F. Supp. at 1030; https://scholarcommons.sc.edu/sclr/vol44/iss2/2
ments are merely minimum standards, imposition of higher standards by the courts does not impair the FDA's regulatory authority over pharmaceutical products. 367

F. A Critique of Preemption Analysis in Products Liability Cases

Most courts seem to employ similar methodologies when deciding products liability preemption cases. The courts first examine the preemptive language of the statute. Since none of the preemption provisions in federal product safety statutes specifically mentions damage claims under state law, most courts conclude that the statute in question does not expressly preempt such claims. 368

The courts then consider whether Congress intended to occupy the field. Courts usually conclude that it did not, because most federal product safety statutes are fairly modest in scope. 369 Even when courts conclude that Congress intended to establish uniform standards in an area, they tend

Kociemba, 680 F. Supp. at 1299.

367. See Callan, 709 F. Supp. at 664-65. In addition, a number of courts have suggested that Congress has tacitly agreed to accept whatever tension might arise between state and federal regulatory objectives. E.g., id. at 665; Kociemba, 680 F. Supp. at 1299. Finally, some courts, relying on Silkwood v. Kerr-McGee Corp., 464 U.S. 238 (1984), have concluded that Congress would have expressed its intent clearly had it intended to destroy existing state-law remedies. E.g., Callan, 709 F. Supp. at 665 Kociemba, 680 F. Supp. at 1300.


369. The district court opinion in Hurley I is one exception. That court held that the FDCA occupied the field with respect to both DPT labeling and design. See Hurley v. Lederle Lab., 651 F. Supp. 993, 1003-1004 (E.D. Tex. 1986), rev'd, 851 F.2d 1536 (5th Cir.), superseded by 863 F.2d 1173 (5th Cir. 1988).
to decide these cases on grounds of actual conflict, rather than federal occupation.370

By the process of elimination, most courts are forced to decide product preemption cases on actual conflict grounds. In theory, an actual conflict between state and federal law may arise because of impossibility, state-law impairment of rights created by federal law, or state-law frustration of federal regulatory objectives.371 However, as a practical matter, courts almost always decide these cases on frustration-of-purpose grounds.

Unfortunately, the frustration-of-purpose analysis does not work very well in the product preemption area. Courts and commentators disagree about the preemptive effect of federal legislation concerning cigarette labeling, airbags, pesticides, and pharmaceutical products. Hence, barring a determinative Supreme Court decision, the courts will continue to have difficulty deciding product preemption cases in a consistent and principled manner.

Frustration-of-purpose analysis, as it is generally applied in product preemption cases, is unsuccessful for a number of reasons: First, its primary analytical concept, "statutory purpose," is inherently indeterminate; second, it requires a court to make factual determinations without adequate information; and third, it excludes meaningful consideration of critical policy issues.

In most instances, a court's characterization of "statutory purpose" will be critical to the outcome of the case. However, unless the court can find an authoritative statement of statutory purpose, either in the text of the statute or in its legislative history, judicial conclusions about statutory purpose are likely to be nothing more than guesswork.

Recent cigarette litigation demonstrates the futility of relying on statutory purpose as the primary basis for deciding preemption issues. One group of courts has determined that the primary purpose of the Cigarette Labeling Act is to warn the public of the health hazards of smoking.372 Not surprisingly, these courts have concluded that the federal act does not preempt common-law damage claims.373 But another group of courts examining the same statute has found that the primary purpose of the federal


371. See supra part II.C.


373. See, e.g., Dewey, 577 A.2d at 1255; Carlisle, 805 S.W.2d at 517.
act is to strike a balance between health and commerce. These courts have ruled in favor of preemption.

A second problem with frustration-of-purpose analysis is that it requires courts to make key findings of fact in an evidentiary vacuum. After the court determines the statute’s purpose, it must decide whether the state action—in this case damage awards—will obstruct the achievement of this statutory purpose. However, because reliable information is seldom available, the court can merely speculate about the effects of possible tort liability on product manufacturers’ future conduct. Different assumptions about manufacturers’ resulting behavior can lead to different preemption decisions. Thus, courts that believe manufacturers can simply accept potential tort liability as a cost of doing business will often refuse to find preemption, but courts that believe manufacturers will overreact in the face of possible damage awards, thus frustrating the purpose of federal standards, are likely to find preemption.

Finally, in addition to being analytically suspect, the statutory-purpose approach often frustrates meaningful discussion of important policy considerations. Clearly, nothing prevents a court from incorporating contemporary values and policies into the process of statutory interpretation. In fact, some courts have demonstrated commendable sensitivity to such critical issues as federalism, institutional competence, and compensation goals. Unfortunately, many other courts treat these issues in a

374. E.g., Pennington, 876 F.2d at 421; Palmer, 825 F.2d at 626; Cipollone v. Liggett Group, Inc., 789 F.2d 181, 187 (3d Cir. 1986).

375. See, e.g., Pennington, 876 F.2d at 421; Palmer, 825 F.2d at 626; Cipollone, 789 F.2d at 187.


378. See infra part IV.A.1.c.

perfunctory fashion, if they consider them at all.

As the author suggests later in this Article, policy considerations are not merely relevant to the process of statutory interpretation, they are absolutely critical when neither the text nor the legislative history of the statute provides the court with authoritative evidence of the statute’s meaning.350

Although no method of statutory interpretation can be entirely satisfactory in every case, the author believes that the conventional approaches are inadequate to decide product preemption cases fairly and consistently. For this reason, Part IV focuses on alternative approaches.

IV. A PROPOSED MODEL OF STATUTORY INTERPRETATION

In Part III the author concludes that most courts in product preemption cases take a one-dimensional approach to statutory interpretation that fails to give proper consideration to many of the policy issues involved. Various alternatives are examined below to determine whether a better approach to resolving product preemption issues exists.

A. Theories of Statutory Interpretation

1. Conventional Approaches

Over the years, courts have employed a number of methods to interpret statutes. The more important conventional theories of statutory interpretation are textualism, originalism, and purposivism.

a. Textualism

Textualism puts primary emphasis on the text of the statute.381 Textualists believe that courts should focus on the statute’s text and refrain from examining other sources when the statutory language is clear.382 The precept that a court should limit itself to the statutory text is sometimes called the “plain meaning” rule.383 Although many legal scholars have

380. See Eskridge & Frickey, Statutory Interpretation, supra note 12, at 359.
criticized the textualist approach, it still retains considerable vitality.

b. Originalism

Originalism focuses on the original intent of the enacting legislature. An originalist interpreter attempts to ascertain how the enacting legislature intended to resolve a particular issue. If the enacting legislature never expressly considered the issue, the interpreter attempts to determine how the legislature would have resolved the issue had it been raised at the time of the statute’s enactment. Under a variant of this approach, known as imaginative reconstruction, the court places itself in the shoes of the enacting legislators and attempts to determine how they would have wanted the statute applied to the case at bar. This process calls for an investigation of both the statute’s legislative history and contemporaneous information.


about the general assumptions, goals, and concerns of the enacting legislature.  

\[ \text{c. Purposivism} \]

Purposivism looks to the purpose of the statute rather than to the actual intent of the enacting legislature. The purposivist approach assumes that a statute can manifest a single purpose, even though those who drafted and approved it may have had a variety of private motives and expectations. Purposivism originated in the "Legal Process" movement of the 1950s. Hart and Sacks, the leading legal process thinkers, believed that unless the contrary unmistakably appears, a court should assume "that the legislature was made up of reasonable persons pursuing reasonable purposes reasonably." According to Hart and Sacks, proper procedures would ensure that legislatures make decisions only after obtaining adequate data and thoroughly discussing policy choices. Because the enactment of every statute is a purposive act, the interpreter merely has to identify the statutory purpose and formulate an interpretation consistent with that purpose.

Unfortunately, even with the aid of legislative history, an interpreter still might be unable to ascertain a single, dominant statutory purpose. Furthermore, recent scholarship suggests that many statutes are simply deals between special interest groups and election-seeking legislators. If this


393. Id. at 715-16.

394. Id. at 166-67.

395. See Eskridge & Frickey, Statutory Interpretation, supra note 12, at 335; Sunstein, supra note 384, at 427.


One branch of public choice theory examines legislation and voting as a game in which rational behavior by game players (legislators) yields unfortunate results for the group as a whole. Game theory suggests that when legislators are faced with a series of
is so, it undercuts the notion that statutes necessarily embody any sort of mutually exclusive alternatives, the ultimate outcome is not determined by reasoned discussion, but instead is largely determined by the order in which the alternatives are considered for decision. This phenomenon, known as “majority cycling,” suggests that results achieved under democratic voting rules may be unprincipled in some cases. See Frank H. Easterbrook, Statutes’ Domains, 50 U. CHI. L. REV. 533, 547-48 (1983); Nicholas S. Zeppos, Legislative History and the Interpretation of Statutes: Toward a Fact-Finding Model of Statutory Interpretation, 76 VA. L. REV. 1295, 1307 (1990).


Interest groups that are formally organized and willing to spend money are likely to be more influential with legislators than are less organized groups. Furthermore, proposed legislation that channels costs or benefits to a narrow segment of the population is more likely to generate interest group activity than are proposals that distribute costs or benefits more broadly. See William N. Eskridge, Jr., Politics Without Romance: Implications of Public Choice Theory for Statutory Interpretation, 74 VA. L. REV. 275, 286-87 (1988). Consequently, the demand for legislation that benefits narrowly focused interests is likely to be much higher than the demand for legislation that benefits the general public. See Frank H. Easterbrook, The Supreme Court, 1983 Term—Foreword: The Court and the Economic System, 98 HARV. L. REV. 4, 15-16 (1984).

The supply of legislation depends on the legislators’ responses to interest-group demand patterns. Eskridge, supra, at 287. “Public choice theory argues that legislative behavior is driven by one central goal—the legislator’s desire to be re-elected.” Id. at 288; see also Daniel A. Farber & Philip P. Frickey, The Jurisprudence of Public Choice, 65 TEX. L. REV. 873, 891 (1987) (“[E]conomists now postulate that legislators are motivated solely by self-interest. In particular, legislators must maximize their likelihood of reelection.”). This goal leads legislators to engage in “pork barrelling” and to avoid, when possible, conflictual demand patterns. When legislators cannot avoid conflictual demands, they will prefer ambiguous laws whose details must later be filled in by courts or agencies. Eskridge, supra, at 288.

If these assumptions are correct, legislation is unlikely to be forthcoming when there is little organized demand for it or when there is strong opposition to the demand because of concentrated costs. Legislators are much more likely to respond to consensual demand patterns involving benefits that are concentrated and costs that are widely distributed. On the other hand, in conflictual demand situations when costs are concentrated, “legislators will often seek to delegate regulation of the group to an agency.” Id. at 288-89; see also William N. Eskridge, Jr., Spinning Legislative Supremacy, 78 GEO. L.J. 319, 324 (1989) [hereinafter Eskridge, Legislative Supremacy] (stating legislatures often pass hard policy questions on to unelected bureaucrats and judges because of the desire to be reelected).
legitimate public purpose.\textsuperscript{397}

2. Modern Constructivist Approaches

Recently, legal scholars have proposed a variety of interpretive theories based on modern developments in philosophy and literary criticism.\textsuperscript{398} Many of these new approaches are constructivist in nature. Constructivism assumes that courts do not passively discover some sort of meaning embedded in a statute by the enacting legislature; rather, courts must "construct" a meaning based upon consideration of current values, beliefs, and knowledge.\textsuperscript{399} Unlike conventional approaches that view the courts as legislative agents, constructivist theories regard statutory interpretation as a partnership in which the court and the departed legislature act as collaborators in creating statutory meaning.\textsuperscript{400}

B. The Eskridge-Frickey "Practical Reasoning" Model

Professors William Eskridge and Philip Frickey have developed a constructivist model they call "practical reasoning."\textsuperscript{401} The philosophical inspirations for this model are hermeneutics, pragmatism, and Aristotle's theory of practical reasoning (phronesis).\textsuperscript{402} This practical reasoning approach can be useful when analyzing preemption issues in products liability cases.

1. Theoretical Underpinnings

The Eskridge-Frickey model makes a number of assumptions about the interpretive process that differ significantly from more conventional theories.

\textsuperscript{397} See Eskridge & Frickey, Statutory Interpretation, supra note 12, at 334.

\textsuperscript{398} See generally, e.g., STANLEY E. FISH, DOING WHAT COMES NATURALLY (1989) (arguing that interpretation is largely based on culturally determined linguistic conventions); Aleinikoff, supra note 381 (advocating a "nautical" approach to statutory interpretation in which courts should interpret statutes to make them fit, as best they can, into the current legal landscape); Ronald Dworkin, Law as Interpretation, 60 Tex. L. Rev. 527 (1982) (arguing that courts should interpret statutes in accordance with the best principles that will support what the legislature has done); Eskridge, Dynamic Interpretation, supra note 386 (arguing that interpretation involves a dynamic interaction between text and interpreter).

\textsuperscript{399} See Schanck, supra note 396, at 850-51.

\textsuperscript{400} See Eskridge, Legislative Supremacy, supra note 396, at 331; Owen M. Fiss, Conventionalism, 58 S. Cal. L. Rev. 177, 180 (1985); Sunstein, supra note 384, at 411-12; Nicholas S. Zeppos, Judicial Candor and Statutory Interpretation, 78 Geo. L.J. 353, 357 (1989).

\textsuperscript{401} See Eskridge & Frickey, Statutory Interpretation, supra note 12, at 345-62.

