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The Impact of the *Cipollone* Case on Federal Preemption Law

Richard C. Ausness

Introduction

The United States Supreme Court handed down an opinion in the *Cipollone* case on June 24, 1992. Justice Stevens, writing for the majority, concluded that the Federal Cigarette Labeling and Advertising Act preempted all tort claims against cigarette manufacturers based on failure to provide adequate warnings about the health risks of smoking. However, the Court also held that claims based on breach of express warranty, misrepresentation, and conspiracy were not preempted by the Act. Thus, although *Cipollone* represents a clear victory for tobacco companies, it also leaves the door open for future litigation.

The first part of this Article will discuss the concept of federal preemption. The second part will examine various theories of statutory interpretation proposed by members of the Court. This portion of the Article will also evaluate the Court’s treatment of the preemption issue in *Cipollone*. Finally, the third part will consider the effect of the *Cipollone* decision on other product liability claims.

Preemption and Cigarette Warnings

*The Health Risks of Smoking*

It is estimated that 350,000 persons die each year from the effects of cigarette smoking. Scientists have known for years that smoking causes lung cancer, but smoking has now been linked to cancer of the stomach, cervix, pharynx, esophagus, bladder, pancreas, and kidney as well. In addition, studies suggest that smoking increases the risk of cardiovascular disease and...
chronic obstructive lung diseases. Furthermore, medical evidence indicates that smoking by pregnant women causes health problems for their unborn children.

Litigation Against Cigarette Manufacturers

For more than three decades, injured consumers have tried to recover against tobacco companies for smoking-related injuries. At first, litigants relied on negligence and implied warranty theories, but later switched to strict liability in tort. Under the this theory, product manufacturers are strictly liable to consumers for injuries caused by manufacturing defects, design defects, or failure to warn. Most claims against cigarette companies have been based on failure to provide an adequate warning of the health risks of smoking.

Warnings must be adequate with respect to factual content, expression, and method of communication. Adequacy in terms of content means that the warning must be accurate and complete. The product seller must disclose an known risks and reveal the specific nature and magnitude of these risks. A warning must also be communicated in language that is clear and understand-

12. E.g., see Ross v. Philip Morris, Inc., 328 F.2d 3 (8th Cir. 1964) (implied warranty); Lattigue v. R.J. Reynolds Tobacco Co., 317 F.2d 19 (5th Cir. 1963), cert. denied, 375 U.S. 865 (1963) (negligence); Green v. American Tobacco Co., 304 F.2d 70 (5th Cir. 1962), question cert. on reh’g, 154 So. 2d 169 ( Fla. 1963), rev’d and remanded on reh’g, 391 F.2d 97 (5th Cir. 1968), aff’d per curiam, 409 F.2d 1166 (5th Cir. 1969), cert. denied, 397 U.S. 911 (1970) (implied warranty); Prichard v. Liggett & Meyers Tobacco Co., 295 F.2d 292 (3d Cir. 1961), aff’d on reh’g, 350 F.2d 479 (3d Cir. 1965), cert. denied, 382 U.S. 987 (1966), modified, 370 F.2d 95 (3d Cir. 1966), cert. denied, 386 U.S. 1009 (1967) (negligence).
13. See Restatement (Second) of Torts §402A (1965).
able. Furthermore, a warning must be phrased with sufficient emphasis to ensure that product users will exercise caution. Thus, statements that minimize dangers or provide misleading assurances of safety will not be considered adequate. Finally, warnings must be communicated to anyone who might be endangered by the product.

Cigarette warnings are clearly inadequate when measured by these standards. There were no health warnings at all on cigarette packaging prior to the enactment of federal labeling legislation in 1965. Even now, health warnings are not conspicuous, nor are they sufficiently forceful to be effective. In addition, existing warnings are not specific enough to satisfy the duty to warn. Until recently, cigarette warnings said nothing about the risk of lung cancer, heart disease, pulmonary disease, or any other specific smoking-related illness. Moreover, warnings still do not inform smokers about the likelihood and magnitude of potential injury. In addition, health warnings say nothing about the addictive qualities of nicotine. Finally, the promotional efforts of cigarette manufacturers have diluted the effects of health warnings.

Although the failure to warn theory would seem to be a compelling one, tobacco companies have avoided liability by contending that such claims are

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preempted by federal cigarette labeling legislation. At the time of the Supreme Court’s decision in *Cipollone*, six federal circuit courts and a number of other federal and state courts had held failure to warn claims to be preemption by federal law. Only a few state courts have refused to accept this preemption argument.

The legislation in question is the Federal Cigarette Labeling and Advertising Act. This statute was first enacted in 1965 and became effective on January 1, 1966. The Act required all cigarette packages to contain the following warning: “Caution: Cigarette Smoking May Be Hazardous to Your Health.” The Act also stated that Congress intended to establish a comprehensive program with respect to cigarette labeling and advertising in order to inform the public about the hazards of smoking and to protect the national economy by excluding diverse and confusing labeling requirements. When the Act was amended in 1969, Congress strengthened the language of the mandatory warning.

Both the 1965 Act and the 1969 Act contained express preemption provisions. The preemption provision of the 1969 Act is presently codified at 15 U.S.C. §1334. Section 1334(a) provides that no statement relating to health risks from smoking shall be required on cigarette packages other that the statement required by section 1333 of the Act. Section 1334(b) declares that no additional requirements or prohibitions relating to smoking and health may be imposed under state law with respect to advertising or promotion activities. These provisions clearly prohibit states from imposing mandatory labeling


35. *Id.* at §4.


38. *Id.* §4. The required warning was changed to read: “Warning: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous to Your Health.”


40. 15 U.S.C. §1334(a) (1982). The statement required by §1333 originally declared “Caution: Cigarette Smoking May Be Hazardous to Your Health.” In 1969, the statement was changed to “Warning: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous to Your Health.” Since 1984, tobacco companies are required to place one of four warnings (on a revolving basis) on cigarette packaging. *Id.* §1333(a)(1) (West Supp. 1987).

41. *Id.* §1334(b) (1982).
requirements for cigarette packaging or advertising by statute or administrative regulation. However, it is not so clear whether section 1334, or any other section of the federal act, preempts damage claims against tobacco companies under principles of state tort law.

