Reconceptualizing Federal Preemption of Tort Claims As the Government Standards Defense

Lars Noah

Repository Citation

Copyright © 1996 by the authors. This article is brought to you by the William & Mary Law School Scholarship Repository. 
https://scholarship.law.wm.edu/wmlr
RECONCEPTUALIZING FEDERAL PREEMPTION OF TORT CLAIMS AS THE GOVERNMENT STANDARDS DEFENSE

LARS NOAH*

I. INTRODUCTION .................................... 904

II. SUPREME COURT RECOGNITION OF PREEMPTION AS A
DEFENSE IN COMMON-LAW TORT ACTIONS .............. 907
   A. Traditional Reluctance To Find Preemption
      of Tort Claims .................................... 908
   B. Cipollone and Its Progeny .................. 913

III. COMPLICATIONS IN APPLYING THE DEFENSE .......... 925
   A. Express Preemption Provisions in Federal
      Safety Statutes .................................. 926
         1. Medical Devices .............................. 926
         2. Pesticides and Other Hazardous Chemicals . 928
         3. Planes, Trains, and Automobiles .......... 932
   B. Differentiating Between Various Degrees
      of Preemption .................................. 938
         1. The Strong Version: Foreclosing Tort
            Remedies Altogether ........................ 939

* Assistant Professor, University of Florida College of Law. B.A., 1986; J.D.,
1990, Harvard University. I would like to thank Richard Ausness, Joseph Little,
Barbara Noah, Richard Pearson, Walter Probert, and Sharon Rush for reviewing
earlier drafts of the manuscript.
Federal preemption arguments in tort actions have proliferated over the last few years. The Supreme Court's decision in Cipollone v. Liggett Group, Inc., announced on June 24, 1992, triggered a notable upsurge in the successful use of preemption as a defense to products liability lawsuits. In an opinion issued less than one month after Cipollone, Judge Jack Weinstein cautioned that "too ready a tendency to declare the state protective shield replaced by the still somewhat spotty federal protections will leave many injured persons without recourse." Rather than heed this admonition, a number of courts apparently have viewed Cipollone as a mandate to dismantle the protections of state tort law, even in extreme situations in which the defendant has not complied with the federal requirements that are being given preemptive effect.

One decision from the United States District Court for the District of Massachusetts, recently affirmed by the First Circuit, provides a remarkable illustration of this tendency. In Talbott v. C.R. Bard, Inc., a manufacturer of cardiac catheters successfully invoked the preemption defense in a wrongful death action notwithstanding that it had already pled guilty to numerous

charges of filing false statements with the Food and Drug Administration (FDA) and other statutory violations, infractions for which the company was ordered to pay $61 million in civil and criminal penalties. Although conceding that this decision “may cause some, including those who enacted the law, to question . . . complete preemption of private rights of action,” both courts in Talbott felt compelled to effectuate what they regarded as the “clearly expressed” intent of Congress.

Increasingly, defendants assert federal preemption as a defense in tort litigation involving, among others, medical devices, pesticides, hazardous chemicals, automobiles, and railroads. This practice represents a departure from the traditional application of preemption as a barrier only to conflicting state and local legislation and regulation, and, more disturbingly, the use of the preemption defense in tort litigation sometimes immunizes defendants from liability irrespective of their conduct. Indeed, as argued herein, lower courts have misinterpreted Cipollone by finding broad preemption of tort claims under other federal safety statutes when the Supreme Court really had nothing more than the “government standards” defense in mind, a defense that would absolve a company of liability only upon a showing of compliance with a relevant safety requirement.

Several questions concerning the proper application of the preemption defense remain unresolved. Because the scope of federal preemption primarily turns on matters of statutory construction, the subject defies simple unitary treatment. Indeed, as applied by the courts, the preemption defense lacks any single, coherent meaning. Nonetheless, these statutory preemption provisions pose important recurring problems. Perhaps the most relevant question concerns the consequence of finding express

4. Id. at 39; see also Barbara Carton, Bard Former Executives Are Convicted of Concealing Data on Heart Catheters, WALL ST. J., Aug. 25, 1995, at B2 (reporting that Bard “paid a $61 million fine to the government—the largest ever imposed nationwide in an FDA investigation”).


6. See infra part IV.B. The Court may clarify some of these issues later this Term. See Lohr v. Medtronic, Inc., 56 F.3d 1335 (11th Cir. 1995), cert. granted, 116 S. Ct. 806 (1996).
preemption in any particular case: Does such a finding mean that tort claims within the preempted domain may never be brought against a company or, instead, may a plaintiff sustain such claims by introducing evidence of noncompliance with federal safety standards? If the latter is true, does noncompliance defeat the preemption defense entirely, or is it the basis for the only type of claim that survives after Congress decides to preempt nonidentical state safety standards for a product or activity? This Article provides tentative answers to these and other perplexing questions.

Part II sketches the Supreme Court's changing treatment of the preemption defense. In the decade before Cipollone, the Court expressed a marked reluctance to find preemption of common-law tort claims, but its decisions from the last several Terms suggest a significant reversal in this attitude. Part III canvasses the lower courts' recent receptiveness to preemption arguments under various federal statutes, and it then categorizes these decisions into three competing interpretations of the preemption defense. One can differentiate among these interpretations based in large measure on whether compliance is relevant and on which party shoulders the burden of proof on that issue: (1) under the "strong" version, preemption entirely forecloses state tort remedies, even in cases in which the defendant has not complied with federal safety requirements; (2) under an "intermediate" version, plaintiffs may pursue claims within the preempted domain only for a violation of the federal safety requirements; (3) under the "weak" version, the defendant must prove compliance as a predicate for invoking the defense, and the plaintiff may still defeat preemption by showing that the defendant misled agency officials.

Finally, Part IV suggests alternatives to the exaggerated reading of Cipollone that a number of courts have adopted, especially those adhering to the strong version. For instance, to ensure that plaintiffs are not deprived entirely of a remedy, courts might reconsider the possibility of finding implied private rights of action under these federal statutes. Barring that, the Court's decision in Cipollone makes the most sense if interpreted as announcing a federal common-law rule accepting the government standards defense rather than as a true preemption de-
fense available in tort actions.