\textsuperscript{402} Id. at 323-24.
of statutory interpretation. First, Eskridge and Frickey believe that
interpretation is a dynamic process that involves interaction between the
interpreter and the text.\textsuperscript{403} Second, because the creation of statutory mean-
ing is not a mechanical operation, the interpreter must often choose among
several competing meanings. Although the range of choices may be limited
by various factors, including the statute’s text and legislative history, no
particular interpretation is “objectively” determinable.\textsuperscript{404} Third, when
interpreters make these choices, they are normally influenced by many
different values.\textsuperscript{405}

The Eskridge-Frickey approach also reflects pragmatistic and hermeneu-
tical insights about the nature of human reasoning. The model assumes that
decisionmaking is spiral and inductive, rather than linear and deductive.\textsuperscript{406}
According to Eskridge and Frickey, human beings usually test different
solutions to a problem by evaluating each solution against a range of signifi-
cant values and beliefs.\textsuperscript{407} Decisionmakers consider the evidence for each

\textsuperscript{403} Id. at 345-47. This assumption is based on hermeneutical theory. Scholars such
as Hans-Georg Gadamer reject the notion that a text has a single “true” meaning;
instead, they believe that meaning results from a dialogue or conversation between a
present interpreter and the historic text. See HANS-GEORG GADAMER, TRUTH AND

According to Gadamer, every text has a context or horizon of assumptions the
author makes about the world around him. The interpreter also has a context or horizon.
Of course, the interpreter’s horizon is different from that of the text because the world
has changed and because the interpreter is a different person than the author of the text.
When applying the text to a specific situation, the interpreter must find a common ground
between these two horizons. See William N. Eskridge, Jr., Gadamer/Statutory
Interpretation, 90 COLUM. L. REV. 609, 617-24 (1990) [hereinafter Eskridge, Gadamer].
Gadamer calls this a “fusion of horizons.” GADAMER, supra, at 273.

When a statute is fresh and new, the horizon of the text and that of the interpreter
will be similar. Therefore, the judicial interpretation of the statute will probably yield the
same result the legislature would have reached had it considered the issue. With the
passage of time, however, the interpreter’s horizon will diverge from that of the text.
Not only will the interpreter have her own policy preferences, but various other
contextual factors will have changed as well. Eskridge, Legislative Supremacy, supra
note 396, at 350.

\textsuperscript{404} Eskridge & Frickey, Statutory Interpretation, supra note 12, at 347.
\textsuperscript{405} Id. at 348.

\textsuperscript{406} Id. The difference between linear and spiral reasoning can be illustrated by
comparing a chain to a cable. A chain is no stronger than its weakest link: the chain will
break if any one of its singly connected links does. In contrast, a cable’s strength is based
not on the strength of an individual thread, but on the cumulative strength of many
threads woven together. Legal arguments are often constructed like chains, but Eskridge
and Frickey believe that the more successful legal arguments are cable-like. Id. at 351.

\textsuperscript{407} Id. at 348. The pragmatistic idea of the “web of beliefs” illustrates well this
concept. All individuals accept a variety of different values and propositions that, taken
together, constitute a web of interwoven beliefs about a particular issue. Although each
person may accord different weight to the specific values, almost no one excludes any
value before making a decision, and then check this preliminary decision against their most esteemed values and beliefs. This theory of decision-making suggests that an individual’s reasoning depends largely on the context of the case at hand, specifically on the relative strength of each consideration.403

The practical reasoning approach also has a dynamic or interactive aspect to it. “The various arguments . . . do not exist in isolation; they interact with one another.”409 The metaphor of Gadamer’s “hermeneutical circle” captures this interaction. “A part can only be understood in the context of the whole, and the whole cannot be understood without analyzing its various parts.”410 In other words, the individual interpretive threads cannot be viewed in isolation; rather, each must be evaluated in relation to the other threads.411

2. Methodology

The Eskridge-Frickey model requires an interpreter to examine a broad range of evidence, including the text of the statute, historical evidence, and the evolution of the text, to form a preliminary view of the statute. The interpreter then refines this view by evaluating possible interpretations in terms of fidelity to the text, historical accuracy, and conformity to contemporary policies and values. Each of these considerations is relevant, but no one consideration necessarily outweighs the others. Thus, text whose interpretation seems indisputable in light of some evidence may yield a contrary interpretation if other considerations cut against it.412
a. Textual Considerations

The statutory text should be the starting point for interpretation; indeed, courts typically regard textual arguments as the most authoritative.\textsuperscript{413} This emphasis on textual primacy is based on a number of considerations. First, only the statutory text is formally enacted into law; therefore, judicial deference to the legislature requires the interpreter to be attentive to the text.\textsuperscript{414} Furthermore, citizens typically look to the text to determine their duties and responsibilities under a statute.\textsuperscript{415} Finally, strict adherence to the text imposes some discipline on activist courts.\textsuperscript{416}

Textual analysis begins with an examination of the actual language of the statutory provision being interpreted. The interpreter should approach

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at 353. Eskridge and Frickey describe this model as "a 'funnel of abstraction.'" Id.

The model is funnel-shaped for three reasons. First, the model suggests a hierarchy of sources. Thus, in formulating and testing preunderstanding of a statute, an interpreter will prefer a good argument based on the statutory text rather than a conflicting but equally strong argument based upon statutory purpose or current values. Id. Second, the model also indicates the amount of abstraction for each source. Sources at the bottom of the diagram involve more focused, concrete inquiries, usually with a more limited range of arguments. As one moves up the diagram, the range of available arguments increases, partly because the inquiry is less concrete. Id. at 353-54. Finally, the model illustrates the pragmatistic and hermeneutical insights discussed previously. As interpreters formulate and test their understanding of the statute, they move up and down the diagram, evaluating and comparing the different considerations represented by each source of argumentation. Id. at 354.


414. See Aleinikoff, supra note 381, at 23; Daniel A. Farber, The Inevitability of Practical Reason: Statutes, Formalism, and the Rule of Law, 45 VAND. L. REV. 533, 543 (1992); Sunstein, supra note 384, at 416. However, statutory interpretation based on textual analysis does not necessarily involve a search for the original intent of the enacting legislature. As Justice Holmes once remarked, "We do not inquire what the legislature meant; we ask only what the statute means." Oliver W. Holmes, The Theory of Legal Interpretation, 12 HARV. L. REV. 417, 419 (1899).


416. See Aleinikoff, supra note 381, at 23; Sunstein, supra note 384, at 416. But see Farber & Frickey, supra note 384, at 453-61 (questioning the appropriateness of this goal as a justification for a textualist theory of statutory interpretation).
the statutory text as a reasonably intelligent reader, giving the text its most sensible reading.\footnote{417. See Paul Brest, The Misconceived Quest for the Original Understanding, 60 B.U. L. REV. 204, 206 (1980); Eskridge, The New Textualism, supra note 384, at 660.} The interpreter should be cognizant of any special meanings that words in the text have acquired and should also consider the syntax and the punctuation of the sentence.\footnote{418. See Eskridge, The New Textualism, supra note 384, at 663-64.}

Structural analysis may also serve as an interpretive tool. The interpreter should consider how a word or phrase is used elsewhere in the same statute or in other statutes,\footnote{419. See, e.g., Kungys v. United States, 485 U.S. 759, 770 (1988); NLRB v. Amax Coal Co., 453 U.S. 322, 329 (1981).} as well as how a possible meaning coheres with the statute as a whole.\footnote{420. See Eskridge, The New Textualism, supra note 384, at 660-62.} Interpretations that render other provisions of the statute duplicative or superfluous should be avoided.\footnote{421. See, e.g., Chan v. Korean Air Lines, Ltd., 490 U.S. 122, 130-35 (1989) (Scalia, J.); United States v. Fausto, 484 U.S. 439, 449-51 (1988) (Scalia, J.).}

Also, the interpreter may examine the interaction of different statutory schemes to ascertain the statute’s meaning.\footnote{422. See, e.g., Jett v. Dallas Indep. Sch. Dist., 491 U.S. 701, 738-39 (1989) (Scalia, J., concurring).}

\section*{b. Historical Considerations}

Another factor that the interpreter should consider is the intent of the enacting legislature.\footnote{423. See Reed Dickerson, The Interpretation and Application of Statutes 67 (1975) (stating that courts should try to determine as accurately as possible the legislature’s intent).} Original legislative expectations are important in a democracy, where the legislature is the primary source of law. An interpreting court that can recover the original meaning of a statute promotes democratic values by enforcing the law as the legislature understood it, thus limiting judicial discretion and power.\footnote{424. See Reed Dickerson, The Interpretation and Application of Statutes 67 (1975) (stating that courts should try to determine as accurately as possible the legislature’s intent).}

A statute’s legislative history may often reveal legislative intent.\footnote{425. See, e.g., Kungys v. United States, 485 U.S. 759, 770 (1988); NLRB v. Amax Coal Co., 453 U.S. 322, 329 (1981).} Because some sources of legislative history are more reliable than others, the interpreter should develop a hierarchy for purposes of statutory interpretation. Professor Eskridge has proposed the following hierarchy of legislative history (moving from most authoritative to least authoritative): (1) committee reports, (2) sponsor statements, (3) rejected proposals, (4) floor

\begin{footnotes}
\item[418] See Eskridge, The New Textualism, supra note 384, at 663-64.
\item[423] See Reed Dickerson, The Interpretation and Application of Statutes 67 (1975) (stating that courts should try to determine as accurately as possible the legislature’s intent).
\item[424] See Eskridge & Frickey, Statutory Interpretation, supra note 12, at 356.
\item[425] See Farber & Frickey, supra note 384, at 437; James M. Landis, A Note on "Statutory Interpretation", 43 HARV. L. REV. 886, 888-90 (1930). Justice Scalia, among others, has expressed deep reservations about using legislative history to interpret statutes. See, e.g., Blanchard v. Bergerson, 489 U.S. 87, 98-99 (Scalia, J., concurring); see also Zeppos, supra note 396, at 1299-1310 (discussing textualists’ views).
\end{footnotes}
and hearing colloquies, (5) views of nonlegislator drafters, and (6) legislative inaction and subsequent legislative history.\textsuperscript{426}

Committee reports are typically regarded as the most authoritative sources of legislative history.\textsuperscript{427} A committee report represents the collective understanding of those legislators most actively involved in drafting the proposed legislation.\textsuperscript{428} Moreover, committee reports may provide evidence of bicameral agreement when the House and Senate reports are identical or when a conference report reveals how the differences between the House and Senate were resolved.\textsuperscript{429}

Courts also rely on statements by sponsors or floor managers of proposed legislation that becomes law.\textsuperscript{430} The views of sponsors and floor managers are persuasive because these individuals are familiar with the language and purpose of the proposed legislation. Furthermore, other legislators are likely to defer to the views of the sponsors and floor managers about the meaning of proposed statutory language.\textsuperscript{431}

The rejection of proposed language by a legislative committee—on the House or Senate floor, or by a conference committee—may also be relevant because it indicates that the legislature expressly considered and rejected a particular course of action.\textsuperscript{432} However, because proposed language is sometimes rejected for nonsubstantive reasons, this source of legislative history is usually less authoritative than committee reports or sponsor statements.\textsuperscript{433}

In general, statements by legislators at hearings or on the floor are less significant than remarks by sponsors or floor managers.\textsuperscript{434} Ordinary

\textsuperscript{426} See Eskridge, The New Textualism, supra note 384, at 636-40.

\textsuperscript{427} Id. at 637.

\textsuperscript{428} See, e.g., Thornburg v. Gingles, 478 U.S. 30, 43 n.7 (1986) (commenting that committee reports are an authoritative source of legislative intent); Garcia v. United States, 469 U.S. 70, 76 (1984) (noting that committee reports are the most authoritative source of legislative intent); Zuber v. Allen, 396 U.S. 168, 186 (1969) (finding that committee report represents “considered and collective understanding” of those involved in the drafting and studying of proposed legislation).

\textsuperscript{429} Eskridge, The New Textualism, supra note 384, at 637.


\textsuperscript{434} See Reed Dickerson, Statutory Interpretation: Dipping into Legislative History,
legislators "are less likely to know . . . the consensus view . . . on the bill, and are more likely to behave strategically."\textsuperscript{435} However, statements by supporters or even opponents of proposed legislation may be considered, especially when such statements reveal the general assumptions held about the legislation when it was enacted.\textsuperscript{436} In contrast, statements by nonlegislative drafters and sponsors, without more, are seldom regarded as informative.\textsuperscript{437} Nevertheless, evidence from nonlegislative sources may be helpful when the statute in question represents a compromise reached outside of the legislature.\textsuperscript{438}

Legislative silence on an issue provides little evidence of legislative intent and is usually relied upon only to support other more authoritative evidence of legislative intent. Such silence may have some persuasive force, even standing alone, when there is no other evidence of legislative intent.\textsuperscript{439} Subsequent legislative action is treated similarly: alone, it is seldom very authoritative, but a court may cite it if no other evidence of legislative intent is available.\textsuperscript{440} 

c. Policy Considerations

Finally, an interpreter should consider contemporary values, such as ideas of justice and fairness, related statutory policies, and constitutional norms.\textsuperscript{441} According to Eskridge and Frickey, current policies and values

\footnotesize{\textsuperscript{11} HOFSTRA L. REV. 1125, 1132-33 (1983).}

\textsuperscript{435} Eskridge, The New Textualism, supra note 384, at 639; see also W. David Slawson, Legislative History and the Need to Bring Statutory Interpretation Under the Rule of Law, 44 STAN. L. REV. 383, 397-98 (1992) (discussing the practice of "manufacturing" legislative history).

\textsuperscript{436} See Eskridge, The New Textualism, supra note 384, at 639 & n.72.

\textsuperscript{437} See, e.g., Kelly v. Robinson, 479 U.S. 36, 50-51 & n.13 (1986) (declining to give significance to statements made by nonlegislators).

\textsuperscript{438} See Eskridge, The New Textualism, supra note 384, at 640.

\textsuperscript{439} See, e.g., Green v. Bock Laundry Mach. Co., 490 U.S. 504, 521-24 (1989) (reasoning that failure to protect certain witnesses from impeachment on account of prior criminal conviction was deliberate since conference committee could have easily extended such protection to them).

\textsuperscript{440} See, e.g., Seatrain Shipbldg. Corp. v. Shell Oil Co., 444 U.S. 572, 596 (1980) (stating that views of subsequent Congresses are entitled to significant weight, particularly when the precise intent of the enacting Congress is obscure).