The Preemption Doctrine

Under the Supremacy Clause, Congress may enact legislation that supersedes state or local laws. In addition, a federal agency, acting within the scope of its delegated authority, may preempt state or local law. Furthermore, state common-law doctrines may also be preempted by federal law. Preemption can arise in various ways. For example, express preemption occurs when a federal statute specifically excludes state regulation in a particular area. State law is also preempted when the federal government occupies a regulatory field. Federal occupation of a field may be based on the existence of a dominant federal interest, or on the existence of a pervasive scheme of federal regulation. Finally, state law will be preempted where there is a direct conflict between state and federal law. A conflict may occur when state law requires a person to do something that federal law forbids. State law may also conflict with federal


43. U.S. Const. Art. VI, § 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."


51. E.g., see McDermott v. Wisconsin, 228 U.S. 115, 137 (1913).
regulatory policies by impairing the exercise of rights created by federal law. Finally, a state law will be preempted if it frustrates federal regulatory goals. Until the Supreme Court's decision in Cipollone, most courts found that section 1334 did not expressly preempt actions under state tort law because they felt that terms like "prohibition" and "requirement," used in that section, could only refer to direct coercion by the state. Furthermore, most courts refused to preempt state law tort claims on "occupation of the field" grounds either. Virtually every court that has preempted state tort claims has done so on actual conflict grounds. In many cases, these courts have found a conflict on the basis that allowance of tort claims against tobacco companies would upset a "balance," reflected in the Act, between health concerns and commercial interests.

**The Cipollone Decision**

**Overview**

The Cipollone saga began in 1983, when Rose Cipollone and her husband brought a tort action against the respondent tobacco companies to recover damages for smoking-related injuries. When Rose Cipollone died of lung cancer in 1984, her husband filed an amended complaint and continued the action. When he died, their son, in his capacity as executor, continued to press the suit. The amended complaint alleged that the cigarettes were defective because the defendants failed to use a safer alternative design for their products and because the harm caused by smoking outweighed the social value of cigarettes. The complaint also stated that the defendants failed to provide adequate warnings about the health consequences of smoking and that they negligently tested, researched,
sold, promoted, and advertised their products. In addition, the complaint declared that the defendants had expressly warranted that their products were not dangerous to the health of consumers. Furthermore, the complaint claimed that the defendants, through their advertising, had attempted to neutralize the effect of the federally mandated warning, and that they had ignored or failed to act upon medical evidence, known to them, about the health risks of smoking. Finally, the complaint charged that the defendants conspired to deprive the public of data on the health effects of smoking.

The defendant cigarette manufacturers maintained that the federal labeling statute preempted all of these claims. In a pretrial ruling, the trial court rejected the preemption defense. However, the defendants brought an interlocutory appeal and succeeded in having the trial court's ruling reversed. On remand, the trial court determined that the failure to warn, express warranty, fraudulent misrepresentation, and conspiracy to defraud claims were all preempted to the extent that they relied on advertising or promotional activities after the effective date of the Act. The trial court also ruled that design defect claims, though not preempted, were not allowed under state law.

At trial, the jury rejected the fraudulent misrepresentation and conspiracy to defraud claims, but found that the defendants had breached their duty to warn and express warranties prior to the Act's effective date. Nevertheless, the jury refused to award damages to Rose Cipollone's estate because it concluded she had voluntarily and unreasonably encountered a known danger by smoking cigarettes. However, the jury awarded $400,000 to the decedent's husband to compensate him for losses caused by the defendants' breach of express warranty. Both parties appealed. The Court of Appeals affirmed the trial court's preemption ruling, but ordered a new trial on other issues. At that point, the Supreme Court granted certiorari. The resulting decision in Cipollone reflected a bitter division within the Court on the issue of federal preemption of common-law damage claims.

Justice Stevens, joined by Chief Justice Rehnquist and Justices White and O'Connor, wrote the plurality opinion in Cipollone. Justice Stevens declared that preemptive language in federal statutes should be narrowly construed.

59. Id. The Court described these allegations as "failure to warn" claims. Id.
60. Id. The Court characterized these allegations as "express warranty" claims. Id.
61. Id. The Court identified these allegations as the "fraudulent misrepresentation" claims. Id.
62. Id. The Court referred to these allegations as "conspiracy to defraud" claims. Id.
66. Id. at 669-72.
68. Id.
69. Id.
72. Cipollone, 112 S. Ct. at 2613-25.
73. Id. at 2618.
With that principle in mind, Justice Stevens found that the 1965 Act's preemption provision prohibited state and federal rulemaking bodies from mandating particular warning language, but did not bar damage claims based on principles of state tort law. However, Justice Stevens also determined that the broader language of the 1969 Act's preemption provision was sufficient to prohibit failure to warn claims arising from conduct after that date. At the same time, Justice Stevens concluded that the 1969 Act did not preempt express warranty claims, fraudulent misrepresentation claims, or conspiracy to defraud claims.

Justice Blackmun, joined by Justices Kennedy and Souter, concurred in part and dissented in part. Justice Blackmun believed that there was no difference in congressional intent between the 1965 Act and the 1969 Act. He reasoned that if the preemption provision in the 1965 Act did not bar common-law damage actions for failure to warn, then the 1969 Act could not do so either, even though Congress had modified the language of the Act's preemption provision slightly. Accordingly, Justice Blackmun concurred in the Court's decision that Cipollone's express warranty, misrepresentation, and conspiracy claims should be allowed, but dissented from the Court's decision to preempt the failure to warn claims.

Justice Scalia, joined by Justice Thomas, also concurred in part and dissented in part. Justice Scalia vigorously objected to the theory of statutory construction proposed by Justice Stevens. According to Justice Scalia, preemptive language in statutes should not be construed either narrowly or broadly, but in accordance with its ordinary meaning. On that basis, Justice Scalia concluded that both the 1965 Act and the 1969 Act preempted all of Cipollone's claims. Accordingly, Justice Scalia concurred in the Court's decision to bar post-1969 failure to warn claims, but dissented from its decision to allow pre-1969 failure to warn claims and post-1969 express warranty, misrepresentation, and conspiracy claims.