II. SUPREME COURT RECOGNITION OF PREEMPTION AS A DEFENSE IN COMMON-LAW TORT ACTIONS

Under the Supremacy Clause of the United States Constitution, federal law may supersede state law in a number of circumstances. First, Congress may, by statute, expressly preempt state law. Second, in the absence of express statutory preemption, congressional intent to preempt state law sometimes may be inferred when a comprehensive scheme of federal regulation leaves no room for supplementation by state law. Finally, even in the absence of implied preemption of an entire field of regulation, state law is preempted to the extent that it stands as an obstacle to the implementation of congressional objectives or actually conflicts with federal law. Although the Court's Supremacy Clause jurisprudence dates back nearly two centuries and the preemption of state law is at least half as old, federal preemption of tort claims is of a much more recent vintage. Apart from preemption of claims under certain federal

7. U.S. Const. art. VI, cl. 2. Arguably, preemption is not properly regarded as grounded in the Supremacy Clause at all. See Stephen A. Gardbaum, The Nature of Preemption, 79 Cornell L. Rev. 767, 782 (1994) ("[T]he power of preemption derives from the Necessary and Proper Clause; it is authorized as a means of effectuating other congressional powers. It has nothing to do with the Supremacy Clause."). Nonetheless, the Court continues to frame its analysis by reference to Article VI. See id. at 802.


13. See Gardbaum, supra note 7, at 785-805.
statutes that provided exclusive remedies, the Court did not directly confront this issue until 1984.

Over the course of the last decade, the United States Supreme Court has struggled to define the extent to which federal safety regulation may foreclose recovery under state tort law. Consistent with its oft-repeated presumption against the displacement of state authority, the Court initially declined to extend preemption to common-law tort actions. Although this reluctance was still evident to some extent in Cipollone, the Court's 1992 plurality decision represented a significant watershed because it found preemption of some tort claims. More recent decisions suggest that this controversial holding is now well-accepted by the members of the Court.

A. Traditional Reluctance To Find Preemption of Tort Claims

In Silkwood v. Kerr-McGee Corp., a closely divided Court addressed the availability of punitive damages in an action for radiation injuries. Just the previous year, in Pacific Gas & Electric Co. v. State Energy Resources Conservation & Development Commission, the Court had decided that the Atomic Energy

---

14. See infra notes 65-66 and accompanying text.
Act 22 impliedly preempted all state safety regulation of nuclear power plants. 23 Nonetheless, the majority in Silkwood held that the plaintiff's claim for punitive damages was not preempted under the Act. 24

While employed at a Kerr-McGee plant, Karen Silkwood was contaminated through exposure to plutonium. 25 After she died from unrelated causes, her father filed suit against the company and, after a jury trial, was awarded $505,000 in actual damages plus $10 million in punitive damages. 26 The district court denied Kerr-McGee's posttrial motions, rejecting the company's argument that its compliance with federal regulations precluded an award of punitive damages. 27 On appeal, the United States Court of Appeals for the Tenth Circuit reversed the bulk of the actual damages award because recovery for personal injuries was governed exclusively by the workers' compensation system, and the court also reversed the punitive damage award as preempted by federal law governing nuclear safety. 28

The Supreme Court disagreed with the Tenth Circuit's preemption holding. Notwithstanding the Court's sweeping preemption decision the previous year in Pacific Gas, the majority in Silkwood focused on the absence of any indication that Congress intended to foreclose common-law tort actions for radiation exposure injuries: "This silence takes on added significance in light of Congress' failure to provide any federal remedy for persons injured by such conduct. It is difficult to believe that Congress

23. See Pacific Gas, 461 U.S. at 212 ("[T]he Federal Government has occupied the entire field of nuclear safety concerns, except the limited powers expressly ceded to the States."). Nonetheless, the Court in Pacific Gas held that the challenged state law was not preempted because it addressed financial, rather than safety, matters. Id. at 207-08.
25. Id. at 241.
26. See id. at 241-45.
would, without comment, remove all means of judicial recourse for those injured by illegal conduct." The majority then noted that the passage and subsequent amendment of the Price-Anderson Act, which limited the industry's liability in the event of a nuclear accident, demonstrated that Congress assumed that tort claims for radiation injuries remained viable. Although it recognized that common-law claims still might be foreclosed if they created a conflict with federal standards or frustrated federal objectives, the majority decided that Silkwood's punitive damage claim was not impliedly preempted as falling within the field occupied by Congress.

Writing for the four dissenting members of the Court in *Silkwood*, Justice Powell focused on the incongruity of allowing a jury to assess what amounted to a $10 million fine against

31. See *Silkwood*, 464 U.S. at 251-56.

No doubt there is tension between the conclusion that safety regulation is the exclusive concern of the federal law and the conclusion that a State may nevertheless award damages based on its own law of liability. But . . . Congress intended to stand by both concepts and to tolerate whatever tension there was between them.

Id. at 256. In an earlier decision upholding the liability limitation of the Price-Anderson Act against constitutional challenge, the Court expressed its doubts "that the Due Process Clause in fact requires that a legislatively enacted compensation scheme either duplicate the recovery at common law or provide a reasonable substitute remedy." Duke Power Co. v. Carolina Envtl. Study Group, Inc., 438 U.S. 59, 88 (1978) (finding that the Act, in any event, provided a reasonably just substitute for the common-law remedies that it had replaced); see also Jenkins v. Amchem Prods., Inc., 886 P.2d 869, 884-86 (Kan. 1994) (rejecting due process challenge to statute interpreted as preempting tort claims), cert. denied, 116 S. Ct. 80 (1995). But cf. Ingraham v. Wright, 430 U.S. 651, 673 (1977) ("Among the historic liberties so protected was a right to be free from, and to obtain judicial relief for, unjustified intrusions on personal security."); Richard B. Stewart & Cass R. Sunstein, *Public Programs and Private Rights*, 95 HARV. L. REV. 1193, 1310 n.479 (1982) (suggesting that due process problems would result if common-law remedies are foreclosed without a substitute).

32. *Silkwood*, 464 U.S. at 256 ("We do not suggest that there could never be an instance in which the federal law would pre-empt the recovery of damages based on state law."). The Court, however, rejected the claim of the United States government, as amicus curiae, that the award of punitive damages conflicted with the federal remedial scheme, which was based on the imposition of civil fines for regulatory infractions. Id. at 257.