\textsuperscript{441} According to Professor Eskridge, interpreting courts often give effect to current values by incorporating them into general rules, presumptions, clear statement rules, gap-filling rules, or background context. See William N. Eskridge, Jr., Public Values in Statutory Interpretation, 137 U. PA. L. REV. 1007, 1009 (1989) [hereinafter Eskridge, Public Values]. General or meta-rules provide that even when the legislature has the constitutional authority to order a particular result by statute, the courts will presume against that result unless the legislature clearly directs it. Id. at 1019-20. Presumptions declare that the legislature is presumed to accept a particular interpretation. Clear
are part of the interpreter’s horizon. If interpretation is a “fusion of horizons” between the historical text and the contemporary interpreter, current values cannot legitimately be excluded from the dialectic of interpretation.442

Contemporary policies and values originate from a variety of sources. Some values are a part of the general heritage of western civilization; other values can be traced to specific constitutional, statutory, or common-law sources. Still other values have no single origin.443 This section considers five values or policies that are relevant to preemption and products liability: (1) protection of interstate commerce; (2) maintenance of the federal system of government; (3) deference to agency decisionmaking; (4) promotion of consumer safety; and (5) provision of compensation to accident victims.

i. Interstate Commerce

Protection of trade and maintenance of national markets has long been a national priority. As early as 1787, many delegates to the Constitutional Convention expressed concern about the divisive effect of protectionist state legislation.444 It is not surprising, therefore, that a number of constitutional provisions were designed to facilitate interstate and international commerce.445 Of course, the most important of these provisions is the Commerce Clause, which declares: “The Congress shall have Power . . . To Regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes.”446 The Supreme Court has regularly invoked the

statement rules provide that the courts will interpret a statute in a certain way unless the legislature clearly expresses a contrary view. Gap-filling rules provide that ambiguity will be resolved in favor of a particular value. *Id.* at 1028-29. Finally, policies articulated in other cases or statutes may provide useful background experience upon which courts can draw for interpretive guidance. *See id.* at 1034.

442. Eskridge & Frickey, Statutory Interpretation, supra note 12, at 360.
443. For example, many constitutional provisions, such as prohibitions against vagueness, ex post facto laws, and cruel and unusual punishments, are grounded in principles of retributive justice.
445. For example, the Constitution grants Congress the power to collect duties, imposts, and excises; and the power to coin money and establish standard weights and measures. U.S. CONST. art. I, § 8.
446. *Id.*
Commerce Clause to protect national markets against parochial state legisla-

tion.447

State products liability doctrines impose some costs on product manufacturers and consumers, in part because liability laws are constantly evolving. This uncertainty makes it difficult for manufacturers and their insurers to calculate potential liability.448 Furthermore, since liability standards often vary from state to state, manufacturers must alter their products accordingly to comply with varying requirements for product quality.449 Finally, because liability insurance premiums are determined on a national basis, states with liberal liability standards are able to shift insurance costs to states with more conservative liability standards.450

For these reasons, the policy of protecting interstate commerce supports a liberal application of the preemption doctrine. State liability doctrines regarding warnings and product design impose costs on product sellers, while uniform federal standards facilitate the marketing of products on a national basis.451

ii. Federalism

The structure and operation of American government reflect a continuing commitment to the principle of federalism. As Professor Herbert


449. Holley, supra note 4, at 818-19. Lack of uniform liability standards also increases legal costs for product manufacturers. See Reed & Watkins, supra note 448, at 442.


Wechsler declared almost forty years ago:

In a far flung, free society, the federalist values are enduring. They call upon a people to achieve a unity sufficient to resist their common perils and advance their common welfare, without undue sacrifice of their diversities and the creative energies to which diversity gives rise. They call for government responsive to the will of the full national constituency, without loss of responsiveness to lesser voices, reflecting smaller bodies of opinion, in areas that constitute their own legitimate concern.  

Federalism encourages participation in the political process, thereby ensuring that government officials are more responsive to public needs and desires. It also promotes diversity by allowing cultural differences to find expression in different places. In addition, the federal system allows states to serve as "social laboratories," experimenting with new solutions to social and economic problems. In the two centuries following the adoption of the Constitution, the national government's powers have steadily increased, while the powers of the states have declined. Nevertheless, the states continue to exercise substantial powers, especially in the areas of public health and safety. The Supreme Court has acknowledged the role of the states in the federal system and has declared that the historic police powers of the states will not be superseded by federal legislation absent the "clear and manifest" purpose of Congress.

454. Id. at 854.
455. New State Ice Co. v. Liebmann, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) ("It is one of the happy incidents of the federal system that a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country.").
456. See generally Kaden, supra note 453, at 857-83.
458. See Eskridge, Public Values, supra note 441, at 1023; Sunstein, supra note 384, at 469.
Federalism appears to cut against a finding of implied preemption in products liability cases. "[C]onsumer product safety has no roots in historically or constitutionally defined [national] interests."\(^\text{460}\) On the contrary, the protection of consumers against injuries from defective products falls squarely within traditional areas of state responsibility.\(^\text{461}\) Therefore, courts would violate the principle of federalism by abrogating a state’s power to protect its citizens’ health and safety absent a clear congressional expression to abrogate that power.\(^\text{462}\)

iii. Agency Decisionmaking

Some commentators have cautioned against allowing litigants to challenge the adequacy of federal safety standards in lawsuits against product manufacturers.\(^\text{463}\) These commentators implicitly assume that federal administrative agencies are more qualified than courts to establish product safety standards.\(^\text{464}\) Administrative standards are clearer and more


\(^{462}\) See, e.g., Puerto Rico Dep’t of Consumer Affairs v. Isla Petroleum Corp., 485 U.S. 495, 503 (1988) ("[A] ‘clear and manifest purpose’ of pre-emption is always required."); Ray v. Atlantic Richfield Co., 435 U.S. 151, 157 (1978) ("[W]e start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress."); (quoting Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977)); Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947); Ferebee v. Chevron Chem. Co., 736 F.2d 1529, 1542 (D.C. Cir.) ("[I]t is necessary to bear in mind . . . the circumspect view courts must take of a claim that Congress has preempted states from exercising their traditional police powers on behalf of their citizens.")., cert. denied, 469 U.S. 1062 (1984); see also Sunstein, supra note 384, at 469 (claiming assumption that states have authority to regulate their own citizens justifies “an interpretive principle requiring a clear statement before judges will find federal preemption of state law”).

\(^{463}\) See Walsh & Klein, supra note 268, at 193 (“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.”); Theroff, supra note 191, at 662 (“A legitimate argument exists against risking potentially outrageous damage awards through litigation if the safety problem can be effectively addressed through regulation by an administrative agency.”); Note, supra note 264, at 788 (“[J]udicial determination [of defectiveness] . . . undermines the aggregate risk calculus properly undertaken by the FDA in its capacity as ‘public health promoter [and] . . . protector.’” (alteration in original) (quoting 50 Fed. Reg. 7452 (1985))).

\(^{464}\) See W. Kip Viscusi, Toward a Diminished Role for Tort Liability: Social
specific than standards arising from the adjudicatory process. Furthermore, because of their superior resources and technical expertise, federal agencies are in a better position than state courts to develop technologically sound safety standards for complex products. Finally, agency decisionmaking procedures are better suited than the courts to deal with polycentric issues. Therefore, if federal agencies are institutionally superior to courts in this regard, public policy supports statutory interpretations that allow agency jurisdiction to keep pace with changing regulatory concerns. Public policy would also support concepts like preemption that insulate agency decisionmaking from collateral attack in the courts.

The principle of deference to agency decisionmaking also suggests that courts should accede to agency interpretations of law whenever a statute is ambiguous. Although the concept of agency deference is not new, the


466. See Landen, supra note 259, at 117 ("Only the FDA is qualified to evaluate data and make the requisite policy judgments involved in drug regulation."); Alan Schwartz, Proposals for Products Liability Reform: A Theoretical Synthesis, 97 Yale L.J. 353, 389 (1988) (claiming that administrative agencies often have more expertise than courts). However, some commentators believe that safety standards promulgated by federal agencies often reflect political compromises rather than what is technologically feasible. See, e.g., Holley, supra note 4, at 812 (noting that federal motor vehicle safety standards typically originate in political compromise); Theroff, supra note 191, at 619 (claiming that administrative safety standards are often the result of compromise).

Even if agency standards are satisfactory when originally enacted, they frequently fail to keep pace with changing knowledge and technology. See Holley, supra note 4, at 812 (stating that motor vehicle standards may become outdated by technological advances). Furthermore, administrative agencies are sometimes "captured" by the very industries they are supposed to regulate. See Theroff, supra note 191, at 619 (claiming that exclusive federal regulation invites agency capture by the regulated industry). In addition, inadequate resources and time-consuming administrative procedures can cause federal agencies to offer weak responses to safety problems. See Teresa M. Schwartz, The Role of Federal Safety Regulations in Products Liability Actions, 41 Vand. L. Rev. 1121, 1151-52 (1988) (stating that agencies can address only the most serious safety problems because of limited resources); Viscusi, supra note 464, at 88 (noting that the regulatory process often involves substantial delays).

467. See James A. Henderson, Jr., Judicial Review of Manufacturers' Conscious Design Choices: The Limits of Adjudication, 73 Colum. L. Rev. 1531, 1540-42 (1973) (arguing that courts are not institutionally suited to adjudicate polycentric product safety questions).

468. See Sunstein, supra note 384, at 493-96 (discussing the role of statutory interpretation in the face of changed circumstances or statutory obsolescence).

469. See Cynthia R. Farina, Statutory Interpretation and the Balance of Power in the

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Supreme Court recently revivified it in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.* In *Chevron* the Court declared that when a statute is silent or ambiguous about a specific issue, a court may not automatically impose its own construction on the statute. Instead, the court must determine whether the agency’s position is based on a permissible construction of the statute. If the agency’s interpretation is permissible, the court must defer to the agency, even if the court would have reached a different interpretation.

The response to *Chevron* has been mixed. A number of legal scholars have applauded the decision because it ensures that the policy choices involved in interpreting statutes will be made by those answerable to the political branches of government. However, other commentators have cautioned against deferring to agency interpretations unless Congress has expressly delegated broad policymaking powers to the agency.

This aspect of agency deference is not likely to arise very often in product preemption litigation. Although product manufacturers have frequently argued for preemption, the agencies themselves have remained

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*Administrative State*, 89 COLUM. L. REV. 452, 454 (1989) (discussing the “deferential model” of statutory interpretation model under which a court can reject an agency’s interpretation only if that interpretation is “patently inconsistent” with the statute or its legislative history).

470. 467 U.S. 837 (1984). *Chevron* involved the EPA’s decision to treat all air pollution-emitting devices within the same industrial grouping as though encased within a single “bubble.” This bubble concept was embodied in the EPA’s definition of the statutory term “stationary source,” 40 C.F.R. § 51.18(j)(1)(i), (ii) (1983). The Court upheld the EPA’s definition against a challenge by environmental groups. *Chevron*, 467 U.S. at 866.


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curiously silent on the issue. So far, only the FDA has taken the position that one of its statutes allows it administratively to preempt damage claims.\textsuperscript{474} As long as most federal agencies refrain from taking a position on preemption, deference to agency interpretation is unlikely to be a significant factor in product preemption decisions.

\textit{iv. Public Health and Safety}

Both federal product safety legislation and state products liability doctrines promote public health and safety, though in different ways. Federal statutes impose mandatory standards upon product manufacturers and enforce these requirements with criminal sanctions; state products liability doctrines rely on economic incentives to achieve safety goals.

Strict liability ensures that the costs of product-related injuries are borne by manufacturers and others in the distributive chain. Manufacturers are usually in the best position to reduce the cost of injuries because of their control over production.\textsuperscript{475} But manufacturers would have little incentive to spend money on product safety if the costs of product-related injuries were borne entirely by accident victims. A strict liability rule forces manufacturers to choose between paying damages for product-related injuries or spending money to prevent them from occurring in the first place.\textsuperscript{476}

In most cases, the federal product safety legislation and state products liability doctrines complement and reinforce each other.\textsuperscript{477} Accordingly, public health and safety considerations militate against preemption when a federal product safety statute says nothing about its effect on the validity of state tort law.\textsuperscript{478}

\textit{v. Compensation}

Both the principles of corrective justice and utilitarian-based theories of risk distribution support compensation of those who are injured by defective products. Corrective justice is concerned with rectifying wrongful gains and losses. The traditional concept of corrective justice provides that wrongfully injured victims should obtain redress and that those profiting from the infliction of such injuries should be forced to disgorge their wrongful gains.\textsuperscript{479} Furthermore, modern tort theorists have suggested that corrective

\textsuperscript{474} See supra note 333 and accompanying text.


\textsuperscript{476} See Ausness, \textit{Unavoidably Unsafe Products}, supra note 126, at 745-46.

\textsuperscript{477} See T. Schwartz, supra note 466, at 1138.

\textsuperscript{478} See Atwell, supra note 1, at 224.

\textsuperscript{479} See generally ARISTOTLE, NICOMACHEAN ETHICS (Terence Irwin trans., 1985).
justice supports compensatory payment to injured parties even if the wrongdoer does not directly profit from his wrongful conduct.\(^{463}\)

The compensation principle in tort law is also based on the utilitarian notion that losses should be shifted to the party who is best able to spread the losses among members of a large group. Implicit in this principle is the assumption that a loss will cause less social and economic disruption if shared by many people.\(^{461}\) Although individual victims can spread some losses through insurance, defendants, particularly profit-making enterprises, can usually spread losses more efficiently.\(^{462}\) Consequently, the loss-spreading rationale strongly supports a rule requiring product manufacturers to compensate victims of defective products.\(^{463}\)

However, the preemption doctrine immunizes manufacturers from liability if their products comply with federal safety standards, regardless of how inadequate such standards may be. In effect, preemption forces the victim, rather than the manufacturer, to bear the personal injury loss, even though the manufacturer could include the loss as a cost of production.\(^{464}\) This analysis suggests that when a federal regulatory statute is ambiguous, preemption should be disfavored to avoid denying compensation to those injured by defective products.\(^{465}\)

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V. PREEMPTION AND PRODUCTS LIABILITY REVISITED

This part of the Article is devoted to reexamining the preemption cases discussed in Part III. The author employs an interpretive approach derived from the Eskridge-Frickey practical reasoning model. This approach differs in a number of respects from the approach the courts generally use in preemption cases. First, the statutory text plays a more important role in the interpretive process. Textual considerations are, of course, essential to express preemption analysis, but the statutory text is also relevant to other aspects of preemption. Additionally, this approach gives considerable weight to legislative history. In product preemption cases, courts often discount the value of legislative history as an interpretive tool.\(^{486}\) Finally, the approach emphasizes policy considerations and subsequent evolution of statutes.