**Theories of Statutory Interpretation in Cipollone**

Justice Stevens proposed two rules of statutory construction to limit the preemptive effect of federal legislation. First, he declared that implied preemption...
Theories should not be used in cases where Congress had included an express preemption provision in the statute. In addition, Justice Stevens stated that preemption provisions in statutes should be interpreted narrowly. Justice Scalia rejected both of these proposals, and argued for a more expansive interpretation of preemptive language.

The first rule of construction was based on the notion that the enactment of a provision defining the preemptive reach of a statute implies that matters beyond that reach are not preempted. Since no other provisions were concerned with the Acts' preemptive scope, Justice Stevens limited himself to an examination of the text of section 5 of each statute. Justice Blackmun agreed with this approach, declaring that the Court should only resort to principles of implied preemption when Congress has been silent with respect to preemption.

Justice Scalia acknowledged that this rule of construction was correct as far as occupation of the field was concerned. In such cases, the existence of a preemption provision in the statute would indicate that Congress did not intend for the statute to reach beyond its stated regulatory limits. However, Justice Scalia maintained that the rule against implied preemption should not apply to direct conflict cases. In his view, such a rule would prevent federal courts from preempting state action that undermined federal regulatory policy in cases where Congress failed to anticipate a conflict.

Justice Stevens also declared in *Cipollone* that the Court should narrowly construe statutory preemption provisions. This narrow construction or "clear meaning" rule was derived from the presumption against preemption, a principle that the Court has recognized for many years. Justice Scalia, however, argued that the Court should interpret preemptive provisions "neither narrowly, nor broadly, but in accordance with their apparent meaning." According to Justice Scalia, the presumption against preemption was more appropriate in implied preemption cases; where congressional intent to preempt was clear, the Court should employ ordinary principles of statutory construction to interpret a statute's preemptive language.

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85. *Id.* at 2618.
86. *Id.*
87. *Id.* at 2633–34.
88. *Id.* at 2618. Justice Stevens characterized this as a variant of the principle *expressio unius est exclusio alterius*. *Id.*
89. *Id.*
90. *Id.* at 2625.
91. *Id.* at 2633.
92. *Id.* at 2633.
93. *Id.* at 2633.
95. *Id.* at 2632.
96. *Id.*
Resolution of Preemption Issues in Cipollone

The Distinction Between the 1965 Act and the 1969 Act

Justice Stevens believed that there was a significant difference between the preemptive language of the 1965 Act and that of the 1969 Act. Section 5(b) of the 1965 Act provided, "No statement relating to smoking and health shall be required in the advertising of any cigarettes the packages of which are labeled in conformity with the provisions of this Act." According to Justice Stevens, this provision was quite narrow in scope and did not preempt damage claims under state tort law principles. The 1969 Act replaced this language with a provision that declared, "No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act." Justice Stevens contended that this change in section 5(b) expanded the Act's preemptive reach. In particular, he pointed out that requirements and prohibitions were broader concepts than statements, and that the scope of section 5(b) was extended to include promotional activities as well as advertising.

Both Justice Scalia and Justice Blackmun maintained that the changes in the 1969 Act did not affect its preemptive scope. Justice Scalia based his argument on a consistency rationale. He claimed that Justice Stevens had construed the phrase "no statement relating to smoking and health shall be required" in the 1965 Act to mean no particular statement relating to smoking and health could be required by the states. Since duties imposed under common law did not require cigarette companies to include any particular statement in their advertising, but merely required them to provide adequate warnings about the health risks of smoking, Justice Stevens was able to conclude that section 5(b) of the 1965 Act did not preempt failure to warn claims. If this was so, Justice Scalia reasoned, section 5(b) of the 1969 Act also should have been construed to mean merely that state law could not impose a specific advertising requirement based on smoking and health. Thus, under this approach, section 5(b) would have allowed general, "noncigarette-specific duties" to be imposed upon cigarette manufacturers by state tort law.

Justice Blackmun, on the other hand, relied on an examination of legislative history to conclude that section 5(b) of the 1969 Act, though textually different from its 1965 predecessor, was no different substantively. He quoted from a Sen-
ate Report that stated that the changes in section 5(b) were mere clarifications of the existing preemption provision.\textsuperscript{107} According to Justice Blackmun, the purpose of these changes was to make it clear that states could not do through prohibitory action that which the 1965 Act already banned through mandatory action.\textsuperscript{108} In addition, portions of the Act’s legislative history indicated that Congress was concerned with the effect of positive enactments, and not with the effect of common-law tort doctrines.\textsuperscript{109}

Justice Blackmun also observed that Congress made no change in the statement of purpose provision when it amended the 1965 Act in 1969.\textsuperscript{110} If the language in the 1965 Act indicated that Congress was solely concerned with state legislative and administrative requirements,\textsuperscript{111} then its failure to change this language in 1969 suggested that Congress was still only concerned with positive enactments and did not intend to enlarge the scope of the 1969 Act’s preemption provision.\textsuperscript{112} Finally, Justice Blackmun argued that nothing in the Act’s legislative history suggested that Congress intended to deprive injured consumers of their existing remedies under state law when it amended the Act in 1969.\textsuperscript{113} According to Justice Blackmun, Congress rarely abolished existing state remedies without replacing them with comparable substitutes under federal law; therefore, it was unlikely that Congress meant to do so in 1969.\textsuperscript{114}

Frankly, it is hard to see any difference between the 1965 Act and the 1969 Act as far as preemption is concerned. None of the lower federal courts had observed any such distinction. The distinction seems to be of little practical importance anyway, since it merely adds four years to the period for which cigarette manufacturers may be liable on a failure to warn basis. As a practical matter, it is unlikely that plaintiffs who smoked before 1969 and continued to smoke for some period of time after that date will be able to provide a realistic formula for apportioning injuries caused by pre-1969 conduct and those caused by post-1969 conduct.

\textit{The Meaning of “Requirement or Prohibition Imposed Under State Law”}

Having decided that the 1969 Act’s preemptive language was broader than that of the 1965 Act, the Court then had to determine whether the 1969 Act expressly preempted some or all common-law damage actions against tobacco companies. Section 5(b) barred any “requirement or prohibition, based on smoking and health” that was “imposed under State law.” There was general agreement that the phrase “requirement or prohibition . . . imposed under State Law” was broad enough to include obligations or duties imposed by common-law tort

\textsuperscript{108} Cipollone, 112 S. Ct. at 2629.
\textsuperscript{109} Id. at 2629–30 (citing Sen. Rep. No. 566, 91st Cong., 1st Sess. 12 (1969)).
\textsuperscript{110} Id. at 2630.
\textsuperscript{111} Id. at 2630.
\textsuperscript{112} Id. at 2630.
\textsuperscript{113} Id.
\textsuperscript{114} Id.
principles. However, the justices could not agree on whether Congress had such common-law duties in mind when referred to requirements and prohibitions in section 5(b).