33. Id.
Kerr-McGee notwithstanding the company's compliance with federal safety standards. He also faulted the majority for its departure from the broad preemption of nuclear safety matters announced in Pacific Gas. Finally, Justice Powell suggested that, for purposes of the preemption analysis, punitive damages should be distinguished from compensatory damages, a point emphasized by Justice Blackmun in a separate opinion:

[T]he purpose of punitive damages is to regulate safety, whereas the purpose of compensatory damages is to compensate victims. Because the Federal Government does not regulate the compensation of victims, and because it is inconceivable that Congress intended to leave victims with no remedy at all, the pre-emption analysis established by Pacific Gas comfortably accommodates—indeed it compels—the conclusion that compensatory damages are not preempted whereas punitive damages are.

According to Justice Blackmun, the majority focused on the wrong question—namely, whether federal law preempted compensatory damages claims—in resolving the very different issue concerning preemption of punitive damages. As to the former

34. See id. at 283-84 (Powell, J., dissenting) ("This case is a disquieting example of how the jury system can function as an unauthorized regulatory medium. . . . [T]he Court attaches no importance to the fact that the AEC—the agency that adopted the regulations and was responsible for their enforcement—investigated the Silkwood incident and found no significant violation of its regulations.").

35. See id. at 279 (Powell, J., dissenting) ("The Court's decision today inexplicably shifts this burden [of proving an exception to broad federal preemption] to allow state law to prevail in the absence of a showing that Congress expressly had intended to pre-empt it."). Justice Powell discounted the relevance of the Price-Anderson Act as evidence of Congress's belief that the Atomic Energy Act had not preempted state common law. See id. at 279-80.

36. See id. at 275-76 & n.3, 282-83 (Powell, J., dissenting).

37. Id. at 263-64 (Blackmun, J., dissenting) (footnote omitted); see also id. at 265 ("It is incredible to suggest that Congress intended the Federal Government to have the sole authority to set safety regulations, but left intact the authority of States to require adherence to a different state standard through the imposition of jury fines."). Justice Blackmun conceded that even an award of compensatory damages would impact the operations of a nuclear facility, but he thought that this effect was sufficiently indirect to avoid being preempted. Id. at 263.

38. See id. at 267 (Blackmun, J., dissenting) ("[T]he Court's analysis never focuses on the real issue; its entire analysis proceeds as if pre-emption of punitive damages would require pre-emption of compensatory damages as well."); id. at 271 ("[T]he
question, though not at issue in the case, all members of the Court seemed to agree that sweeping federal preemption in the field of nuclear safety would not cut off the availability of compensatory damages under state tort law.\textsuperscript{39}

Six years later, in \textit{English v. General Electric Co.},\textsuperscript{40} the Supreme Court confirmed its hesitancy to find preemption of common-law claims. The Court unanimously held that federal occupation of the field of nuclear safety did not preempt a discharged employee's state law claim for intentional infliction of emotional distress.\textsuperscript{41} It decided that the effect of liability judgments on safety decisions by operators of nuclear facilities was "neither direct nor substantial enough to place petitioner's claim in the pre-empted field."\textsuperscript{42} The Court acknowledged its heavy reliance in \textit{Silkwood} on the legislative history of the Price-Anderson Act, and it conceded that this history offered no guidance on the treatment of the employee's claim now before it.\textsuperscript{43} The other factor deemed important by the majority in \textit{Silkwood}—namely, Congress's failure to provide a remedial substitute—was also absent because the whistleblower statute provided a federal remedy to discharged employees.\textsuperscript{44} Nonetheless, the Court in \textit{Eng-
lish embraced the assumption found in all three Silkwood opinions that compensatory damages claims survived the sweeping federal regulation of the nuclear safety field.\textsuperscript{45}

B. Cipollone and Its Progeny

Cipollone v. Liggett Group, Inc.,\textsuperscript{46} decided just two years after English, signalled a dramatic break from the consensus against the preemption of claims for compensatory damages apparent in Silkwood and English. The question before the Court was whether the Federal Cigarette Labeling and Advertising Act preempted common-law tort claims. Since 1965, Congress has prescribed the warnings that must appear on the labels of cigarette packages.\textsuperscript{47} Section 5(b) of the Act, as amended in 1969, provided that "[n]o 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."\textsuperscript{48}
Although a number of lower courts previously had found only implied preemption of common-law claims under this provision,49 the Supreme Court in Cipollone viewed its task as limited to interpreting the scope of the statutory language: "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted."50 In a plurality decision on the issue, a majority of the Justices agreed that the 1969 provision preempts products liability actions grounded on failure-to-warn (but not other) claims, even though the statute did not explicitly delineate any such claims as subject to preemption.51

Justice Stevens, writing for himself and three other Justices, focused on the breadth of the statutory phrase "requirement or prohibition," concluding that it "sweeps broadly and suggests no

---


50. Cipollone, 505 U.S. at 517 ("When Congress has considered the issue of pre-emption and has included in the enacted legislation a provision explicitly addressing that issue, . . . 'there is no need to infer congressional intent to pre-empt . . .'") (quoting California Fed. Sav. & Loan Ass'n v. Guerra, 479 U.S. 272, 282 (1987)).

51. See id. at 518-30 (concluding that breach of express warranty and certain fraudulent misrepresentation claims were not preempted). Justices Scalia and Thomas found an even broader preemptive effect in the statute and would have held all common-law claims preempted under the 1969 amendment. See id. at 544-56 (Scalia, J., concurring in the judgment in part and dissenting in part, joined by Thomas, J.). Justices Blackmun, Kennedy, and Souter would have held none of the claims preempted. See id. at 531-44 (Blackmun, J., concurring in part, concurring in the judgment in part, and dissenting in part, joined by Kennedy and Souter, JJ.). Because the Court was fragmented on the preemptive force of the 1969 provision, "and no single rationale explaining the result enjoy[ed] the assent of five Justices," Marks v. United States, 430 U.S. 188, 193 (1977), the holding may be viewed as the position taken by those concurring on the narrowest grounds, id.; see also Nichols v. United States, 114 S. Ct. 1921, 1926 (1994) ("This test is more easily stated than applied to the various opinions supporting the result in a particular case.").
distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common law rules." Although he conceded that "Congress was primarily concerned with positive enactments by States and localities," Justice Stevens believed that "the language of the Act plainly reaches beyond such enactments." He added, however, that section 5(b) does not preempt all common-law claims, only those predicated on a legal duty that constitutes a "requirement or prohibition" of the sort contemplated by that provision, as narrowly construed by the Court in light of the strong presumption against preemption.