A. The Federal Cigarette Labeling and Advertising Act

The text of the Federal Cigarette Labeling and Advertising Act\(^{487}\) is fairly short. Only two provisions, sections 1334 and 1331, are relevant to the preemption issue. Section 1334 is the statute’s express preemption provision. Section 1334(a) provides that no health warning “shall be required” on any cigarette package other than the warning “required” by this Act.\(^{488}\) Presumably, Congress intended this subsection to prevent states from requiring additional warnings on cigarette packages. Section 1334(b) is broader. It declares that “[n]o requirement or prohibition . . . shall be imposed under State law with respect to the advertising or promotion of any cigarettes” that are labeled in conformity with this Act.\(^{489}\)

Section 1334 uses the terms “required” and “requirement” to describe the type of state action Congress intended to preempt.\(^{490}\) Therefore, it is necessary to determine exactly what those terms mean. According to Webster’s, the word “require” means, among other things, “to ask for

\(^{486}\) See, e.g., Palmer v. Liggett Group, Inc., 825 F.2d 620, 626 (1st Cir. 1987) (“Because the language of the Act is straightforward and unambiguous, we need not resort to legislative history to determine congressional intent.”), called into doubt by Cipollone v. Liggett Group, Inc., 112 S. Ct. 2608 (1992); Cipollone v. Liggett Group, Inc., 789 F.2d 181, 186 (3d Cir. 1986) (“[W]e find the language of the statute itself a sufficiently clear expression of congressional intent without resort to the Act’s legislative history.”); Kolbeck v. General Motors Corp., 702 F. Supp. 532, 537 (E.D. Pa. 1989) (“I disagree with the emphasis these courts place on the legislative history . . . .”).


\(^{488}\) Id. § 1334(a) (emphasis added).

\(^{489}\) Id. § 1334(b) (emphasis added).

\(^{490}\) Section 1334(b) also refers to “prohibitions,” id., but that term is not directly relevant to claims based on failure to provide adequate warnings.
authoritatively or imperatively; claim by right and authority; insist upon, usually with certainty or urgency" or "to impose a compulsion or command upon (as a person) to do something." 491 "Requirement," which is derived from "require," means "something that is wanted or needed" or "something that is called for or demanded." 492 These definitions convey the idea of a peremptory command issued by some authoritative source. As Justice Blackmun noted in Cipollone, legislative and administrative standards are consistent with this idea, but common-law rules are not. 493 Legislative and administrative commands give the regulated party no choice but to comply. Tort liability, on the other hand, encourages compliance by subjecting the defendant to economic pressure, but does not compel or mandate compliance. 494 For this reason, contrary to the plurality in Cipollone, textual considerations alone do not clearly show that Congress intended to preempt existing common-law rules by including the term "requirements" in section 1334.

Furthermore, none of the discussions and debates about preemption that appear in congressional reports or hearings suggests that section 1334 was intended to preempt common-law tort claims. 495 Most references in the legislative history to tort liability deal with the assumption-of-risk defense. 496 The legislative hearings reveal that most parties assumed that assumption of risk, based on the statutory warnings, would not bar tort actions against cigarette manufacturers. 497 Most members of Congress

492. Id.
494. Id. at 2627-28; see also Ausness, Cigarette Company Liability, supra note 125, at 926-27.
497. See 111 CONG. REC. 16,543-44 (1965).

The legislative record makes it clear that passage of this law and compliance by the manufacturer in no way affects the right to raise the defense of "assumption or [sic] risk" and the legal requirement for such a defense to prevail; nor does it shift the burden of proof, nor could it be
apparently assumed that the Act would not bar tort claims against tobacco companies. This view was shared by the Department of Health, Education, and Welfare.\textsuperscript{498} Moreover, when Congress amended the Cigarette Labeling Act in 1969, members of the House Committee on Interstate and Foreign Commerce reaffirmed that the Act should have no effect on personal injury claims.\textsuperscript{499}

Since neither the text of the Act nor its legislative history clearly indicates that Congress intended to preempt state tort-law damage claims, contemporary values and policies may aid in the interpretation of the statute. The protection of commerce is a policy that is clearly relevant to preemption. Section 1331 declares that the Act’s labeling requirement is intended to protect “commerce and the national economy.”\textsuperscript{500} However, the Act’s legislative history reveals that Congress was largely concerned about the economic effects of diverse state labeling requirements. For example, a 1965 House Report mentioned that many of the witnesses who testified at committee hearings on the bill warned that “a multiplicity of State and local regulations pertaining to labeling of cigarette packages could create chaotic marketing conditions and consumer confusion.”\textsuperscript{501} Similar concerns were raised in 1969 when the Cigarette Labeling Act was revised.\textsuperscript{502} On the other hand, nothing in the Act’s legislative history suggests that Congress was concerned about the economic effects of tort liability upon the tobacco industry or the national economy.

Subsequent events also indicate that state statutes and administrative regulations, not tort law, are the proper focus of the Act’s preemption section. The experience of the past thirty years has shown that product manufacturers can adjust to varying state standards of tort liability because tort law, unlike government regulations, allows for flexible responses.\textsuperscript{503}

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considered a legal or factual bar to the plaintiff user.

\textit{Id.} (statement of Rep. Fascell).

\textsuperscript{498} \textit{Hearings on H.R. 2248}, supra note 496, at 176 (HEW considers such suits to be “a private matter . . . not . . . regulated by this bill”) (statement of Theodore Ellenbogen).

\textsuperscript{499} \textit{See Hearings on H.R. 643}, supra note 496, at 579 (“\textit{N}owhere in the act of 1965 does it preclude an individual or prevent an individual from pursuing a common-law liability [action] against any tobacco company . . . .”) (statement of Rep. Watson).


\textsuperscript{503} Ausness, \textit{Cigarette Company Liability}, supra note 125, at 933.
In addition, when Congress enacted the Comprehensive Smokeless Tobacco Health Education Act of 1986, which closely resembles the Cigarette Labeling Act, it included a savings clause that expressly preserved common-law claims based on failure to warn. The Senate Committee Report stated that manufacturers and sellers could add additional warnings to those required by the Smokeless Tobacco Act. This evidence suggests that Congress believes state tort liability does not necessarily conflict with federal labeling requirements or impose an unreasonable burden on interstate commerce.

Federalism values are also relevant to preemption. As a number of courts have acknowledged, health and safety are traditional state concerns. States have a strong interest in compensating their citizens who are injured by defective products. The Supreme Court has acknowledged the need to respect legitimate state interests by creating a presumption against preemption to prevent federal legislation from inadvertently overriding state law. This presumption has persuaded a number of

505. 15 U.S.C. § 4406(c) (1988). This provision states: “Nothing in this chapter shall relieve any person from liability at common law or under State statutory law to any other person.” Id.
508. Forster v. R.J. Reynolds Tobacco Co., 437 N.W.2d 655, 658 (Minn. 1989) (“This state has a vital interest in protecting the health and safety of its citizens.”); Forster v. R.J. Reynolds Tobacco Co., 423 N.W.2d 691, 696 (Minn. Ct. App. 1988) (“That health and safety matters lie within the domain of the states has been long recognized by the Supreme Court.”), aff’d in part and rev’d in part, 437 N.W.2d 655; Carlisle, 805 S.W.2d at 507 (“[T]he Act regulates in an area of traditional state control.”).
courts to reject preemption arguments.⁵¹¹

Ironically, in *Cipollone* Justice Stevens declared that federalism principles dictate that the Court should narrowly construe preemption provisions and not preempt state law unless required to do so by the "clear meaning" of the statutory text.⁵¹² Nevertheless, he concluded that the federal cigarette labeling statute preempted common-law failure-to-warn claims.⁵¹³ Similarly, Justice Blackmun stated that the Court should narrowly construe preemption provisions to avoid improper encroachment upon state power.⁵¹⁴ His interpretation of the Act’s preemption provision appears to be more consistent with the application of the Court’s "clear meaning" rule.

Public health and safety policies are also relevant to interpreting the Act. The text of section 1331 declares as a purpose of the Act that "the public may be adequately informed about any adverse health effects of cigarette smoking."⁵¹⁵ The legislative history also indicates that the Act represented a congressional response to public concerns about the health effects of smoking. For example, in its report to Congress, the House Committee on Interstate and Foreign Commerce declared: "The principal purpose of the bill is to provide adequate warning to the public of the potential hazards of cigarette smoking."⁵¹⁶

Commentators have noted that tort liability also promotes product safety by encouraging cigarette manufacturers to make their products safer,⁵¹⁷ to engage in additional product safety research,⁵¹⁸ and to provide timely and

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⁵¹¹ E.g., *Dewey*, 577 A.2d at 1247 ("[W]e are not to conclude that Congress legislated the ouster of [traditional common-law remedies] in the absence of an unambiguous congressional mandate to that effect.") (second alteration in original) (quoting Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 146-47 (1963)); *Carlisle*, 805 S.W.2d at 508 ("It is in such close and difficult cases that a presumption against preemption seems to us most appropriate . . . ."); *Forster*, 423 N.W.2d at 695 ("The preservation of that [federal] system requires a presumption 'that Congress did not intend to displace state law.'") (quoting *Maryland*, 451 U.S. at 746).


⁵¹³ *Id.* at 2621-22.

⁵¹⁴ *Id.* at 2625-26 (Blackmun, J., concurring in part, concurring in the judgment in part, and dissenting in part).


⁵¹⁷ See Donald W. Garner, *Cigarettes and Welfare Reform*, 26 EMORY L.J. 269, 275-76 (1977) (suggesting that more efficient filters would reduce smoking-related injuries); Levin, *supra* note 126, at 216-17 (suggesting that cigarette manufacturers could reduce health risks by removing additives, pesticides, and other dangerous substances from tobacco).

effective warnings about smoking-related risks. 519 A finding of preemption immunizes cigarette manufacturers from tort liability, thereby weakening the economic incentive to make their products safer. This result contradicts the Act’s health and safety objectives. 520

Compensation is the final policy that an interpreter should consider. Conventional wisdom suggests that a product manufacturer has a responsibility to compensate those who are injured by its defective products. 521 The arguments for imposing liability on product manufacturers seem especially applicable to cigarette manufacturers. 522 Because preemption leaves injured parties without a remedy, compensation values support an interpretive rule that discourages a finding of preemption, at least when Congress has failed to speak clearly. 523

cigarette manufacturers would lead to an optimization of accident costs and safety costs). But see Ausness, Compensation for Smoking-Related Injuries, supra note 479, at 1106 (discussing several factors that discourage research when health effects are long-term).

519. Ausness, Cigarette Company Liability, supra note 125, at 946; Garner, Cigarette Dependency, supra note 126, at 1461-62.

520. See Carlisle v. Philip Morris, Inc., 805 S.W.2d 498, 511 (Tex. Ct. App. 1991) ("Moreover, holding common-law claims preempted would remove the motivation for cigarette manufacturers to voluntarily include additional health information and/or warnings in or on cigarette packages and advertisements. That sort of disincentive would actually hinder the Act’s primary purpose of achieving wide dissemination of such information.").

Some courts have denied that the Act is really concerned with the protection of public health and safety. According to these courts, Congress intended to establish a “balance” or compromise between public health and commerce. The terms of this compromise are set forth in the warning language mandated by § 1333; therefore, any state action that encourages manufacturers to depart from this statutory language would disturb this “balance” and would be contrary to the purpose of the Act. See Pennington v. Vistron Corp., 876 F.2d 414, 421 (5th Cir. 1989), called into doubt by Cipollone v. Ligget Group, Inc., 112 S. Ct. 2608 (1992); Roysdon v. R.J. Reynolds Tobacco Co., 849 F.2d 230, 234-35 (6th Cir. 1988), called into doubt by Cipollone, 112 S. Ct. 2608; Palmer v. Liggett Group, Inc., 825 F.2d 620, 626, (1st Cir. 1987), called into doubt by Cipollone, 112 S. Ct. 2608; Cipollone v. Liggett Group, Inc., 789 F.2d 181, 187 (3d Cir. 1986); Forster v. R.J. Reynolds Tobacco Co., 437 N.W.2d 655, 658 (Minn. 1989). The present status of this theory is unclear because the Supreme Court did not rely on it in Cipollone.

521. See supra part IV.B.2.c.

522. See Ausness, Cigarette Company Liability, supra note 125, at 942-44.

523. See Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 250-51 (1984); Forster, 423 N.W.2d 700-01 ("Therefore, remedies provided by state tort law will not be withdrawn from Minnesota citizens without either an express statement from Congress or a clear and unequivocal finding of implied preemption."); Dewey, 577 A.2d at 1251 ("We are convinced that had Congress intended to immunize cigarette manufacturers from packaging, labeling, misrepresentation, and warning claims, it knew how to so with unmistakable specificity."); Carlisle, 805 S.W.2d at 512 ("To infer that Congress set out to eliminate such remedies without even commenting on their elimination would be even
Justice Blackmun raised this issue in Cipollone. He acknowledged that the compensatory function of tort law is distinct from the regulatory purposes of the cigarette labeling statute. He also expressed doubt that Congress would destroy existing state remedies for injured parties without replacing such remedies with a substitute remedial scheme.

To summarize, neither the Act’s text nor its legislative history clearly indicates that Congress intended to preempt state-law damage claims. Furthermore, there is no evidence to suggest that preemption is necessary to implement the provisions of the Act. Finally, an interpretation of the text that preserves existing tort remedies is more consistent with contemporary values and policies than is an interpretation that destroys state tort remedies.