Justice Stevens conceded that Congress was primarily concerned with positive enactments by state and local governments, but he also declared that there was no reason to assume that Congress intended to exclude any particular type of state regulatory action from the sweep of section 5(b), as long as it fell within the definition of "regulation or prohibition." Justice Stevens also relied on the Act's legislative history to support an expansive reading of section 5(b). He pointed out that when section 5(b) was revised in 1969, a Conference Committee changed the words "any State statute or regulation" to "State law," indicating a desire to extend the reach of section 5(b) to common-law rules. For these reasons, Justice Stevens concluded that Congress intended to preempt any common-law rule that had a regulatory effect on cigarette labeling.

Justice Blackmun argued that the term "requirement or prohibition imposed under State law" was ambiguous. He observed that the dictionary definition of "requirement" and "prohibition" suggested specific actions mandated or disallowed by a formal governing authority and did not include duties imposed by common-law doctrines. Moreover, Justice Blackmun attached great significance to the fact that common-law damage actions did not exert the same sort of influence on products manufacturers as statutory or administrative regulations. Relying on Goodyear Atomic Corporation v. Miller, a recent decision, Justice Blackmun declared that a product manufacturer could meet its common-law duty to warn in a variety of ways, including payment of damage awards. According to Justice Blackmun, the availability of such choices distinguished common-law duties from those imposed positive enactments:

The level of choice that a defendant retains in shaping its own behavior distinguishes the indirect regulatory effect of the common law from positive enactments such as statutes and administrative regulations.

115. Id. at 2620; id. at 2627; id. at 2634.
116. Id. at 2620.
117. Id. at 2621.
118. Id. Justice Scalia also agreed that Congress intended the phrase "requirement and prohibition imposed under state law" to preempt damage claims based on breach of common-law duties. Id. at 2634.
119. Id. at 2627.
120. Id.
121. Id. at 2627.
123. Cipollone, 112 S. Ct. at 2628.
124. Id.
Justice Blackmun also observed that tort law was different from positive regulatory enactments because it had an entirely different function—that of compensating injured parties.  

Justice Blackmun seems to have had the better of the argument on this issue. First of all, common-law rules regulate only indirectly and leave the regulated party with a great deal of flexibility. Consequently, common-law rules usually present less of an impediment to federal regulation than positive enactments like statutes and administrative regulations. Furthermore, the Court has recognized this fact on a number of occasions by finding positive enactments to be preempted, but not common law rules. In addition, there were virtually no references to common-law damage awards in the Act's legislative history, suggesting that Congress was not concerned about the possible regulatory effects of such awards. In contrast, there are numerous references in the act's legislative history about the undesirable effects of state or local mandatory labeling requirements. Finally, it is unlikely that Congress would destroy existing remedies by implication, instead of doing so expressly. Thus, it is remarkable that the Court found a congressional intent to preempt common-law damage claims, particularly in light of the "clear meaning" rule that was supposed to apply in express preemption cases.

**Preemption of Specific Claims**

Justice Blackmun would have allowed all of Cipollone's claims. Justice Scalia would have preempted all of these claims. However, Justice Stevens, writing for

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125. Id.
131. See Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 251 (1984) ("it is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct"); Dewey v. R.J. Reynolds Tobacco Co., 577 A.2d 1239, 1251 (N.J. 1990) ("We are convinced that had Congress intended to immunize cigarette manufacturers from pack-
the majority, preempted only the plaintiff's post-1969 failure to warn claims, and allowed the others to stand.

**Failure to Warn Claims.** The plaintiff in *Cipollone* claimed that the defendant cigarette companies were negligent in the manner in which they tested, researched, sold, promoted, and advertised their products. In addition, it was alleged that the defendants failed to provide adequate warnings of the health consequences of smoking. Since the common-law duty to warn was a state law “requirement with respect to advertising or promotion,” Justice Stevens concluded that any claim based on breach of such a duty after 1969 would be preempted to the extent that it penalized the defendants for failing to provide additional, or more specific, warnings than those required by the Act. On the other hand, claims based on inadequate testing or research presumably would not be preempted since they were not related to advertising or promotional activities.

**The Express Warranty Claim.** The plaintiff also contended that the defendant cigarette companies breached an express warranty. Liability was based on assurances in the defendants' advertising that cigarettes did not present any serious health risks to smokers. According to Justice Stevens, the appropriate inquiry for the Court was not whether a claim challenged the propriety of advertising or promotion, but whether the source of the duty upon which the claim was based constituted a state law requirement or prohibition based on smoking and health with respect to advertising or promotion. Justice Stevens reasoned that duties under the law of express warranty arose from, and were measured by, the terms of the warranty. Therefore, a common-law remedy for breach of a voluntary contractual commitment would not be regarded as a requirement imposed under state law. Accordingly, Justice Stevens concluded, the plaintiff could maintain an action for breach of express warranty, regardless of how the warranty was communicated.

Justice Scalia strongly disagreed with this analysis. He argued that background legal principles (in this case the law of express warranty), not the actor's voluntary conduct, supplied the element of legal obligation. He also pointed

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133. *Id.*
134. *Id.* at 2621-22.
135. *Id.* at 2622.
138. *Id.*
139. *Id.*
140. *Id.* at 2622-23.
141. *Id.* at 2635.
out that the Court had recently rejected Justice Stevens’s rationale in *Norfolk & Western Railroad v. American Train Dispatchers Association*, where it construed an exemption from antitrust laws “and from all other law” to include an exemption from contract obligations. Consequently, Justice Scalia concluded that the plaintiff’s express warranty claim, since it was based on statements made in advertising, should have been preempted.