Justice Stevens proceeded to evaluate each of the plaintiff's claims to determine whether it was preempted. First, and not surprisingly, he found preemption of the failure-to-warn claim. Second, in contrast, the plaintiff's express warranty claim was not preempted because the imposition of liability

52. Cipollone, 505 U.S. at 522 ("[C]ommon law damages actions of the sort raised by petitioner are premised on the existence of a legal duty and it is difficult to say that such actions do not impose 'requirements or prohibitions.'"); see also International Paper Co. v. Ouellette, 479 U.S. 481, 495 (1987) (holding that Clean Water Act preempted common-law nuisance suits against polluters in different states because of the potential regulatory effect of monetary or injunctive relief); San Diego Bldg. Trades Council v. Garmon, 359 U.S. 236, 247 (1959) (noting that an award of damages under state law can exert a regulatory effect).

53. Cipollone, 505 U.S. at 522 (adding that "it is the essence of the common law to enforce duties that are either affirmative requirements or negative prohibitions"). Although Congress did not explicitly reference common-law claims in the preemption provision, as it had done in other statutes, Justice Stevens pointed out that Congress also had not included a savings clause for such claims, as it has done in other statutes. Id. at 523 n.22. But cf. Bethlehem Steel Co. v. New York State Labor Relations Bd., 330 U.S. 767, 780 (1947) ("Congress can speak with drastic clarity whenever it chooses to assure full federal authority, completely displacing the States.").

54. Cipollone, 505 U.S. at 523-24. Justice Stevens noted, for instance, that section 5(b) would not preempt tort claims alleging defects in manufacturing or product design. Id. at 523.

55. Id. at 524.

Thus, insofar as claims under either failure to warn theory require a showing that respondents' post-1969 advertising or promotions should have included additional, or more clearly stated, warnings, those claims are pre-empted. The Act does not, however, pre-empt petitioner's claims that rely solely on respondents' testing or research practices or other actions unrelated to advertising or promotion. Id. at 524-25.
would arise from the breach of "a contractual commitment voluntarily undertaken" by the warrantor rather than from a violation of any requirement imposed under state law.\textsuperscript{56} Third, Justice Stevens subdivided the plaintiff’s fraudulent misrepresentation claim into two distinct theories: one alleging that the companies’ advertising neutralized the effect of the warnings mandated by Congress, a claim that was preempted just as was the failure-to-warn claim,\textsuperscript{57} and one alleging violations of a more general duty not to conceal material facts, a claim that was not preempted "insofar as those claims rely on a state law duty to disclose such facts through channels of communication other than advertising or promotion."\textsuperscript{58} For example, section 5(b) would not foreclose recovery on a fraud claim alleging a failure "to disclose material facts about smoking and health to an administrative agency" if state law created a duty to disclose such information.\textsuperscript{59}

Justice Blackmun, joined by Justices Kennedy and Souter, dissented from the Court’s holding that some tort claims were preempted. At the outset of his opinion, Justice Blackmun emphasized the traditional presumption against preemption:

The principles of federalism and respect for state sovereignty that underlie the Court’s reluctance to find pre-emption

\textsuperscript{56} Id. at 525-27. "[A] contractual requirement, although only enforceable under state law, is not ‘imposed’ by the state, but rather is ‘imposed’ by the contracting party upon itself." Id. at 526 n.24; see also American Airlines, Inc. v. Wolens, 115 S. Ct. 817, 824-26 (1995) (holding that Airline Deregulation Act did not preempt breach of contract claims involving frequent flyer program).

\textsuperscript{57} Cipollone, 505 U.S. at 527-28.

Such a claim is predicated on a state-law prohibition against statements in advertising and promotional materials that tend to minimize the health hazards associated with smoking . . . In this light it seems quite clear that petitioner’s first theory of fraudulent misrepresentation is inextricably related to petitioner’s first failure to warn theory, a theory that we have already concluded is largely pre-empted by § 5(b).

Id.

\textsuperscript{58} Id. at 528. "State law prohibitions on false statements of material fact do not create ‘diverse, nonuniform, and confusing’ standards. Unlike state law obligations concerning the warning necessary to render a product ‘reasonably safe,’ state law proscriptions on intentional fraud rely only on a single, uniform standard: falsity.” Id. at 529. Similarly, Justice Stevens took the position that the plaintiff’s claim of a conspiracy to commit such fraud was not preempted. Id. at 530.

\textsuperscript{59} Id. at 528.
where Congress has not spoken directly to the issue apply with equal force where Congress has spoken, though ambiguously. In such cases, the question is not whether Congress intended to pre-empt state regulation, but to what extent. We do not, absent unambiguous evidence, infer a scope of pre-emption beyond that which clearly is mandated by Congress' language.60

Given this reluctance, Justice Blackmun found Justice Stevens's reading of the preemption provision at issue in the case "little short of baffling," noting that the phrase "requirement or prohibition" is "far from unambiguous and cannot be said clearly to evidence a congressional mandate to pre-empt state common-law damages actions."61 Citing English,62 he also disagreed with Justice Stevens's premise that tort liability would exert the same sort of regulatory effect on companies as state statutes or regulations.63

More importantly, Justice Blackmun found it implausible that Congress intended to deprive injured persons of a compensatory mechanism: "Unlike the Court, I am unwilling to believe that

60. Id. at 533 (Blackmun, J., concurring in part, concurring in the judgment in part, and dissenting in part) (footnote omitted).

61. Id. at 534-35 (Blackmun, J., concurring in part, concurring in the judgment in part, and dissenting in part). Justice Blackmun observed that, in comparable circumstances, Congress has expressed its intention not to affect tort liability. Id. at 537 n.2; see also 15 U.S.C. § 4406(b)-(c) (1994) (The Comprehensive Smokeless Tobacco Health Education Act preempts only state statutes or regulations, and "[n]othing in this chapter shall relieve any person from liability at common law or under State statutory law to any other person."). This point, however, can cut two ways. See Cipollone, 505 U.S. at 523 n.22 ("Congress . . . was simply pre-empting particular common law claims, while saving others."); Gade v. National Solid Wastes Management Ass'n, 505 U.S. 88, 100-01 (1992) (plurality opinion).