B. National Traffic and Motor Vehicle Safety Act

1. Motor Vehicle Safety Standards in General

Several provisions of the National Traffic and Motor Vehicle Safety Act (NTMVSA) are relevant to the preemption issue. Section 1392(d) declares that “no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, . . . any safety standard . . . which is not identical to the Federal standard.” However, section 1397(k) of the statute states: “Compliance with any Federal motor vehicle safety standard issued under this subchapter does not exempt any person from any liability under common law.”

These provisions lend themselves to a variety of interpretations. For example, one could argue that the “safety standards” that section 1392(d) purports to preempt only safety standards that have been formally promulgated by a legislature or an administrative agency. This interpretation would exclude tort doctrines from preemption under section 1392(d). Thus, section 1397(k) could be construed to preserve all tort claims against automobile manufacturers. This interpretation is plausible if tort doctrines are considered to be inherently different from legislative and administrative standards.
Of course, one could also argue that tort liability doctrines are "safety standards" for purposes of section 1392(d).

However, this interpretation is difficult to reconcile with the exclusion of tort liability in section 1397(k). Nevertheless, sections 1392(d) and 1397(k) can be reconciled by interpreting section 1397(k) as preserving common-law tort liability doctrines from preemption even if these state-law doctrines are considered "safety standards."

Another interpretation is that section 1397(k) merely preserves common-law liability for product defects not covered by federal safety standards. However, if this interpretation is correct, section 1397(k) would apparently be unnecessary because section 1392(d) does not preempt state standards for aspects of performance not regulated by a federal standard. Thus, common-law actions based on product conditions not covered by the Act would not need the protection of the savings clause.


531. See, e.g., Cox v. Baltimore County, 646 F. Supp. 761, 763 (D. Md. 1986) (stating that a judicial decision sustaining a jury verdict is state action that establishes a "safety standard"); Vanover v. Ford Motor Co., 632 F. Supp. 1095, 1096-97 (E.D. Mo. 1986) (stating that state tort law damages are "a form of state regulation subject to the Supremacy Clause"); see also Miller, supra note 186, at 912 (discussing the argument that § 1392(d) preempts common-law actions).

532. Wood, 865 F.2d at 401 ("Section 1392(d) says nothing about being limited to legislatively established state standards."); Cox, 646 F. Supp. at 763 (D. Md. 1986) ("[T]here is nothing in the language of the Safety Act or in its legislative history to suggest that the term 'safety standard' is intended to encompass only standards adopted by a regulatory body.").

533. Wood, 865 F.2d at 401-02; cf. Gingold, 567 A.2d at 322-23 (reasoning that even if common-law liability is the equivalent of state regulation, "the issue would then be . . . 'whether it is the type of regulation Congress intended section 1392(d) to preempt'") (quoting Murphy v. Nissan Motor Corp., 650 F. Supp. 922, 927 (E.D.N.Y. 1987)).


535. See Wood, 865 F.2d at 412 ("If the federal government has not issued a safety standard on a certain aspect of performance, the states are allowed to set their own standards in these areas.").

536. See Taylor v. General Motors Corp., 875 F.2d 816, 824 (11th Cir. 1989) ("Such
Some courts have maintained that Congress did not anticipate the development of design defect litigation based on strict liability in tort. According to these courts, Congress would not have wanted section 1397(k) to protect strict liability design defect claims from preemption under section 1392(d). However, this interpretation of section 1397(k) is questionable because, as a matter of historical fact, many states had accepted modern theories of products liability when the Act was passed.

Textual analysis of sections 1392(d) and 1397(k) suggests a number of possible interpretations, but does not provide any clear answer to the preemption question. Consequently, one should look to the statute's legislative history for interpretive guidance. Unfortunately, nothing in the legislative history indicates that Congress considered the Act's effect on state tort liability doctrines. A Senate Report on the Motor Vehicle Safety Bill devoted only two paragraphs to a discussion of the relationship between state and federal law. The Report clearly indicates that Congress intended the states to have some role in the regulation of motor vehicles. The Report

a construction, however, would render the savings clause a mere redundancy since the preemption clause itself provides that where a federal standard does not govern 'the same aspect of performance' as the state standard, the state standard is not [expressly] preempted.

357. See Wood, 865 F.2d at 404-06; Schwartz, 554 So. 2d at 931 (Stegall, J., concurring) ("The clear meaning of the saving clause is that compliance with any safety standard issued under the Safety Act will not exempt any person from any liability under the common law as it existed at the time of the Safety Act's passage.").

358. See Taylor, 875 F.2d at 825 (quoting with approval Wood, 865 F.2d at 421 (Selya, J., dissenting) ("[A]n unbiased glimpse of tort law circa 1966 indicates to me that design defect litigation, although then a relatively recent phenomenon, was not so new as to catch the Congress unawares."); Schwartz, 554 So. 2d at 941 (Hornsby, C.J., concurring in part and dissenting in part) ("[M]y review of the law convinces me that negligent design cases were, in fact, part of the common law by 1966.").

also declared that "the Federal minimum safety standards need not be interpreted as restricting State common law standards of care. Compliance with such standards would thus not necessarily shield any person from product liability at common law." This language suggests that Congress did not intend section 1392(d) to preempt state tort law. A House Report discussing section 1397(k) also briefly addressed the preemption issue. The Report stated: "It is intended, and this subsection specifically establishes, that compliance with safety standards is not to be a defense or otherwise to affect the rights of parties under common law particularly those relating to warranty, contract, and tort liability." This language reinforces the plain meaning of section 1397(k) that the Act does not preempt state tort actions. Statements on the House floor also indicate that Congress did not intend to displace common-law remedies. For example, Representative Dingell, the Bill's sponsor, declared:

[W]e have preserved every single common-law remedy that exists against a manufacturer for the benefit of a motor vehicle purchaser. This means that all of the warranties and all the other devices of common law which are afforded to the purchaser, remain in the buyer, and they can be exercised against the manufacturer.

Additional support for this interpretation can be found in remarks Senator Magnuson made when the Bill went to a conference committee. At that point, the Senate version of the Bill did not have a savings clause. The conference committee voted to adopt the savings clause that appeared in the House version of the Bill. Referring to the savings clause, which subsequently became section 1397(k), Senator Magnuson remarked: "This provision makes explicit, in the bill, a principle developed in the Senate Report." The Senator went on to declare that "[t]his provision does not prevent any person from introducing in a lawsuit evidence of compliance or


543. See Welsh, 745 F. Supp. at 317; Kolbeck, 702 F. Supp. at 540; Richart, 681 F. Supp. at 1467; Murphy, 650 F. Supp. at 926; Gingold, 567 A.2d at 330.


545. Id. at 21,487 (statement of Sen. Magnuson).
noncompliance with Federal standards." 546 These statements are inconsistent with the view that Congress intended to preempt state tort law. 547

According to some courts, however, the Act's legislative history indicates that Congress intended to make federal motor vehicle safety standards uniform throughout the country, thereby preempting nonidentical common-law requirements. 548 For example, the Senate Report declared: "The centralized, mass production, high volume character of the motor vehicle manufacturing industry in the United States requires that motor vehicle safety standards be not only strong and adequately enforced, but that they be uniform throughout the country." 549 Some language in the House Report also supports a uniformity theory. In its analysis of the Bill's preemption provision, the House Report stated: "Basically, this preemption subsection is intended to result in uniformity of standards so that the public as well as industry will be guided by one set of criteria rather than by a multiplicity of diverse standards." 550

However, nothing in the Act itself suggests that uniformity was a goal at all, much less one that would override an express statutory provision preserving common-law actions. 551 Moreover, the uniformity theory is undercut by provisions in the Act and in the legislative history that create exceptions to the uniformity requirement. 552 Thus, an argument for

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546. Id.
547. See Miller, supra note 186, at 920-21.
552. For example, states are allowed to impose higher standards on manufacturers for
uniformity based solely on legislative history is fairly weak.\textsuperscript{553}

Since neither the text nor the legislative history reveals a clear congressional position on the preemption issue, it is necessary to consider contemporary values and policies. One policy, that of encouraging trade and economic activity, appears to support an interpretation of the Act that preempts nonuniform common-law liability rules. Liability rules that vary from state to state impose substantial economic costs on automobile manufacturers.\textsuperscript{554} Uniform standards provide regulatory certainty and allow manufacturers to use their economic resources more productively.\textsuperscript{555} Hence, interpreting the Act to achieve national uniformity in motor vehicle safety regulation would promote trade and economic activity.\textsuperscript{556}

Deference to agency decisionmaking also seems to support preemption of state tort law. Administrative agencies have superior expertise and greater access to information than do courts.\textsuperscript{557} In addition, regulatory agencies are better equipped to consider economic, environmental, and energy issues in formulating safety standards.\textsuperscript{558} However, the force of this institutional competence argument is weakened by evidence that the administering agency, the National Highway Traffic Safety Administration (NHTSA), has


\textsuperscript{553} See Welsh ex rel. Welsh v. Century Prods., Inc., 745 F. Supp. 313, 319 (D. Md. 1990) ("The legislative history also reveals no intent to promote uniformity per se."); see also Theroff, supra note 191, at 613 ("These bald statements undercut court findings that Congress intended primarily . . . to establish a uniform regulatory regime . . . ").


\textsuperscript{555} See Holley, supra note 4, at 818-19.

\textsuperscript{556} See Wilton, supra note 186, at 30 ("[U]niformity of the [safety] standards is crucial for the motor vehicle manufacturing industry as well as for the safety of the public.").

\textsuperscript{557} A. Schwartz, supra note 466, at 389 (stating that administrative agencies usually have more expertise and greater economies of scale than do courts); see also Comment, \textit{Automobile Design Liability: Larsen v. General Motors and Its Aftermath}, 118 U. PA. L. REV. 299, 305 (1969) ("Independent research can give a regulatory body a better understanding of design complexities than judges and juries are able to achieve through expert testimony."). See generally supra part IV.B.1.c.iii.

\textsuperscript{558} See Werber, supra note 182, at 47 (noting that federal motor vehicle safety standards "balance energy and air pollution requirements, cost factors and feasibility, and the effects upon other vehicles in accident circumstances").
not aggressively pursued the consumer safety goals of the Act.\textsuperscript{559} In addition, the automotive industry historically has exercised considerable influence over the NHTSA.\textsuperscript{560} Accordingly, the principle of agency deference does not provide overwhelming support for preemption in motor vehicle safety standards cases.

Federalism values undermine a finding of preemption. Consumer safety regulation has traditionally been left to the states.\textsuperscript{561} Hence, the presumption against preemption cautions against ousting the states from this acknowledged area of state responsibility.\textsuperscript{562}

Retaining state tort law is also consistent with the policy of promoting health and safety. Consumer safety is clearly a principal goal of the Act.\textsuperscript{563} The Act’s declaration of policy states “that the purpose of this chapter is to reduce traffic accidents and deaths and injuries to persons resulting from traffic accidents.”\textsuperscript{564} The legislative history confirms that Congress considered automotive safety to be the Act’s primary purpose.\textsuperscript{565}


\textsuperscript{560} See Miller, supra note 186, at 909 (contending that the history of airbag regulation demonstrates industry influence over NHTSA).


\textsuperscript{563} Welsh, 745 F. Supp. at 318 (“The Safety Act was enacted in 1966 to achieve one overriding objective: to counteract the ‘soaring rate of death and debilitation on the Nation’s highways.’”) (quoting S. REP. No. 1301, supra note 539, at 1, reprinted in 1966 U.S.C.C.A.N. at 2709); Murphy v. Nissan Motor Corp., 650 F. Supp. 922, 926 (E.D.N.Y. 1987) (“[Congress’] primary goal was to improve and promote automotive safety.”); Schwartz, 554 So. 2d at 933 (Hornsby, C.J., concurring in part and dissenting in part) (“[T]he primary objective of Congress was to promote safety.”); Gingold, 567 A.2d at 328 (“The primary goal of the Act is to reduce traffic accidents and injuries on the highways.”).


\textsuperscript{565} S. REP. NO. 1301, supra note 539, at 6, reprinted in 1966 U.S.C.C.A.N at 2714 (“The committee intends that safety shall be the overriding consideration in the issuance
Tort liability also promotes consumer safety;\textsuperscript{566} thus, the Act and state tort law share the same objective. Furthermore, no serious conflict exists between the two systems. In fact, they complement each other in a way that enhances overall product safety.\textsuperscript{567} Therefore, safety policies support a finding of no preemption.\textsuperscript{568}

Finally, the compensation goal also supports an interpretation of the Act that preserves state tort liability doctrines. Existing tort doctrines provide compensation to those injured by defective products. These parties would be left without a remedy if the Act was construed to preempt state tort law. Furthermore, since compensation of tort victims is traditionally a state responsibility, courts should not destroy existing remedies in the absence of a clear congressional mandate.\textsuperscript{569}

In summary, neither the text of the statute nor its legislative history indicates that Congress intended to impose a general ban on common-law tort actions for motor vehicle safety. Furthermore, there is no evidence that federal motor vehicle regulations and state tort liability cannot coexist.

\textsuperscript{566} See Reed & Watkins, supra note 448, at 445.

\textsuperscript{567} See T. Schwartz, supra note 466, at 1161.

\textsuperscript{568} The primacy of safety in the Act also undercuts the argument in favor of preemption based on uniform safety standards. Even if uniformity is desirable for economic reasons, it is subordinate to the achievement of safety. Welsh \textit{ex rel.} Welsh \textit{v.} Century Prods., Inc., 745 F. Supp. 313, 319 (D. Md. 1990) ("[U]niformity in regulation is a goal of the Safety Act only insofar as it promotes safety."); Richart \textit{v.} Ford Motor Co., 681 F. Supp. 1462, 1469 (D.N.M. 1988) ("While promoting uniformity was an objective of Congress, its primary goal was to improve and promote automotive safety."); rev'd sub nom. Kitts \textit{v.} General Motors Corp., 875 F.2d 787 (10th Cir. 1989), cert. denied, 494 U.S. 1065 (1990); Schwartz \textit{v.} Volvo N. Am. Corp., 554 So. 2d 927, 933 (Ala. 1989) (Hornsby, C.J., concurring in part and dissenting in part) ("As a \textit{subordinate} purpose, Congress sought to achieve uniformity in the standards by which automobile manufacturers are governed.").