**Fraudulent Misrepresentation Claims.** The plaintiff set forth two theories of fraudulent misrepresentation: First, he claimed that the defendants, through their advertising, neutralized the effect of the federally mandated warnings; second, he alleged that the defendants falsely represented that smoking was safe, and they failed to disclose evidence in their possession that smoking was harmful. Justice Stevens determined that the first claim was preempted because it was the converse of Cipollone’s failure to warn claim, which the Court had already held to be preempted. However, he concluded that the second claim was not prohibited by section 5(b). First of all, because section 5(b) only preempted state requirements with respect to advertising or promotion, Justice Stevens declared that no claim would be barred that required the defendants to disclose material facts through other channels of communication. Moreover, Justice Stevens stated that even claims arising from statements in advertising would not be preempted, because they were not predicated on a duty related to smoking and health, but rather arose from a more general duty not to deceive.

Justice Scalia chided Justice Stevens for not applying his analysis consistently. Justice Scalia declared that both the duty to warn and the duty not to deceive were general obligations, and neither was specifically concerned with smoking and health. Therefore, if fraudulent misrepresentation claims based on false advertising were not preempted, then failure to warn claims should not be preempted either. According to Justice Scalia, the Court should not have focused on the ultimate source of the duty, but on its proximate application. Thus, whether the duty arose from statute, administrative regulation, or some general principle of common law, it would fall within the purview of section 5(b) if it imposed on obligation on cigarette companies with respect to smoking and health. Under this approach, Justice Scalia concluded, both of the plaintiff’s fraudulent misrepresentation claims would be preempted.

142. 111 S. Ct. at 1164.
143. *Cipollone*, 112 S. Ct. at 2636.
144. *Id.*
145. *Id.* at 2623–24.
146. *Id.* at 2623.
147. *Id.*
148. *Id.* at 2624.
149. *Id.* at 2636.
150. *Id.*
151. *Id.*
152. *Id.* at 2637.
153. *Id.*
Justice Stevens acknowledged that there was some merit to Justice Scalia’s criticism, but maintained that his approach came closest to carrying out the intent of Congress. According to Justice Stevens, to analyze fraudulent misrepresentation claims at the lowest level of generality, as Justice Scalia recommended, would result in a broad interpretation of section 5(b) that was contrary to a congressional intent that the states retain some power in this area.

Conspiracy Claims. Finally, the plaintiff claimed that the defendants had conspired to misrepresent or conceal material facts concerning the health risks of smoking. Justice Stevens declared that these claims were based on a general duty under state law not to conspire to commit fraud, and not only any state requirement based on smoking and health. Therefore, he concluded that these claims were not preempted by section 5(b).

An Assessment of the Cipollone Decision

It is obvious from Cipollone that the Court is strongly divided over the scope of federal preemption in the products liability area. Only three other justices completely agreed with Justice Stevens’s analysis. Two other justices joined with Justice Blackmun in concluding that none of the plaintiff’s claims should have been preempted, while one other justice agreed with Justice Scalia that all of the plaintiff’s claims should have been preempted.

One point that everyone agreed upon was that Cipollone should be treated as an express preemption case. This is somewhat surprising in light of the fact that most courts have rejected an express preemption analysis. However, an express preemption analysis is desirable to the extent that it induces the Court to start with the statutory text when seeking an answer to preemption questions. Ordinarily, it should not be necessary for the Court to engage in an implied preemption analysis if the express preemption provision is clear. An exception to this approach might be made in cases where a conflict between state and federal law occurs that was obviously not foreseen by Congress when it enacted the statute.

Most of the justices also agreed that the Court should not find preemption unless supported by the “clear meaning” of the statutory text. Unfortunately, the

154. Id. at 2624 n. 27.
155. Id.
156. Id. at 2624.
157. Id.
158. Id. at 2624–25.
160. See Eskridge, Jr., & Frickey, Statutory Interpretation as Practical Reasoning, 42 STAN. L. REV. 321, 340 (1990) (arguing that one should start with the text first when interpreting a statute).
161. Cipollone, 112 S. Ct. at 2633–34.
justices could not seem to agree on whether the language of section 5(b) satisfied this requirement. Since the text of section 5(b) was ambiguous, one would have expected the Court to have rejected the preemption argument if it was serious about employing a "clear meaning" approach.

Perhaps the greatest area of disagreement within the Court was over the proper treatment of general principles of state law. Justice Blackmun, applying a high level of generality, maintained that any duty based on state common law should be excluded from preemption unless the duty itself was confined to advertising with respect to smoking and health. This approach would have exempted virtually every tort-based duty from the reach of section 5(b). Justice Scalia, on the other hand, chose to focus exclusively on the effect of a common law duty on advertising with respect to smoking and health. This approach would have extended the Act's preemptive scope to almost all advertising with respect to smoking and health. Justice Stevens steered a middle course between these two extremes, but his approach was conceptually flawed. As a consequence, the outcome of Cipollone is likely to strike most legal scholars as profoundly unsatisfactory.

For better or for worse, Cipollone leaves the door open for future litigation against cigarette companies. Presumably, injured parties will continue to bring actions based on express warranty, misrepresentation, and conspiracy theories. However, it remains to be seen whether any of these theories will prove successful.

Express warranty does not appear to be a very attractive theory. To recover under express warranty, the plaintiff must show that the defendant made a specific representation about product quality or safety, and that the plaintiff relied on this representation.¹⁶² As late as the mid-1950s, some cigarette advertisements explicitly claimed that smoking was safe;¹⁶³ however, since that time representations of safety have become more subtle.¹⁶⁴ Consequently, it may be difficult for an injured consumer to establish that the subliminal assurances of safety often found in current cigarette advertising should be treated as express warranties.¹⁶⁵

Fraudulent misrepresentation looks more promising. The first theory discussed in Cipollone appears to have been based on a manufacturer's duty to disclose known health risks associated with its product. There is no doubt that cigarette companies, despite growing scientific evidence of the health risks of smoking, failed to disclose any of these risks until required to do so by federal legisla-


¹⁶⁴ For example, many advertisements feature young, attractive smokers engaging in sports or other physical activities, thereby suggesting that smoking does not impair one's health. See Note, Constitutional Realism: Legislative Bans on Tobacco Advertisements and the First Amendment, 1986 U. Ill. L. Rev. 1193, 1207.

¹⁶⁵ But see Levin, The Liability of Tobacco Companies—Should Their Ashes Be Kicked?, 29 Ariz. L. Rev. 195, 239–41 (1987) (arguing that current advertising does give rise to an express warranty that cigarettes are safe).
tion. The only question is whether very many states would recognize a cause of action, independent of the duty to warn in products liability, for failure to disclose health risks in some manner other than by advertising or product labeling.