63. Cipollone, 505 U.S. at 536-38 (Blackmun, J., concurring in part, concurring in the judgment in part, and dissenting in part). "The level of choice that a defendant retains in shaping its own behavior [in response to the imposition of tort liability] distinguishes the indirect regulatory effect of the common law from positive enactments such as statutes and administrative regulations." Id. at 536-37. Whether a manufacturer would have appreciably fewer options in selecting a response to a particular state statute remains unclear. For instance, just as they might be willing to absorb tort judgments rather than alter their products or conduct, companies might choose to pay fines for noncompliance with state statutes or regulations as a cost of doing business in that state. Thus, it is not obvious that state common law has any less of a direct regulatory effect than state positive law.
Congress, without any mention of state common-law damages actions or of its intention dramatically to expand the scope of federal pre-emption, would have eliminated the only means of judicial recourse for those injured by cigarette manufacturers' unlawful conduct." He noted that, in other statutes, Congress had established alternative remedies to substitute for preempted common-law claims. Indeed, most of the earlier preemption decisions involving tort claims had arisen in labor cases, and the Court repeatedly had held that the National Labor Relations Board (NLRB) enjoyed primary or exclusive jurisdiction in the field of labor-management relations and that the federal remedial scheme foreclosed actions under state law. In contrast,

64. Id. at 542 (Blackmun, J., concurring in part, concurring in the judgment in part, and dissenting in part). Of course, the plurality did not decide that all claims for relief were preempted but only those premised on a failure to warn. Justice Blackmun took issue, however, with Justice Stevens's varied treatment of different types of tort claims: "I can perceive no principled basis for many of the Court's asserted distinctions among the common-law claims, and I cannot believe that Congress intended to create such a hodge-podge of allowed and disallowed claims . . . ."


the Cigarette Labeling and Advertising Act provides no alternative remedies, and it delegates to the Federal Trade Commission only limited enforcement powers.

Justice Scalia, joined by Justice Thomas, went to the other extreme, dissenting from the Court's holding that some common-law claims were not preempted. At the outset of his opinion, Justice Scalia chided the other members of the Court for suggesting a special rule of narrow construction for statutory pre-emption provisions, though he found some comfort in the fact that Justice Stevens evidently proceeded to ignore this rule in order to find preemption of some common-law claims in this case. Applying ordinary principles of statutory construction, Justice Scalia concluded that all of the plaintiff's tort claims were preempted under section 5(b), including breach of express warranty and fraudulent misrepresentation. "The test for pre-emption in this setting should be one of practical compulsion, i.e., whether the [common] law practically compels the manufacturers to engage in behavior that Congress has barred the States from prescribing directly."
Complaining that Justice Stevens had employed different levels of generality to distinguish among various claims for recovery, Justice Scalia feared that the Court's judgment would pose serious interpretive difficulties for the lower courts, a concern echoed by Justice Blackmun. Although preemption decisions involving tort claims against cigarette manufacturers have abated for the moment, the courts have struggled to make sense of *Cipollone* in other contexts.

In *CSX Transportation, Inc. v. Easterwood*, a case decided during the following Term, a clear majority of the Court accepted the basic premise of the plurality's decision in *Cipollone*, namely, that a statutory preemption provision could preempt tort claims "expressly" even if not specifically enumerated by Congress. The Federal Railroad Safety Act of 1970 (FRSA)
calls for national uniformity in "laws, rules, regulations, orders, and standards relating to railroad safety."\textsuperscript{81} Citing Cipollone, the Court observed that the "duties imposed on railroads by the common law fall within the scope of these broad phrases."\textsuperscript{82}

The Easterwood litigation arose from a collision between a CSX train and a truck driven by the plaintiff's husband. In her wrongful death action, the plaintiff alleged that CSX was negligent in two respects: failing to maintain adequate warning devices at the railroad crossing and operating its train at an excessive speed.\textsuperscript{83} The district court granted the defendant's motion for summary judgment as to both claims, but the United States Court of Appeals for the Eleventh Circuit decided that only the excessive speed claim was preempted.\textsuperscript{84} The Supreme Court affirmed, agreeing that the grade crossing negligence claim was not preempted because no federal regulation governed the use of warning devices at this particular crossing.\textsuperscript{85} Although it con-

\textsuperscript{81} 49 U.S.C.A. § 20106 (West 1995). The substantially identical earlier version of the provision that was before the Court in Easterwood provided as follows:

The Congress declares that laws, rules, regulations, orders, and standards relating to railroad safety shall be nationally uniform to the extent practicable. A State may adopt or continue in force any law, rule, regulation, order, or standard relating to railroad safety until such time as the Secretary has adopted a rule, regulation, order, or standard covering the subject matter of such State requirement. A State may adopt or continue in force an additional or more stringent law, rule, regulation, order, or standard relating to railroad safety when necessary to eliminate or reduce an essentially local safety hazard, and when not incompatible with any Federal law, rule, regulation, order, or standard, and when not creating an undue burden on interstate commerce.


\textsuperscript{83} Easterwood, 113 S. Ct. at 1737. In the immediately preceding paragraph of its opinion, the Court reiterated its oft-stated reluctance to find federal preemption of "a subject traditionally governed by state law." \textit{Id.} Later it observed that § 434 "displays considerable solicitude for state law in that its express pre-emption clause is both prefaced and succeeded by express saving clauses." \textit{Id.} at 1738.

\textsuperscript{84} \textit{Id.} at 1736.


\textsuperscript{86} Focusing on the word "covering" in § 434, Easterwood, 113 S. Ct. at 1738, the Court found that none of the federal regulations cited by CSX covered the safety of grade crossings of the type where this accident occurred. \textit{Id.} at 1742. First, the Court discounted the force of regulations requiring that states work to improve traffic safety as a condition for receiving federal highway funds. \textit{Id.} at 1739 ("In
ceded that Department of Transportation (DOT) regulations governed the selection and installation of warning devices at certain grade crossings and that these would preempt common-law tort claims where applicable, the Court found that the regulations did not apply to the particular crossing in question.86

The Court did, however, hold that the plaintiff’s negligence claim premised on excessive speed was preempted.87 DOT regulations establish maximum operating speeds for freight and passenger trains for each class of railroad track.88 The plaintiff conceded that CSX’s train was traveling at less than sixty miles per hour, the maximum permitted for a class four track, but she nonetheless argued that CSX breached a common-law duty to operate its train at a safe speed.89 Although the Court recognized that the regulation only purported to set a ceiling on train speeds, it found that these speeds were established to account for safety concerns and, therefore, precluded additional state regulation on the subject.90 The Court also rejected Ms.
Easterwood's effort to invoke the statute's savings clause to avoid preemption of her excessive speed claim.91