\textsuperscript{569} See Taylor \textit{v.} General Motors Corp., 875 F.2d 816, 823 (11th Cir. 1989) ("[A] strong presumption exists against finding express preemption when the subject matter, such as the provision of tort remedies to compensate for personal injuries, is one that has traditionally been regarded as properly within the scope of states' rights"); cert. denied, 494 U.S. 1065 (1990); \textit{Welsh}, 745 F. Supp. at 316-17; \textit{Richart}, 681 F. Supp. at 1466 ("It is difficult to believe that Congress would remove all means of judicial recourse for injuries negligently caused by a manufacturer without comment or express language."); Garcia \textit{v.} Rivera, 541 N.Y.S.2d 880, 885 (Sup. Ct. 1989) ("There is a presumption against preemption in the areas of traditional state power, such as compensation for torts."); \textit{reversed}, 553 N.Y.S.2d 378 (App. Div. 1990), \textit{appeal denied}, 567 N.E.2d 980 (N.Y. 1991); Ginogold \textit{v.} Audi-NSU-Auto Union, A.G., 567 A.2d 312, 318 (Pa. Super. Ct. 1989) ("The presumption against preemption is explained on grounds which recognize, . . . the States' long-established interest in providing compensation for victims of torts.").
Finally, many contemporary values and policies favor the retention of state tort remedies for injured consumers. Therefore, federal motor vehicle safety standards should not preempt common-law tort claims in most circumstances.

2. FMVSS 208

Statutes often undergo a lengthy process of implementation by courts or agencies. Therefore, courts must consider evolitional factors when interpreting such statutes or their regulatory progeny. Federal Motor Vehicle Safety Standard (FMVSS) 208 is a paradigm of a regulation with a lengthy and convoluted history. Both Congress and the NHTSA have played significant roles in the development of FMVSS 208.

The most important instance of congressional involvement in the airbag controversy occurred in 1974, when Congress amended the Act to remove the NHTSA’s ability to require the installation of airbags in passenger cars. The 1974 amendments declared that no federal safety standard could require a manufacturer to provide airbags. The amendments also specifically approved the existing FMVSS 208, which did not mandate the installation of airbags. Furthermore, Congress specified certain procedures that the NHTSA would have to follow before recommending mandatory use of airbags. Finally, the amendments provided for a bicameral legislative veto of any motor vehicle standard requiring airbags.

The current version of FMVSS 208 allows manufacturers to choose among three options, depending on when the automobile was manufactured: (1) a passive restraint system, such as airbags, used in conjunction with seatbelts; (2) a combination of passive restraints, detachable shoulder

570. See Eskridge & Frickey, Statutory Interpretation, supra note 12, at 359.
571. 49 C.F.R. § 571.208 (1991). FMVSS 208 specifies equipment requirements for occupant restraint systems, including airbags. Id.
572. This safety standard has undergone numerous changes since its initial enactment in 1967. See supra notes 186-190 and accompanying text.
573. Theroff, supra note 191, at 584 n.37.
576. Id. § 1410b(b)(3)(A).
580. Id. § 571.208, S4.1.2.1.
harnesses, lap belts, and warning systems; or (3) a combination of nondetachable shoulder harnesses, lap belts, and warning systems. According to the Department of Transportation (DOT), which oversees the NHTSA's administration of the Act, the purpose of the option provision in FMVSS 208 is to provide "sufficient latitude for industry to develop the most effective systems" of occupant restraint rather than "mandating the specific use of one device such as airbags."

Arguably, the current status of FMVSS 208 reflects an explicit congressional and administrative policy that favors caution and flexibility in the area of occupant restraints. This reading of FMVSS 208 has led several courts to conclude that state tort claims should be preempted because such claims would limit manufacturer choice, thus frustrating this explicit congressional and administrative policy. However, some courts have denied the existence of a policy that favors manufacturer choice. Moreover, other courts have concluded that damage awards would not compel manufacturers to install airbags and, therefore, would not deprive manufacturers of any options provided by FMVSS 208.

581. Id. § 571.208, S4.1.2.2.
582. Id. § 571.208, S4.1.2.3. See generally Theroff, supra note 191, at 584-85 (summarizing options under 49 C.F.R. § 571.208 (1988)).
585. See, e.g., Gingold v. Audi-NSU-Auto Union, A.G., 567 A.2d 312, 324 (Pa. Super. Ct. 1989) (stating that § 1410b does not ensure that passive restraints will remain only an option); see also Wood v. General Motors Corp., 865 F.2d 395, 425 (1st Cir. 1988) (Selya, J., dissenting) ("One searches in vain for anything in the statute or the standard intimating that the provision of choice is an 'objective of federal law.'"), cert. denied, 494 U.S. 1065 (1990).
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To some extent, FMVSS 208 appears to reflect a policy of manufacturer choice concerning airbags. In this respect, it is unlike other safety standards promulgated under the Act. Presumably, Congress expects manufacturers to consider such factors as effectiveness, cost, and technological feasibility, when choosing an occupant safety system. If common-law damage awards threaten to skew this process, they may interfere with an important aspect of the Act’s regulatory scheme. Hence, preemption may be warranted in “no airbag” cases even if it is rejected in motor vehicle design litigation generally.

C. Federal Insecticide, Fungicide, and Rodenticide Act

Section 136v(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) allows states to regulate the sale or use of federally registered pesticides as long as the states do not permit any sales or uses that are prohibited by the Act. However, section 136v(b) declares that no state “shall . . . impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.” Section 136v(b) clearly preempts state statutes and administrative regulations that impose nonidentical labeling requirements on pesticide manufacturers and sellers. Whether this provision also preempts tort claims against pesticide manufacturers based on allegedly inadequate warnings is less clear.

As a number of courts have observed, section 136v(b) does not specifically mention common-law tort actions. Instead, Congress used the term “requirements” in that section to describe the type of state action that the Act preempts. As previously discussed, the dictionary definition of “requirements” is entirely consistent with statutory or administrative

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Court . . . does not accept the premise that a state damage award ‘compels’ a manufacturer to install passive restraints, and thereby frustrate [sic] the policy of flexibility afforded by Standard 208.”), rev’d sub nom. Kitts v. General Motors Corp., 875 F.2d 787 (10th Cir. 1989), cert. denied, 494 U.S. 1065 (1990).


589. 7 U.S.C. § 136v(b) (emphasis added).


commands.\textsuperscript{592} Common-law tort doctrines, however, do not fit the definition of "requirements" very well because they do not dictate or prohibit behavior with the same degree of compulsion as do statutes and administrative regulations.\textsuperscript{593} Consequently, the textual argument for preemption initially seems weak.

The legislative history of FIFRA is also ambiguous about federal preemption of tort claims.\textsuperscript{594} It indicates that Congress intended to vest the federal government with extensive powers over the manufacture, labeling, and use of pesticides.\textsuperscript{595} Section 136v(b) in particular was intended to establish the federal government's regulatory primacy over pesticide labeling. One House Committee Report declared: "In dividing the responsibility between States and the Federal Government for the management of an effective pesticide program, the Committee has adopted language which is intended to completely preempt State authority in regard to labeling and packaging."\textsuperscript{596} However, nothing in the legislative history indicates that Congress considered state tort law tantamount to state regulation of labeling.\textsuperscript{597}

As in most product preemption cases, the main issue is whether damage awards are functionally equivalent to statutory or administrative commands. Some courts have concluded that because of its coercive effect, tort liability is a "back door" form of regulation and should be treated, for purposes of federal preemption, the same as any other form of state regulation.\textsuperscript{598} However, other courts have found that tort liability does not compel behavior in the same manner as statutes or administrative regulations because manufacturers can elect to pay damage awards instead of changing their labeling.\textsuperscript{599}

The closeness of this issue makes it desirable to look at contemporary values and policies. The first policy to consider is the protection of trade

\textsuperscript{592} See supra text accompanying notes 490-494.
\textsuperscript{593} See supra text accompanying notes 490-494.
\textsuperscript{594} But see Gleeson & Davidson, supra note 215, at 319 ("FIFRA's legislative history amply demonstrates that Congress intended to pre-empt all state regulation, other than through FIFRA, of pesticides and the pesticide industry.") (emphasis added).
\textsuperscript{596} H.R. REP. NO. 511, 92d Cong., 1st Sess. 16 (1971).
\textsuperscript{598} See cases cited supra note 253.
\textsuperscript{599} See cases cited supra note 252.
and commerce. One practical effect of concentrating regulatory authority over pesticide labeling in one federal agency is the achievement of consistent and uniform labeling practices. Uniform regulatory standards reduce production costs for manufacturers and make it easier for them to sell products in a national market.\textsuperscript{600} This argument has led some courts and commentators to conclude that label uniformity is not merely a beneficial side effect of FIFRA, but rather an avowed purpose of the Act. They maintain that tort liability should be preempted because it constitutes a threat to this uniformity goal.\textsuperscript{601}

However, neither the statute nor its legislative history expressly identifies uniformity of labeling as a legislative goal. The only textual reference to uniformity is in the heading to section 136v(b)—"Uniformity"—which Congress added in 1988 without changing the language of the preemption provision itself.\textsuperscript{602} Also, nothing in the statute or in EPA regulations requires uniform labeling if different manufacturers make the same product.\textsuperscript{603} Finally, even if uniformity is a legislative goal, tort actions do not destroy uniformity because only the EPA can approve or modify pesticide labeling.\textsuperscript{604}

As in most preemption cases, federalism values support a policy of judicial deference to traditional state interests unless Congress mandates otherwise.\textsuperscript{605} Since neither the Act nor its legislative history indicates that

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\textsuperscript{601} See cases cited supra note 255; Gleeson & Davidson, supra note 215, at 320 ("Both the House and the Senate recognized the need for federal pre-emption on labeling in order to effect the stated policy of national uniformity desired by Congress."); Timothy J. Kuester, Comment, FIFRA as an Affirmative Defense: Pre-emption of Common-Law Tort Claims of Inadequate Labeling, 40 U. KAN. L. REV. 1119, 1136 (1992) (arguing that uniformity in labeling is an objective of FIFRA).


\textsuperscript{604} See infra notes 615-618 and accompanying text.

\textsuperscript{605} E.g., Ferebee v. Chevron Chem. Co., 736 F.2d 1529, 1542 (D.C. Cir.) ("[I]n defining the scope of the Act's preemption provision, it is necessary to bear in mind . . . the circumspect view courts must take of a claim that Congress has preempted states from exercising their traditional police powers on behalf of their citizens."), cert. denied, 469 U.S. 1062 (1984); Roberts v. Dow Chem. Co., 702 F. Supp. 195, 197 (N.D. Ill. 1988) (following Ferebee's view that preemption of state law requires the clear intent of Congress).
Congress intended to preempt state tort law, a finding of preemption would be contrary to federalist principles.\textsuperscript{606}

On the other hand, the policy of deferring to agency decisionmaking favors preemption. The EPA's regulatory authority over pesticide production and use is very comprehensive,\textsuperscript{607} perhaps even excluding tort liability doctrines.\textsuperscript{608} However, this "occupation of the field" argument is weakened by the states' significant role in FIFRA's regulatory scheme.\textsuperscript{609}

An additional consideration favoring preemption is that the EPA is more competent than juries to evaluate the risks of pesticides.\textsuperscript{610} Finally, as the court declared in \textit{Papas v. Upjohn Co.},\textsuperscript{611} Congress has given the EPA exclusive authority to balance socially competing interests when deciding whether to register a product.\textsuperscript{612} According to \textit{Papas}, because labeling decisions are part of the registration process, juries should not be allowed to second-guess EPA decisions about the adequacy of pesticide labeling.\textsuperscript{613}

To assess the validity of the \textit{Papas} court's argument, one must consider the probable impact of jury verdicts on the regulatory process. Ordinarily, the EPA would not be a party to a tort action between private parties and, therefore, would not be bound by a state-law finding that the warning on a particular label is inadequate. Furthermore, pesticide manufacturers cannot place additional material on their product labels without EPA approval.\textsuperscript{614} Thus, the EPA would retain its exclusive power over product labeling even if common-law tort actions were allowed.\textsuperscript{615}

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\textsuperscript{606} \textit{See} Burke v. Dow Chem. Co., 797 F. Supp. 1128, 1141 (E.D.N.Y. 1992) ("The federalism issue[] is] too important to warrant foreclosing recovery to an injured party on a questionable theory of implied preemption.").

\textsuperscript{607} \textit{See} Howarth, \textit{supra} note 600, at 1305-06.

\textsuperscript{608} \textit{See} Papas v. Upjohn Co., 926 F.2d 1019, 1025 (11th Cir. 1991) (per curiam) ("[W]e hold that the federal government has occupied the entire field of labeling regulation, leaving no room for the states to supplement federal law, even by means of state common law tort actions.")., \textit{vacated sub nom.} Papas v. Zoecon Corp., 112 S. Ct. 3020 (1992). \textit{Contra} Fisher v. Chevron Chem. Co., 716 F. Supp. 1283, 1287 (W.D. Mo. 1989) ("[T]he scheme created by FIFRA is not 'so pervasive' or the federal interest 'so dominant' as to demonstrate an intent to preempt all state law claims."); \textit{Roberts}, 702 F. Supp. at 199 ("FIFRA regulations are not so comprehensive as to occupy the entire field.").

\textsuperscript{609} \textit{E.g.,} Ferebee, 736 F.2d at 1543 ("[T]he fact that Congress has chosen to allow the states to regulate the use of pesticides approved by the EPA means that states retain the lesser power to control the use of such pesticides by requiring that at least some of the resulting injuries be compensated.").

\textsuperscript{610} \textit{See} Howarth, \textit{supra} note 600, at 1323.

\textsuperscript{611} 926 F.2d 1019.