The other theory of fraudulent misrepresentation discussed in Cipollone involved false representation and concealment of material facts. In the case of affirmative misrepresentations, the defendant must make a false statement of material fact, and the plaintiff must detrimentally rely on this statement. Thus, as in express warranty, plaintiffs would have to establish that cigarette advertising contained factual misstatements. In addition, plaintiffs would have to prove that they continued to smoke in reliance upon these false statements. The concealment theory is potentially more advantageous to plaintiffs. There is evidence that cigarette companies have used their economic power to discourage negative media coverage of smoking-related health issues. If this practice is widespread, it might provide the basis for a fraudulent concealment claim.

The final theory approved by the Court in Cipollone was conspiracy to misrepresent or conceal material facts. This theory is similar to fraudulent misrepresentation, but would require the plaintiff also to prove collective action by tobacco companies. The tobacco industry is highly concentrated and oligopolistic in character, and tends to act cooperatively in response to common problems. Of course, plaintiffs would have to prove the existence of a conspiracy within the industry to conceal or misrepresent material facts about health and smoking. However, the experience of the asbestos industry indicates that conspiracies of this sort do occur. Since the industry generally acts through its trade association, the Tobacco Institute, an inquiry into the actions of this organization might yield evidence of a conspiracy.


170. For example, the Tobacco Institute has characterized as "biased" and "nonscientific" medical studies that reveal the health risks of smoking. See THE SMOKING CONTROVERSY: A PERSPECTIVE, A STATEMENT BY THE TOBACCO INSTITUTE (December 1978) (cited in P. TAYLOR, THE SMOKE RING: TOBACCO, MONEY, AND MULTINATIONAL POLITICS 11-12 (1984)). In addition, the Council on Tobacco Research, an organization funded by tobacco companies, has conducted experiments designed to cast doubts on the link between cigarette smoking and cancer. See Comment, Strict Products Liability on the Move: Cigarette Manufacturers May Soon Feel the Heat, 23 SAN DIEGO L. REV. 1137, 1142 (1986).
The Impact of *Cipollone* on Other Preemption Controversies

The preemption issue has not been limited to cigarettes; over the past few years, it has been raised in connection with motor vehicles, pesticides, vaccines, and medical devices. The potential effect of *Cipollone* in each of these areas will be discussed below. Three aspects of that decision arguably provide some guidance for future litigation. First, the Court seems to prefer to base its decision on express preemption when the statute in question contains a preemption provision. Second, the Court purports to apply a "clear meaning" rule of statutory interpretation in preemption cases, although it is questionable whether such a rule was actually applied in *Cipollone*. Third, the Court appears to believe that state product liability doctrines are just as coercive as statutes or administrative regulations. Finally, policy concerns, such as federalism, fairness, economic efficiency, and risk distribution, are not likely to have much impact on the Court's decision making in preemption cases.

**Motor Vehicles**

The Federal Motor Vehicle Safety Act\(^{171}\) authorizes the Department of Transportation to promulgate federal motor vehicle safety standards (FMVSS).\(^{172}\) The Act contains a preemption provision that prohibits nonidentical state regulation when a federal safety standard deals with the same aspect of performance.\(^{173}\) However, the Act also contains a "savings clause" that purports to preserve common-law remedies against automobile manufacturers.\(^{174}\)

In recent years, there has been a considerable amount of litigation over the preemptive effect of FMVSS 208, a federal safety standard that specifies equipment requirements for motor vehicle occupant restraint systems.\(^{175}\) FMVSS 208 allows automobile manufacturers to comply by installing airbags or by installing various combinations of lapbelts and shoulder harnesses.\(^{176}\) Until recently, many carmakers equipped their vehicles with seatbelts rather than airbags. Injured consumers have sought recovery against automobile manufacturers, claiming that they should have installed airbags in their vehicles. Most courts, however, have determined that the federal statute preempts such claims.\(^{177}\) Only a few courts

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\(^{172}\) Id. §1395.
\(^{173}\) Id., §1392(d).
\(^{174}\) Id., §1397(c).
\(^{175}\) 49 C.F.R. §571.208 (1990).
\(^{176}\) Id., §571.208.S4·1.2·1-1.2·3.
have reached a contrary conclusion. Almost no courts have found express preemption or implied preemption based on occupation of the field; instead, they have concluded that damage claims frustrate federal regulatory objectives because they deprive automakers of the choices provided for them in FMVSS 208.

Under a *Cipollone* analysis, the Court would probably focus on the text of the statute. The Act’s preemption provision declares that no state may establish or continue in effect any safety standard that is not identical to a corresponding federal standard. However, the Act also contains a savings provision that declares that compliance with a federal standard does not exempt one from liability under common law. Some courts have attempted to resolve this apparent inconsistency by deciding that common-law design defect doctrines are not safety standards. In light of *Cipollone’s* broad interpretation of the terms “requirement” and “prohibition” in the cigarette labeling act, one would not expect the Court to agree with this analysis. Rather, the Court would probably conclude that Congress intended to treat common-law rules as safety standards for purposes of preemption.

If common-law rules are regarded as safety standards, what is the effect of the “savings clause”? The Court might find that the savings clause merely preserves common-law liability for product defects not covered by federal safety standards. However, since the Act’s preemption provision purports to exempt

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only nonidentical state standards that cover an area of performance already covered by federal regulation, this interpretation would make a savings clause unnecessary. Furthermore, there is nothing in the Act or its legislative history to suggest that Congress intended to preempt design defect claims in every area covered by federal safety standards.

The peculiar history of FMVSS 208 provides another avenue for preemption analysis. Unlike most administrative regulations, Congress has played a major role in the formulation of FMVSS 208. Thus, the Court might plausibly find that the substantive provisions of FMVSS 208 reflect a conscious and explicit decision by Congress to allow seatbelts as an alternative to airbags. If the Court does conclude that Congress wanted to leave automakers with a choice, it will probably also hold that "no airbag" claims effectively deprive them of the right to choose seatbelts in lieu of airbags. Thus, the Court could rule that FMVSS administratively preempts such claims.