Most recently, in Freightliner Corp. v. Myrick,92 a unanimous Court held that the National Traffic and Motor Vehicle Safety Act of 1966 (NTMVSA)93 did not preempt certain design defect claims against manufacturers of eighteen wheel tractor-trailers.94 Ben Myrick suffered severe, permanent injuries when his vehicle collided with a truck that had jackknifed into on-coming traffic, and he sued the truck's manufacturer for its failure to install an anti-lock braking system (ABS).95 The district court granted the manufacturer's motion for summary judgment based on federal preemption, but the United States Court of Appeals for the Eleventh Circuit reversed.96 The Supreme Court affirmed, rejecting both express and implied preemption arguments because there was no federal requirement then in effect governing the brakes used on trucks.97

91. See id. at 1743 ("The state law on which respondent relies is concerned with local hazards only in the sense that its application turns on the facts of each case. The common law of negligence provides a general rule to address all hazards caused by lack of due care, not just those owing to unique local conditions.").
   (b) Preemption.—(1) When a motor vehicle safety standard is in effect under this chapter, a State or political subdivision of a State may prescribe or continue in effect a standard applicable to the same aspect of performance of a motor vehicle or motor vehicle equipment only if the standard is identical to the standard prescribed under this chapter. . . .
   (e) Common law liability.—Compliance with a motor vehicle safety standard prescribed under this chapter does not exempt a person from liability at common law.
94. See Freightliner, 115 S. Ct. at 1487-88. Justice Scalia concurred in the judgment, but without comment. Id. at 1488 (Scalia, J. concurring).
95. Id. at 1495.
97. Freightliner, 115 S. Ct. at 1487-88. DOT had promulgated a regulation that would have required anti-lock brakes on trucks, but it suspended the operation of this rule after a successful judicial challenge by the industry. Id. at 1486. The National Highway Traffic Safety Administration (NHTSA) had not undertaken new
Because it found no federal safety standard that would trigger the statute's preemption provision, the Court in Freightliner did not reach Myrick's separate argument that tort claims would never be preempted by the NTMVSA, either because the term "standard" in the preemption provision did not include common-law claims or because the savings clause explicitly preserved "any liability under common law." Nonetheless, it also considered the possibility that such claims might be impliedly preempted even if not within the express terms of the statute. The Court explained that Cipollone did not "announce[e] a categorical rule precluding the coexistence of express and implied pre-emption"; rather, it meant only that an express preemption provision "supports a reasonable inference" that "Congress did not intend to pre-empt other matters." Ultimately, the Court in Freightliner rejected the implied preemption arguments for the same reason that the express preemption defense failed, namely, the absence of any federal requirement with which a common-law tort judgment might conflict. Even so, by considering implied preemption arguments in a case in which Congress had

rulemaking on this issue, but the Court refused to find preemption premised on a conscious decision by the Agency that no regulation was necessary. Id. at 1487.

98. Id. at 1487 n.3. Even so, a few weeks after issuing its opinion in Freightliner, the Court vacated and remanded for further consideration a decision that had rejected a preemption defense on these grounds. See Hernandez-Gomez v. Leonardo, 884 P.2d 183, 190-91 (Ariz. 1994) (denying preemption even though defendant had complied with the applicable NHTSA standard), vacated sub nom. Volkswagen of Am., Inc. v. Hernandez-Gomez, 115 S. Ct. 1819 (1995). Although it is hazardous to read anything into such a disposition, see Henry v. City of Rock Hill, 376 U.S. 776, 777 (1964), the decision to vacate and remand the case for further consideration suggests that the Court might support preemption under the NTMVSA in cases in which federal rules apply, see generally Arthur D. Hellman, The Supreme Court's Second Thoughts: Remands for Reconsideration and Denials of Review in Cases Held for Plenary Decisions, 11 HASTINGS CONST. L.Q. 5, 17 (1983) (finding that "a reconsideration order, if not tantamount to reversal, does indicate a strong leaning in that direction," but adding that lower courts frequently adhere to their original judgments). The remand, however, may reflect only a direction to reconsider the possibility of implied preemption, something that the Arizona court had refused to do on the strength of Cipollone. See Hernandez-Gomez, 884 P.2d at 188-89 & n.13.


100. Id. ("First, it is not impossible for petitioners to comply with both federal and state law because there is simply no federal standard for a private party to comply with. . . . [Second, a] finding of liability against petitioners would undermine no federal objectives or purposes with respect to ABS devices, since none exist.").
spoken to the issue, the Court weakened the one aspect of its decision in Cipollone that appeared to make the test for preemption of tort claims somewhat more stringent than it had been under prior decisions.101

Taken together, the Supreme Court's most recent preemption decisions stand in sharp contrast to its clear reluctance in Silkwood and English to find tort claims foreclosed by federal law. Nor can these disparate decisions be reconciled by noting that the earlier cases involved only implied preemption, while Cipollone and its progeny arose under explicit statutory preemption provisions. The provisions in the latter cases made no mention of tort claims, and the Court in Freightliner entertained both express and implied preemption arguments. At the most fundamental level, therefore, Cipollone can be understood as a repudiation of the consensus evident in Silkwood and English that tort claims did not have a sufficiently direct regulatory effect to fall prey to a federal preemption defense. As evidenced by Easterwood and Freightliner, however, in each case courts must still decide whether federal requirements apply to trigger preemption and which types of claims are then foreclosed. This task will, of course, vary under different statutory provisions.

III. COMPLICATIONS IN APPLYING THE DEFENSE

More than three years have elapsed since Cipollone was decided. As feared by a number of the Justices in that case, the lower courts have struggled to apply the plurality's judgment in other contexts.102 Preemption provisions appear in statutes regulating, inter alia, medical devices, pesticides and other hazardous chemicals, and various modes of transportation. Because these provisions express congressional intent in different terms and, in some cases, are accompanied by savings clauses of varying


102. See Cipollone v. Liggett Group, Inc., 505 U.S. 504, 543-44 (1992) (Blackmun, J., concurring in part, concurring in the judgment in part, and dissenting in part) ("I can only speculate as to the difficulty lower courts will encounter in attempting to implement the Court's decision."); id. at 555-56 (Scalia, J., concurring in the judgment in part and dissenting in part).
breadth, courts have encountered difficulties when interpreting the proper scope of federal preemption. A number of lower courts have read *Cipollone* quite expansively, finding preemption of most or all tort claims, sometimes even in cases in which the defendants have not complied with the applicable federal safety requirements.