\textsuperscript{612} \textit{Id.} at 1022-23.

\textsuperscript{613} \textit{Id.} at 1025-26.


\textsuperscript{615} Of course, a manufacturer faced with substantial tort liability who could not get https://scholarcommons.sc.edu/sclr/vol44/iss2/2
The *Papas* court also claimed that if injured parties recovered damages on the basis of inadequate warnings, manufacturers "would likely press the EPA to change its labeling requirements to reflect the jury awards so as to free the manufacturer from future tort liability for the same jury-found 'inadequacies' in labeling."\(^{616}\) According to the court, this "outside pressure on the regulatory process would hinder the development of an orderly, systematic, and uniform nationwide labeling scheme."\(^{617}\)

Although damage awards against pesticide manufacturers would likely induce them to petition the EPA to approve new labeling, it is difficult to view this effect as an interference with the regulatory process. The EPA, like other regulatory agencies, is constantly besieged by requests from consumers, manufacturers, environmentalists, and others. As long as the EPA retains the power to act according to its best judgment, tort liability should pose no real threat to the EPA's regulatory authority.\(^{618}\)

As in most product preemption cases, a finding against preemption in pesticide cases appears to advance public health and safety. Public safety is one of FIFRA's most important statutory objectives.\(^{619}\) As the *Ferebee*

…the EPA to change the labeling on its product would be placed in an unenviable position. As the *Ferebee* court noted, compliance with both state and federal law is not impossible because the manufacturer can comply with both "by continuing to use the EPA-approved label and by simultaneously paying damages to successful tort plaintiffs." *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1541 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984). However, the court apparently ignored the inequity of placing a product manufacturer in such a dilemma. *See id.* at 1543.

\(^{616}\) *Papas*, 926 F.2d at 1026.

\(^{617}\) *Id.*

\(^{618}\) An important difference exists between pesticide cases and cigarette or airbag cases. In the cigarette labeling cases, several courts have implied that tort liability would compromise the achievement of uniform labeling because the potential liability would induce manufacturers to place additional material on their labeling. *See Pennington v. Vistron Corp.*, 876 F.2d 414, 421 (5th Cir. 1989), *called into doubt by Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992); *Roysdon v. R.J. Reynolds Tobacco Co.*, 623 F. Supp. 1189, 1191 (E.D. Tenn. 1985), *aff'd*, 849 F.2d 230 (6th Cir. 1988), *called into doubt by Cipollone*, 112 S. Ct. 2608. Likewise, in the airbag cases a number of courts have concluded that tort liability would pressure manufacturers to install airbags instead of allowing manufacturers to choose from among the various options allowed by FMVSS 208. *See cases cited supra* note 213.

However, in cigarette and airbag cases, the courts were concerned with the effect tort liability would have on manufacturers because the regulatory schemes in question allow manufacturers some control over the regulated area. That is not the case with labeling decisions under FIFRA. Pesticide manufacturers can petition the EPA to authorize a change in labeling, but they cannot change EPA-approved labeling on their own initiative. *See Cox*, 704 F. Supp. at 87. Moreover, since FIFRA does not allow manufacturers to choose not to label products, no regulatory policy in favor of choice is violated if tort claims are allowed.

\(^{619}\) According to the Senate Committee that drafted amendments to FIFRA, the
court observed, products liability also promotes safety in various ways. The threat of tort liability encourages manufacturers to discover potential pesticide-related risks and to reduce them, when possible, by improving product design or providing better warnings.\(^{620}\) In addition, private litigation may expose pesticide-related risks that were previously unknown to the EPA or the general public.\(^{621}\) Finally, successful tort actions may cause manufacturers to request that better warnings be placed on pesticide labels; alternatively, common-law suits may induce the EPA to require improved warnings on pesticide products.\(^{622}\) Thus, imposition of tort liability on manufacturers of defectively labeled products seems to be completely consistent with consumer safety goals in general, and with FIFRA's statutory goals in particular.

The compensation principle also supports a finding of no preemption. Admittedly, FIFRA is concerned with allocating risks and benefits in an efficient manner rather than achieving compensatory objectives.\(^{623}\) Thus, the EPA Administrator must consider both the risks and the benefits of a pesticide before allowing it to be registered.\(^{624}\) Similarly, before approving proposed labeling, the EPA must determine that the information included is adequate to protect the public and the environment.\(^{625}\) Even though FIFRA gives the EPA Administrator the exclusive right to determine the level of acceptable risk for purposes of pesticide registration and labeling, the Act says nothing about who should bear these risks. Arguably, therefore, the

amended Act "provides for the more complete regulation of pesticides in order to provide for the protection of man and his environment and the enhancement of the beauty of the world around him." S. Rep. No. 838, supra note 597, at 3, reprinted in 1972 U.S.C.C.A.N. at 3995; see also Continental Chemiste Corp. v. Ruckelshaus, 461 F.2d 331, 335 (7th Cir. 1972) ("The basic purpose of the statute [is] to regulate the labeling of such products to provide purchasers with assurance of effectiveness and safety when used in compliance with the manufacturer's instructions."); Fisher v. Chevron Chem. Co., 716 F. Supp. 1283, 1287 (W.D. Mo. 1989) ("The principle [sic] purpose of FIFRA is to protect consumers by keeping unhealthy or unsafe pesticides off the market and by preventing deceptive labeling.").

621. See id. at 1541.
622. Id.
624. The Senate Report also declared: "In each case the Administrator must take into account all relevant factors and decide whether it is better for man and the environment that this product be registered." Id. pt. 2, at 10, reprinted in 1972 U.S.C.C.A.N. at 4033.
states should be free to make decisions about risk distribution as long as they do not interfere with the EPA’s risk-benefit decisions. 626

In summary, nothing in the text or legislative history of FIFRA suggests that Congress intended to preempt tort liability. Furthermore, no evidence exists that state-law damage awards undermine the purposes of the Act. Finally, refusal to preempt state tort claims is consistent with a number of contemporary values and policies.

D. The Federal Food, Drug, and Cosmetic Act

1. Pharmaceutical Products in General

Neither the Federal Food, Drug, and Cosmetic Act (FDCA) 627 nor its companion legislation, the Public Health Service Act (PHSA), 628 expressly preempts state-law tort claims. 629 The FDCA’s legislative history is also silent on the preemption issue. 630 Therefore, contemporary values and policies must be examined with particular care.

Several values and policies are relevant to the question of FDCA preemption of state tort law. As in the previously discussed cases, the policy of promoting trade and commerce provides a possible justification for preemption. Tort liability affects the cost, and in some cases the availability, of pharmaceutical products. 631 On the other hand, uniformity of product labeling may reduce production costs and eliminate some of the uncertainty associated with tort liability. 632 Furthermore, the FDA has apparently adopted a policy of promoting uniform labeling standards for drugs. 633

Because regulation of health and safety is a traditional area of state concern, 634 implied preemption would seem to be inconsistent with

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626. See Ferebee, 736 F.2d at 1541 ("Even if [the manufacturer] could not alter the label, [the state] could decide that, as between a manufacturer and an injured party, the manufacturer ought to bear the cost of compensating for those injuries that could have been prevented with a more detailed label than that approved by the EPA.").


630. Landen, supra note 259, at 112.

631. Ausness, Unavoidably Unsafe Products, supra note 126, at 753-55; see Note, supra note 264, at 782.

632. See Del Giorno, supra note 266, at 639.

633. See 50 Fed. Reg. 51,403 (1985) ("FDA has a well-established policy of promoting uniformity in the area of labeling."); see also Hurley v. Lederle Lab., 651 F. Supp. 993, 999 (E.D. Tex. 1986) ("Drug labeling is an area where national uniformity is to be promoted, and constitutes a dominant federal interest."); rev’d, 851 F.2d 1536 (5th Cir.), superseded by 863 F.2d 1173 (5th Cir. 1988); Naile, supra note 278, at 691.

634. Lindquist v. Tambrands, Inc., 721 F. Supp. 1058, 1061 (D. Minn. 1989); see
federalism values. However, the federal government also has a longstanding interest in the promotion of public health, including drug safety. Congress enacted the first federal drug safety statute almost a century-and-a-half ago, and the federal government has maintained a significant regulatory presence in this area since the turn of the century. Consequently, the argument that preemption is contrary to federalist values is less persuasive when applied to the FDCA than when raised in connection with other product safety legislation.

Initially, the principle of deference to agency decisionmaking appears to support preemption. The FDA has the expertise to review the large amounts of scientific and technical data necessary to make a proper decision about drug safety. In contrast, courts and juries possess little or no ability to evaluate scientific evidence. Therefore, the FDA's judgment on drug safety issues should be authoritative.

However, this idealized view of FDA decisionmaking is not universally accepted for several reasons. First, like many other federal agencies, the FDA has experienced budget cutbacks and staff reductions over the past decade. This lack of resources limits the FDA's ability to obtain information about drug risks from independent sources and forces the agency to rely heavily on information provided by drug manufacturers.


637. See Landen, supra note 259, at 99-101, 116-17; Naile, supra note 278, at 694; see Walsh & Klein, supra note 268, at 192.

638. Walsh & Klein, supra note 268, at 193; see Note, supra note 264, at 780-82; Del Giorno, supra note 266, at 630.


640. For example, budget restraints have resulted in the loss of about 2000 FDA employees since 1980. Bruce A. Silverglade, Preemption—The Consumer Viewpoint, 45 FOOD DRUG COSM. L.J. 143, 144 (1990).

641. Jones ex rel. Jones v. Lederle Lab., 695 F. Supp. 700, 711 (E.D.N.Y. 1988) (“Because of the myriad drugs submitted for licensing, as well as its relatively limited resources, the FDA must depend on would-be manufacturers to perform the bulk of the
In addition, the FDA does not have the power to force manufacturers to make better products. In *Hurley v. Lederle Laboratories*, the court noted that the FDA can consider a new product or design only after a manufacturer comes forward with a proposal. Thus, even though pharmaceutical products are licensed by the FDA, they may not be the safest products potentially available.

On first impression, preemption does not seem to comport very well with the FDCA’s health and safety goals. Drug safety is, of course, one of the Act’s most important objectives, but tort law also encourages manufacturers to provide safer drugs. Because preemption displaces state tort law and thereby lessens the incentive to produce safer products, preemption seems inconsistent with the promotion of health and safety.

Nevertheless, tort liability has the potential to undermine product safety, at least when warnings are concerned. According to some commentators, fear of potential tort liability may cause drug manufacturers to include excessive material on product labels, thereby impairing the effectiveness of work involved in the procurement of a license.”; see *Hurley v. Lederle Lab.*, 851 F.2d 1536, 1542 (5th Cir.) (explaining that the FDA is a “passive” agency, largely dependent upon manufacturer-applicants for information), superseded by 863 F.2d 1173 (5th Cir. 1988).

642. *Hurley*, 851 F.2d at 1540.

643. See *White v. Wyeth Lab., Inc.*, 533 N.E.2d 748, 757 (Ohio 1988) (Douglas, J., concurring in part and dissenting in part) (“If a drug manufacturer had come to the FDA with an improved drug, the FDA would have decided whether to license it. However, if a drug manufacturer had elected not to improve its drug, the FDA would not have required that the drug manufacturer attempt to make it safer.”). This may explain why many courts have concluded that FDA regulations are usually nothing more than minimum standards. E.g., *Hill v. Searle Lab.*, 884 F.2d 1054, 1068 (8th Cir. 1989); *Allen v. G.D. Searle & Co.*, 708 F. Supp. 1142, 1152 (D. Or. 1989); *Spychala v. G.D. Searle & Co.*, 705 F. Supp. 1024, 1030 (D.N.J. 1988).


645. *MacGillivray v. Lederle Lab.*, 667 F. Supp. 743, 745 (D.N.M. 1987); see also *Ausness, Unavoidably Unsafe Products*, supra note 126, at 745-49 (discussing the allocative efficiency rationale for holding manufacturers strictly liable); cf. *Jones ex rel. Jones v. Lederle Lab.*, 695 F. Supp. 700, 711-12 (E.D.N.Y. 1988) (stating that the essence of a successful products liability claim is that the defendant could have marketed a superior design).

646. See *Wack v. Lederle Lab.*, 666 F. Supp. 123, 128 (N.D. Ohio 1987) (“For this Court to deprive the plaintiffs of these theories of recovery would, in effect, grant defendants immunity from liability for their alleged tortious conduct.”); see also *Westerfield*, supra note 461, at 283 (stating that preemption immunizes drug manufacturers from liability for tortious conduct and removes incentive for improving products).
warnings by creating an information overload and obscuring critical information. Additionally, tort liability threatens to defeat the FDA's policy of "rational prescribing" by encouraging manufacturers to place warnings on their products that exaggerate known risks or raise unwarranted concerns about hypothetical or unproven risks.

Although these arguments raise legitimate concerns, they ignore the fact that the FDA has complete control over the content of labeling. If the FDA is concerned that unnecessary or misleading information on product labeling undermines its regulatory policies, it can deny manufacturers' requests to place additional warnings on their products. Furthermore, the FDA has the power expressly to preempt state tort law if the agency concludes that tort liability frustrates its regulatory objectives. The FDA's failure to expressly preempt state common law suggests that the agency does not believe that preemption is necessary. If the agency does not perceive a danger to its regulatory program, there is no reason for a court to find one.

Compensation policies also militate against a finding of preemption. Tort liability provides a means of compensating injured parties; however, the preemption doctrine immunizes manufacturers from liability and leaves victims without a remedy. Therefore, courts should be cautious about destroying state-law remedies in the absence of strong evidence that Congress intended to preempt state remedies.