**Pesticides**

The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) gives the U.S. Environmental Protection Agency the power to oversee most aspects of pesticide development, manufacture, sale, and use. Although the states are given authority to regulate pesticide use to the extent that their activities do not con-

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189. For a history of FMVSS 208, see Miller, Deflating the Airbag Pre-emption Controversy, 37 EMORY L.J. 897, 901-09 (1988); Wilton, Federalism Issues in "No Airbag" Tort Claims: Preemption and Reciprocal Comity, 61 NOTRE DAME L. REV. 1, 3-7 (1985).


192. Although most courts have reached this conclusion through a direct conflict preemption analysis, the Court may prefer to characterize it as a form of express preemption by an administrative regulation. For a discussion of administrative preemption, see Foote, Administrative Preemption: An Experiment in Regulatory Federalism, 70 VA. L. REV. 1429 (1984).

Conflict with FIFRA, the EPA retains exclusive control over pesticide labeling. Numerous persons have brought suit against pesticide manufacturers, claiming that EPA-approved warning labels were inadequate. As might be expected, pesticide manufacturers have argued that FIFRA preempts such claims.

The majority of courts have ruled in favor of the pesticide manufacturers, but a considerable minority have refused to preempt failure to warn claims. Virtually all courts have rejected express preemption and occupation of the field theories, electing instead to approach the preemption issue in terms of an actual conflict analysis. As in other preemption areas, most of these cases have turned on whether common-law claims are considered to be a form of regulation.

Applying the Cipollone Court’s preemption analysis to FIFRA, one would start with the statute’s preemption provision. This provision does not expressly preempt common-law claims; rather, it prohibits state law “requirements” inconsistent with federal safety standards. FIFRA’s legislative history is also silent on the question of whether Congress intended to preempt state law failure to warn claims. Nevertheless, the Court, if it chose, could argue that FIFRA expressly preempts failure to warn claims because they rely on a state requirement with respect to labeling that differs from the requirement imposed by the EPA.

194. Id. at §136v(a).
195. Id. at §136v(b).
199. But see Papas v. Upjohn Co., 926 F.2d 1019, 1025 (11th Cir. 1991) (holding that the federal government had occupied the entire field of pesticide labeling regulation).
202. One House committee report declared that “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.” See H.R. REP. No. 92-511, 92nd Cong., 1st Sess. 16 (1971). However, two Senate reports on FIFRA merely paraphrase section 136v(b), and do not discuss its potential effect on failure to warn claims. See SEN. REP. No. 92-838, 92nd Cong., 2d Sess. (1972), reprinted in 1972 U.S. CODE CONG. & ADMIN. NEWS 3993, 4021; SEN. REP. 92-970, 92nd Cong., 2d Sess. (1972), reprinted in 1972 U.S. CODE CONG. & ADMIN. NEWS 4092, 4128.
Drugs and Medical Devices

Pursuant to authority delegated to it by the Food, Drug and Cosmetic Act\textsuperscript{204} and the Public Health Service Act,\textsuperscript{205} the Food and Drug Administration (FDA) supervises the manufacture and marketing of most pharmaceutical products.\textsuperscript{206} In the past decade, there has been a good deal of litigation over pharmaceutical design and labeling. However, notwithstanding the pervasive nature of FDA regulation, most courts have not responded favorably to preemption arguments.\textsuperscript{207}

DPT Vaccine

A large number of preemption cases have involved claims against the manufacturers of DPT vaccine.\textsuperscript{208} These claims are based on both failure to warn and defective design. Failure to warn claims typically involve allegations that vaccine manufacturers have failed to provide adequate information about the inherent risk of DPT vaccine\textsuperscript{209} or have failed to communicate this information to vaccine users.\textsuperscript{210} Design defect claims allege that manufacturers have used a whole-cell pertussis vaccine design rather than less toxic split-cell or acellular vaccine designs.\textsuperscript{211}

Vaccine manufacturers have responded to failure to warn claims by contending that they should be immune from liability because their products contain

\begin{itemize}
\item 204. 21 U.S.C. §§301–393 (1982).
\item 205. 42 U.S.C. §§274b, 262 (1982).
\item 206. See Comment, \textit{Warnings and the Pharmaceutical Companies: Legal Status of the Package Insert}, 16 \textit{Houston L. Rev.} 140, 143 (1978) (the entire process of drug manufacture is closely regulated by the FDA).
\item 208. DPT vaccine provides protection against diphtheria, pertussis (whooping cough), and tetanus. Injuries from DPT are usually caused an adverse reaction to toxins contained in the pertussis component of the vaccine. See \textit{Graham v. Wyeth Laboratories, 666 F. Supp. 1483, 1485–6 (D. Kan. 1987)}.
\item 211. The pertussis component of DPT contains killed whole-cell organisms. These organisms contain toxins that, if not removed, can cause adverse reactions. See \textit{Toner v. Lederle Laboratories, 779 F.2d 1429, 1430 (9th Cir. 1986)}; \textit{Jones v. Lederle Laboratories, 695 F. Supp. 700, 702 (E.D.N.Y. 1988)}.
\item 212. Split-cell vaccines contain pertussis cells that have been fragmented by a chemical process. Split-cell vaccines contain fewer toxins than whole-cell vaccines. See \textit{White v. Wyeth Laboratories, Inc.}, 533 N.E.2d 748, 749 (Ohio 1988). Acellular vaccines contain antigens rather than whole cells of the pertussis organism. They are also less toxic than whole-cell vaccines. See \textit{David & Jalilian-Marian, DPT: Drug Makers' Liability in Vaccine Related Injuries, 7 J. Legal Medicine 187, 202 (1986)}.
\end{itemize}
FDA-approved warnings. However, most courts have rejected this argument. Manufacturers have resisted design defect claims by arguing that the FDA has only approved the manufacture of whole-cell pertussis vaccine, and therefore, design defect claims based on failure to use non-approved designs should be preempted. Once again, the courts have generally rejected the manufacturers' preemption argument.

Nothing in either the FDCA or the PHSA expressly preempts common-law claims. The legislative history of these provisions is also silent on the issue of preemption. The same is true of the National Childhood Vaccine Injury Act of 1986, which established a compensation scheme for victims of vaccine-related injuries. Consequently, *Cipollone*, with its emphasis on express preemption, is not likely to provide much help in resolving the OPT vaccine preemption controversy.