A. Express Preemption Provisions in Federal Safety Statutes

This section provides a brief summary of recent lower court decisions applying express preemption provisions in the context of tort litigation as a foundation for exploring certain recurring questions in the sections that follow. Companies have raised the preemption defense in recent litigation involving medical devices, pesticides, hazardous substances, automobiles, boats, railroads, and airlines. Although the courts in these cases are interpreting the language of different statutes, several common issues arise.

1. Medical Devices

Both before and after *Cipollone*, express preemption as a defense to tort liability has arisen most frequently in products liability litigation against manufacturers of medical devices. Unlike most other industries subject to regulation by the FDA, medical device manufacturers benefit from a statutory provision expressly preempting nonidentical state requirements.\(^{103}\)

---

103. The applicable section states:
Except as provided in subsection (b) [which allows States to petition the agency for an exemption], 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.

most without exception, the lower courts have held that this provision preempts tort claims to the extent that the FDA regulates a particular medical device.\textsuperscript{104}

For instance, courts have dismissed claims against tampon manufacturers for failure to warn of toxic shock syndrome because the FDA imposes specific warning requirements for these products.\textsuperscript{105} More recent preemption decisions involving medical devices are even more sweeping, holding that premarket approval by the FDA defeats a variety of common-law claims, including those alleging defective design, testing, manufacture, or labeling.\textsuperscript{106}

Courts have been only slightly more hesitant to find preemption of tort claims against manufacturers of devices distributed without full premarket approval, such as those being used in


\textsuperscript{105} See Moore v. Kimberly-Clark Corp., 867 F.2d 243, 246-47 (5th Cir. 1989); Sloman v. Tambrands, Inc., 841 F. Supp. 699, 701 n.2 (D. Md. 1993) (listing cases). Under the regulation, every tampon package must, at a minimum, include the following statement: "ATTENTION: Tampons are associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and save the enclosed information." 21 C.F.R. § 801.430(c),(e) (1995). The accompanying package insert must include a number of detailed statements describing the precise risks of TSS and instructions for minimizing those risks. Id. § 801.430(d).

clinical trials pursuant to the FDA's investigational device exemption or devices cleared for marketing as substantially equivalent to an existing product. Although no court has suggested that federal law preempts all tort claims against all devices, courts have reached a consensus that such claims are preempted to the extent that the FDA regulates a particular device, whether through published regulations or through the individualized review and approval of an application to market a medical device.

2. Pesticides and Other Hazardous Chemicals

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), enacted in 1947, governs the registration and labeling of pesticides. The Environmental Protection Agency (EPA) currently implements these requirements. FIFRA includes a


provision preempting nonidentical state labeling and packaging requirements, but the preemption provision is coupled with a limited savings clause expressly permitting state regulation of the sale and use of pesticides.\footnote{111}

The lower courts remain divided about whether this provision of the statute preempts common-law tort claims against pesticide manufacturers, especially failure-to-warn claims. Before \textit{Cipollone}, many courts declined to find either express or implied preemption of tort claims against pesticide manufacturers,\footnote{112} although several others found implied preemption of failure-to-warn claims.\footnote{113} In the wake of \textit{Cipollone}, however, most courts

\begin{itemize}
  \item [(a)] In general 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.
  \item [(b)] Uniformity 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.
\end{itemize}


now find express preemption of these claims under FIFRA,114 a reversal that critics have greeted with some cynicism.115

One of the most broadly applicable statutes governing warning labels on consumer products is the Federal Hazardous Substances Labeling Act of 1960.116 Although it excludes food, drugs, cosmetics, tobacco, pesticides, and fuel, the Act governs all substances that are toxic, corrosive, irritating, or flammable, including products such as household cleaners and paint removers.117 The Consumer Product Safety Commission (CPSC) enforces the statute, which now is designated as the Federal Hazardous Substances Act (FHSA).118

The FHSA includes a provision preempting nonidentical state warning label requirements,119 though the courts have been
divided over its application to positive enactments by states and localities. Although courts previously had rejected the pre-emption defense to tort claims, the most recent decisions have found FHSA preemption in such cases.

2. Although courts previously had rejected the pre-emption defense to tort claims, the most recent decisions have found FHSA preemption in such cases.


120. Compare Toy Mfrs. of Am., Inc. v. Blumenthal, 986 F.2d 615, 620-24 (2d Cir. 1992) (holding that FHSA does not preempt Connecticut law requiring a warning of the risk to children under the age of three of choking on small parts of toys intended for use by older children) and Chemical Specialties Mfrs. Ass'n v. Allenby, 958 F.2d 941, 949-50 (9th Cir.) (holding that FHSA does not preempt carcinogen warning requirements of California's Proposition 65), cert. denied, 506 U.S. 825 (1992) with Chemical Specialties Mfrs. Ass'n v. Clark, 482 F.2d 325, 327-28 (5th Cir. 1973) (per curiam) (holding that local ordinance requiring detergent labeling to list ingredients was expressly preempted).


3. Planes, Trains, and Automobiles

The Airline Deregulation Act of 1978 (ADA) added a preemption provision to the Federal Aviation Act (FAA), a statute that already included a savings clause for existing common-law remedies. As the Supreme Court held in two recent decisions, the ADA broadly preempts state laws relating to rates, routes, or services. Although tort claims were not at issue in either case, the Court suggested that such claims would not be preempted. In fact, lower courts generally have rejected arguments that the ADA preempts personal injury claims against airline carriers, though the statute may foreclose claims


124. 49 U.S.C.A. § 40120(c) (West 1995) (“A remedy under this part is in addition to any other remedies provided by law.”). This provision was previously codified at 49 U.S.C. app. § 1506 (1988) (current version at 49 U.S.C.A. § 40120(c)) (“Nothing contained in this chapter shall in any way abridge or alter the remedies now existing at common law or by statute, but the provisions of this chapter are in addition to such remedies.”).