647. Clarke, supra note 629, at 537; Del Giorno, supra note 266, at 651-52.
648. See Richard M. Cooper, Drug Labeling and Products Liability: The Role of the Food and Drug Administration, 41 FOOD DRUG COSM. L.J. 233, 238 (1986); Walsh & Klein, supra note 268, at 187-88.
654. See Callan v. G.D. Searle & Co., 709 F. Supp. 662, 665 (D. Md. 1989) ("It is difficult to believe that Congress, would, without comment, remove all means of judicial recourse for those injured by illegal conduct.") (quoting Silkwood v. Kerr-
2. DPT Vaccine

Because the FDA regulates DPT and other vaccines under the same statutory authority that empowers the agency to regulate chemical drugs, the preemption issues should be similar. However, several factors are unique to preemption analysis of vaccine regulations. First, the federal government has comprehensively regulated vaccine production. Second, the federal government has long maintained a policy of supporting public vaccination programs. A final consideration is the National Childhood Vaccine Injury Act of 1986 (NCVIA).655

The FDA regulates vaccines and other biological products more comprehensively than drugs or other nonbiological products.666 The comprehensiveness of this regulatory scheme suggests that the FDA has occupied the field of vaccine regulation, even though the agency has not done so with pharmaceutical products regulation in general.657 The force of this argument, however, is weakened by the Supreme Court’s admonition against finding preemption based solely on comprehensive regulation.658

The longstanding federal policy of protecting the public against communicable childhood diseases also supports preemption.659 For many years, the federal government has provided financial support and technical assistance to state and local vaccination programs.660 The NCVIA and the Vaccine Compensation Amendments of 1987661 provide additional evi-

McGee Corp., 464 U.S. 238, 251 (1984)); Kociemba v. G.D. Searle & Co., 680 F. Supp. 1293, 1300 (D. Minn. 1988) ("If Congress wants to take the extraordinary step of giving drug manufacturers immunity from personal tort actions, it would expressly state such intentions whether by statute or legislative history."); see also Westerfield, supra note 461, at 282-83 (concluding that Congress did not intend to preempt state tort law).


656. Naile, supra note 278, at 688. The FDA requires manufacturers to test each lot of vaccine according to specific procedures formulated by the agency. The manufacturer must then submit the test results, along with vaccine samples from each lot, to the FDA for review before the vaccine is released for sale. Labeling requirements for vaccines are also comprehensive. Id. at 688-89.

657. Id. at 689.


660. The Center for Disease Control (CDC) provides public health advisors to state and local health departments. The CDC also administers a federal grant program authorized by the Vaccination Assistance Act of 1962, codified as amended at 42 U.S.C. § 247b (1988). Under this program, the federal government purchases vaccine directly from the manufacturers and provides it to state health departments at reduced cost for distribution in local public health clinics. Naile, supra note 278, at 691-92.

661. Pub. L. No. 100-203, §§ 4301-07, 101 Stat. 1330-221 to -225 (codified as...
idence of a substantial federal commitment to the safety and availability of vaccines.  

According to some commentators, the prospect of tort liability has caused vaccine manufacturers to leave the market or raise their prices substantially. Accordingly, tort liability arguably conflicts with the federal policy of ensuring a reliable supply of vaccine.

The final factor to consider is the effect of the NCVIA and the Vaccine Compensation Amendments. These statutes created a compensation scheme for children who are injured by certain vaccines. However, these statutes do not prohibit injured parties from bringing state tort actions against vaccine manufacturers. Because the federal statutes were concerned with ensuring that vaccine supplies would remain adequate to meet public health needs, the tacit acceptance of tort liability for vaccine manufacturers suggests that Congress did not believe tort liability would interfere with this objective.

The legislative history of the NCVIA also suggests that Congress assumed vaccine manufacturers were subject to tort liability in the past and would continue to be liable in the future. For example, a House Report declared: "Currently, vaccine-injured persons can seek recovery for their damages only through the civil tort system or through a settlement arrangement with the vaccine manufacturer." Another part of the Report stated: "Vaccine-injured persons will now have an appealing alternative to


662. See Naile, supra note 278, at 700.

663. See David & Jalilian-Marian, supra note 306, at 188 (reporting that manufacturers threatened to cease or limit production of DPT vaccine because of the fear of tort liability); Richard A. Epstein, The Temporal Dimension in Tort Law, 53 U. CHI. L. REV. 1175, 1204 (1986) (stating that manufacturers of pertussis vaccine withdrew their products from the market because they did not think that they could recover litigation and liability costs); Neraas, supra note 322, at 160 (stating cost and uncertainty of defending claims created disincentive for manufacturers to continue production of vaccines).

664. The prospect of tort liability has caused a dramatic increase in the price of DPT vaccine. In 1982, manufacturers charged 11 cents ($0.11) per dose for DPT vaccine. By 1986, the price had risen to $11.40 per dose. Reportedly, manufacturers used $8.00 of this increase to provide for an insurance reserve against future tort liability. See Tim Moore, Comment, Comment K Immunity to Strict Liability: Should All Prescription Drugs Be Protected?, 26 Hous. L. REV. 707, 718 (1989).

665. For a general discussion of these statutes, see Dark, supra note 276, at 843-50; Schwartz & Mahshigian, Childhood Vaccine Injury Act, supra note 322, at 389-93; Sturges, supra note 322, at 938-46.

666. See supra note 323 and accompanying text.


https://scholarcommons.sc.edu/sclr/vol44/iss2/2
the tort system." These observations indicate that Congress did not expect the FDA’s DPT regulations to preempt state tort law.

Thus, it appears that Congress and the FDA have treated vaccines differently from other pharmaceutical products. In particular, the federal government has developed a policy of ensuring that adequate supplies of vaccine will be available to protect against childhood diseases. Arguably, design defect claims against DPT manufacturers should be preempted because such claims threaten the availability of this vaccine. However, both the FDA’s failure to expressly preempt such claims, and Congress’s refusal to preempt tort claims under the NCVIA, greatly undermine the case for preemption. Although the question is close, the courts should continue to reject preemption in DPT cases until Congress or the FDA acts on the preemption issue.

E. The Medical Device Amendments of 1976

Congress amended the FDCA by enacting the Medical Device Amendments of 1976 (MDA), which gave the FDA regulatory authority over medical devices. Unlike the FDCA, the MDA contains an express preemption statement in section 360k(a). This provision declares that no state or political subdivision may establish “any requirement” differing from or in addition to any FDA safety or effectiveness standard applicable to a medical device regulated by the Amendments. Notably, section 360k(a) applies to FDA regulations promulgated under the MDA, but does not extend to regulations issued pursuant to other provisions of the FDCA.

Congress chose the term “requirement” to describe the type of state regulatory action that section 360k(a) prohibits. Both the Federal Cigarette Labeling and Advertising Act and FIFRA contain the same expression in their preemption provisions. As previously discussed, the term “requirement” connotes a command or mandate that gives the regulated party no choice but to comply. Since damage awards do not involve this degree of compulsion, perhaps Congress did not intend section 360k(a) to preempt common-law tort liability. However, common-law damage awards are


673. Id. The text of § 360k(a) is set forth supra note 332.

674. See supra text accompanying notes 490-494.

supposed to have a deterrent effect on product manufacturers who might place defective products on the market.\textsuperscript{676} Hence, it would not be unreasonable for a court to treat tort liability as a "requirement" for purposes of preemption.\textsuperscript{677}

The legislative history of the Amendments does not indicate whether Congress intended to preempt state tort law. A House Report on the proposed Bill described some existing state legislative programs and indicated that they would be preempted unless the FDA granted them an exemption.\textsuperscript{678} However, the House Report says nothing about the Bill's preemptive effect on state tort law.\textsuperscript{679} This legislative silence is strong evidence that Congress did not intend section 360k(a) to preempt state tort law.

A brief examination of contemporary values and policies indicates that preemption is consistent with some values and policies, but apparently inconsistent with others. The policy of protecting interstate commerce supports the goal of uniform, national regulation of medical devices by the FDA.\textsuperscript{680} However, federalism values caution against a finding of preemption when it displaces the traditional state interests protecting of public health and safety.\textsuperscript{681} Although some courts have expressed doubts about
governing the sale and distribution of devices, not to state common law."); Kociemba v. G.D. Searle & Co., 680 F. Supp. 1293, 1298 (D. Minn. 1988) ("It is doubtful that the term 'requirement' as used in section 360k is broad enough to encompass an action pursued under state tort law").


677. See Stewart v. International Playtex, Inc., 672 F. Supp. 907, 909 (D.S.C. 1987) ("Plaintiff's common law tort claim alleging 'inadequate warnings' seeks, by definition, to establish a tort labeling requirement which could be different from or in addition to the existing and applicable FDA requirement."); Edmondson v. International Playtex, Inc., 678 F. Supp. 1571, 1574 (N.D. Ga. 1987) ("A requirement imposed by a State Court is no less a requirement than one imposed by a State legislature."). This conclusion is bolstered by the Supreme Court's finding in Cipollone that the term "requirement" in the Cigarette Labeling Act was sufficiently broad to preempt expressly some tort claims. See Cipollone v. Liggett Group, Inc., 112 S. Ct. 2608, 2620 (1992).


679. See Lindquist v. Tambrands, Inc., 721 F. Supp. 1058, 1061 (D. Minn. 1989) ("There is . . . nothing in the legislative history of the MDA indicating that Congress intended section [360k(a)] to preempt the application of the remedies available under state tort law."); Callan, 709 F. Supp. at 668 ("The House Report demonstrates a clear concern with statutory programs administered by States and localities and never even hints to inclusion of state common law.").

680. Lindquist, 721 F. Supp. at 1063; see also Landen, supra note 259, at 114-15 (discussing the goal of uniformity in the labeling and design of drugs).

the reliability of FDA decisionmaking, the policy of deferring to agency judgment supports preemption. Finally, both consumer safety and compensation policies favor the retention of state tort law.

Based on these factors, a court might reasonably conclude that the MDA does not preempt state tort law. However, an additional factor may tip the balance in favor of preemption. Unlike the FDCA, which has no preemption provision, section 360k(a) of the Amendments expressly preempts state requirements. Furthermore, the FDA has specifically interpreted this section to preempt state tort law as well as legislative and administrative regulations. Although one might claim that section 360k(a) does not give the FDA the power to preempt state tort law, the holding in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.* requires courts to defer to an agency’s interpretation if the interpretation is based on a permissible construction of the statute in question. Because the FDA’s interpretation of section 360k(a) is apparently permissible, the courts should defer to the FDA’s judgment and rule that tort claims against manufacturers who comply with the requirements of the MDA are preempted.

VI. CONCLUSION

Part V offers the following conclusions: (1) The Federal Cigarette Labeling and Advertising Act should not be interpreted to preempt failure-to-warn claims under state tort law; (2) In general, safety standards issued pursuant to the National Traffic and Motor Vehicle Safety Act should not be given preemptive effect. However, perhaps FMVSS 208, which concerns

682. See supra cases cited note 641.


685. 21 C.F.R. § 808.1(b) (1992). The text of this section is set forth supra note 333.

686. See Callan v. G.D. Searle & Co., 709 F. Supp. 662, 668 (D. Md. 1989) (“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.”).


688. Id. at 842-45.

occupant safety, should preempt state tort law because Congress intended to give automobile manufacturers the right to choose devices other than airbags to satisfy occupant restraint requirements; (3) The preemption provision in the Federal Insecticide, Fungicide, and Rodenticide Act should not be interpreted to preclude damage claims against pesticide manufacturers; (4) Although FDA regulations are comprehensive, they should not preempt common-law tort doctrines; and (5) The Medical Device Amendments’ preemption section applies to state tort law because the FDA has expressed a clear intention to preempt common-law claims under this provision.

Most of these conclusions are consistent with the courts’ results, with two major exceptions. This Article suggests that the Cigarette Labeling Act should not preempt state failure-to-warn claims; however, the United States Supreme Court in Cipollone v. Liggett Group, Inc. concluded otherwise. In addition, this Article concludes that Congress did not intend FIFRA to preempt state tort law; however, the courts are evenly split on this issue.

What do these results suggest about the practical reasoning approach? Do they indicate that courts which use this approach will generally uphold tort liability in product preemption cases? The answer would seem to be “yes,” because many of the contemporary values and policies discussed earlier promote the same interests as tort law. However, one must remember that each interpreter approaches a statutory text from a different perspective or horizon. This author concludes that preemption is not appropriate in cigarette labeling cases, at least in part, because he values federalism, safety, and compensation more highly than commercial convenience or agency deference. Another interpreter might value these factors differently and reach a different conclusion. The value of the Eskridge-Frickey approach lies not in producing more determinate results, but in ensuring that courts which employ the model will not ignore or marginalize important values when interpreting statutes.

The Author does not intend to suggest that state tort law is inherently superior to federal product safety legislation. Although various factors weigh against preemption in the cases discussed above, one of the most significant considerations is the absence of a clear statement of intent by either Congress or the regulatory agency to preempt state tort law. Many situations exist in which federal agencies can make better decisions about product safety than can courts or juries. It is entirely appropriate for federal agencies to invoke their preemptive power in these situations, as long as they do so clearly and unequivocally.

Finally, federal safety standards play an important role in products liability litigation even when they do not preempt state tort doctrines. In appropriate cases, compliance with federal safety standards should create a

691. See Eskridge & Frickey, Statutory Interpretation, supra note 12, at 346-47.
rebuttable presumption that the product is not defective or that a warning is adequate. In this way, federal product safety regulations and state tort liability rules can complement and reinforce each other.

Both federal law and common-law tort principles play a major role in the operation of products liability law. One hopes this useful partnership will continue in the future. Much of the friction that typically arises between these two systems can be avoided if Congress and the appropriate federal agencies make known with greater clarity their intentions. Until then, courts should exercise their interpretive functions in a responsible and principled manner.

692. See, e.g., Henderson, Manufacturers' Liability, supra note 465, at 632 (stating that manufacturers should not be liable for product designs that meet federal standards unless the plaintiff proves by clear and convincing evidence that the standards were "inadequate to protect the class of persons of which the plaintiff is a member from unreasonable risks of injury or damage"); cf. RICHARD A. EPSTEIN, MODERN PRODUCTS LIABILITY LAW 83-84 (1980) (suggesting that compliance with regulatory standard should be conclusive unless plaintiff gives reasons why it should not).

693. Cf. T. Schwartz, supra note 466, at 1161-63 (discussing the interaction of state tort law and federal safety regulations).