It has been suggested that the pervasiveness of federal regulation over pharmaceutical products in general, and vaccines in particular, indicates that the federal government has occupied the field. However, the Court has indicated in the past that common-law claims will not be preempted merely because of the existence of a comprehensive regulatory scheme. Thus, if the Court decides to preempt either failure to warn claims or design defect claims, it will probably have to do so on direct conflict grounds.


In the case of failure to warn claims, some commentators argue that tort liability would interfere with the FDA’s policy of “rational prescribing” by inducing drug manufacturers to place warnings on their products that exaggerate known risks or raise unwarranted concerns about unproven risks. However, this argument ignores the fact that the FDA has complete control over the content of drug labeling and can refuse to approve any proposed labeling. In addition, the FDA has the power to expressly preempt failure to warn claims if it feels that they interfere with its regulatory objectives.

It has also been suggested that design defect claims based on the use of whole-cell pertussis organisms in DPT vaccine undermine the FDA’s regulatory authority by allowing juries to substitute their judgment for that of the agency. However, as a number of courts have observed, the FDA cannot force a manufacturer to develop a safer design; it can only evaluate a design when a manufacturer submits it for approval. Therefore, an approved design is not necessarily safer than one that has not been approved. For this reason, a jury finding that an alternative design is safer than an approved design does not challenge the FDA’s regulatory authority unless the agency has actually disapproved the alternative design.

A final argument for preemption is that tort claims have caused vaccine manufacturers to raise prices substantially or leave the market altogether, thus threatening the supply of essential vaccines. However, the failure of Congress to preempt tort claims against vaccine manufacturers when it enacted the NCVIA suggests that Congress did not believe that tort actions would seriously interfere with the statute’s protective scheme for vaccine manufacturers.

**Medical Devices**

The Medical Device Amendments of 1976 authorize the FDA to approve the manufacture and sale of medical devices. Section 360k(a) specifically limits

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the power of states and localities to impose "requirements" for medical devices that are additional to, or inconsistent with, federal regulations.\textsuperscript{228} Furthermore, the FDA has concluded that this provision applies to court decisions, as well as legislation and administrative regulations.\textsuperscript{229} For this reason, the courts have usually accepted preemption arguments.\textsuperscript{230} Many of these cases have involved claims against tampon manufacturers for failure to warn against the risk of Toxic Shock Syndrome (TSS). The FDA has required manufacturers to warn about the risk of TSS, but it has not required that any specific language be used.\textsuperscript{2\textsuperscript{31}} So far, almost every court has found these claims to be preempted.\textsuperscript{232}

Injured consumers have also brought suit against the makers of intrauterine devices for failing to warn about the risks of pelvic inflammatory disease (PID) in some users. Most of these suits have involved the Cu-7 IUD, a plastic and copper device that releases small amounts of copper into the uterus.\textsuperscript{233} Because the Cu-7 IUD was not composed of chemically inert materials, the FDA approved it as a prescription drug, rather than as a medical device, in 1974.\textsuperscript{2\textsuperscript{34}} Since the Cu-7 IUD was not approved as a medical device, many courts have refused to apply section 360k(a), to these products.\textsuperscript{2\textsuperscript{35}} Moreover, a few courts have

\begin{itemize}
\item 228. Id., §360k(a).
\item 229. 21 C.F.R. §808.1(b) (1990).
\item 230. E.g., see Slater v. Optical Radiation Corp., 961 F.2d 1330, 1333 (7th Cir. 1992) (design defect claim against manufacturer of interocular lens preempted under "investigational device exemption"); but see Mitchell v. Iolab Corp., 700 F. Supp. 877, 879 (E.D. La. 1988) (claim against manufacturer of intraocular lens based on lack of informed consent not preempted).
\item 233. See Sychalla v. G.D. Searle & Co., 705 F. Supp. 1024, 1026 (D.N.J. 1988). The copper irritates the lining of the uterus and interferes with the implantation of the egg onto the uterine wall. Id.
\end{itemize}
rejected the FDA's interpretation of section 360k(a) and ruled that Congress did not intend for it to apply to common-law tort actions. This, of course, is inconsistent with the rationale of the tampon cases.

Like *Cipollone*, the medical device cases involve the interpretation of a specific preemption provision. If the Court follows *Cipollone*'s reasoning, it will probably apply an express preemption analysis. Although the text of section 360k(a) differs somewhat from the text of the cigarette labeling statute's preemption provision, it does use the term "requirement" to describe the sort of state action that is preempted. Thus, one might expect the Court to reach the same conclusion here as it did in *Cipollone*. Arguably, the case for preemption is even stronger than it was in *Cipollone*, because the regulatory agency involved has interpreted section 360k(a) to preempt common-law claims. For these reasons, the Court is likely to uphold preemption of common-law claims with respect to medical devices in cases where the manufacturer has complied with FDA design or labeling standards.

**Conclusion**

Justice Stevens's attempt to reach a reasonable compromise on the preemption issue in *Cipollone* ultimately satisfied no one. Advocates of a broad view of federal preemption undoubtedly preferred Justice Scalia's reasoning, whereas critics of preemption probably agreed with Justice Blackmun. It must be admitted that Justice Scalia's observations were both forceful and perceptive. Unfortunately, his analytical approach avoided any discussion of the policy concerns involved in *Cipollone*. For example, nothing was said about the effect of preemption on the accident-cost avoidance and risk-distribution objectives of product liability law. Justice Blackmun's opinion addressed these issues, and also showed some sensitivity to the concerns of federalism and state sovereignty. A preemption analysis should take these factors into account, at least in cases like *Cipollone*, where Congress has not made its intentions clear. For this reason, to this author at least, Justice Blackmun's reasoning was more persuasive.


237. See *Chevron USA, Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-43 (1984) (holding that courts should defer to agency interpretation of its statute, if its interpretation is a permissible one, when the statute is silent or ambiguous with respect to the issue in question). See also *Pierce, Chevron and Its Aftermath: Judicial Review of Agency Interpretation of Statutory Provisions*, 41 VAND. L. REV. 301, 305-08 (1988) (agencies, not courts, should resolve policy issues).

238. However, the Court would probably not treat the Cu-7 IUD as a medical device. Therefore, claims against the manufacturer of this particular IUD may not be preempted.