125. See American Airlines, Inc. v. Wolens, 115 S. Ct. 817 (1995) (holding that ADA preempted claims under state consumer protection statute but not breach of contract claims involving frequent flyer program); Morales v. Trans World Airlines, Inc., 504 U.S. 374, 383-85 (1992) (observing that the words “relating to” in the statute “express a broad pre-emptive purpose,” and discounting the relevance of the older savings clause, characterizing it as a “relic of the pre-ADA/no pre-emption regime”).

126. See Wolens, 115 S. Ct. at 825 n.7 (“American [Airlines] does not urge that the ADA preempts personal injury claims relating to airline operations.”); id. at 830 (O'Connor, J., concurring in the judgment in part and dissenting in part) (“Morales does not mean that personal injury claims against airlines are always preempted.”).

127. See, e.g., Hodges v. Delta Airlines, Inc., 44 F.3d 334, 340 (5th Cir. 1995) (en banc) (finding no preemption of personal injury claim alleging negligence by airline in allowing case of rum to be stowed in overhead storage compartment); Smith v. America West Airlines, Inc, 44 F.3d 344, 347 (5th Cir. 1995) (en banc) (finding no preemption of claim alleging that airline was negligent in failing to prevent visibly deranged passenger from boarding and then attempting to hijack aircraft); Jamerson v. Atlantic S.E. Airlines, 860 F. Supp. 821, 824-26 (M.D. Ala. 1994) (listing cases finding no preemption); Stagl v. Delta Air Lines, Inc., 849 F. Supp. 179, 182 (E.D.N.Y. 1994) (finding no preemption of claim alleging negligence of airline in fail-
arising more directly from the "services" provided by a carrier.\textsuperscript{128} The Act, however, does not expressly or impliedly pre-empt design defect claims against airline manufacturers.\textsuperscript{129}

As discussed in connection with \textit{CSX Transportation, Inc. v. Easterwood},\textsuperscript{130} the Federal Railroad Safety Act includes a pre-emption provision.\textsuperscript{131} In light of the Supreme Court's decision in \textit{Easterwood}, lower courts have held excessive speed claims preempted, as long as the train was not operated in violation of the applicable federal speed limit.\textsuperscript{132}
Courts have experienced somewhat greater difficulty in deciding whether the FRSA preempts inadequate warning device claims. In *Easterwood*, the Supreme Court found no preemption because no federal requirement applied to the grade crossing involved in that case, but the Court suggested that such claims would be preempted if the federal government prescribed the choice of warning devices as a condition of funding a highway improvement project.\(^{133}\) Pursuant to DOT regulations, the warning devices installed at grade crossings must include automatic gates with flashing lights or else meet the approval of the Secretary of Transportation, if federal funds participate in the project.\(^{134}\) Courts, however, have rejected preemption arguments in recent cases in which the DOT had passively accepted rather than specifically approved the proposed warning device,\(^{135}\) federal funding had not yet been authorized,\(^{136}\) or, al-

---

133. See *Easterwood*, 113 S. Ct. at 1741 ("[F]or projects in which federal funds participate in the installation of warning devices, the Secretary has determined the devices to be installed and the means by which railroads are to participate in their selection."); see also Lusby v. Union Pac. R.R., 4 F.3d 639, 641-42 (8th Cir. 1993) (rejecting preemption defense where there was no evidence of federal funding); Richard Perez-Pena, *Experts Fault U.S. on Safety Rules for Railroads*, N.Y. TIMES, Feb. 25, 1996, at 26.


135. See, e.g., *Shots v. CSX Transp.*, Inc., 38 F.3d 304, 307-09 (7th Cir. 1994) (noting that the "Secretary has never expressed his approval of cross-bucks or of any other specific warning device at this crossing," and rejecting the suggestion that his acceptance of a 1975 agreement between railroad and state constituted such approval); Eldridge v. Missouri Pac. R.R., 832 F. Supp. 328, 335 (E.D. Okla. 1993).

136. See, e.g., *Armijo v. Atchison, T. & S.F. Ry.*, 27 F.3d 481, 482-83 (10th Cir. 1994) (remanding preemption question to trial court for purposes of determining whether federal funds had participated in the installation of warning devices at the grade crossing before the date of the accident); Hatfield v. Burlington N. R.R., 1 F.3d 1071, 1072 (10th Cir. 1993) ("[M]ore than a casual financial connection between
though federally approved and funded, the improvement project had not been completed at the time of the accident.137 Products liability claims against locomotive manufacturers have been held impliedly preempted by a different federal statute.138

As previously noted in the discussion of *Freightliner Corp. v. Myrick,*139 the NTMVOA contains both a preemption provision and a savings clause.140 The Court in *Freightliner* did not, however, decide whether this statute preempts common-law claims because it found no federal requirement applicable in that case.141 Before *Cipollone,* many lower courts had found implied preemption of some tort claims, though only those claims premised on a failure to install airbags.142 Because the DOT had

---


139. 115 S. Ct. 1483 (1995); see supra notes 92-101 and accompanying text.

140. 49 U.S.C.A. § 30103 (West 1995); see supra note 93 for the text of the provision.

141. See *Freightliner,* 115 S. Ct. at 1487 n.3; see also supra note 98 (describing subsequent remand by the Court of a decision rejecting preemption under the Act).

decided to allow manufacturers to choose among different passive restraint systems rather than mandate the use of airbags, courts in these cases felt that the plaintiffs' claims would frustrate the federal government's decision, and the courts disagreed that the statute's savings clause would preserve such claims.\textsuperscript{143}

In contrast, lower courts generally did not hold preempted tort claims involving other aspects of automobile safety and design, even in cases in which federal regulations applied.\textsuperscript{144} After \textit{Cipollone}, this division has remained, and courts have accepted implied (or sometimes express) preemption in cases alleging a failure to install airbags\textsuperscript{145} but rejected the defense in other

\textsuperscript{143} See, e.g., Pokorny, 902 F.2d at 1125 & n.10; Taylor, 875 F.2d at 827 & n.20 (stating that savings clause could not preserve common-law claims that would create an actual conflict with federal law); Wood, 865 F.2d at 415 (quoting with approval the position taken in one amicus brief that "general savings clauses may not be read literally to permit common law actions that contradict and subvert a [federal] statutory scheme").


crashworthiness cases.\textsuperscript{146}

Much like the NTMVSA, the Federal Boat Safety Act (FBSA)\textsuperscript{147} includes a provision preempts nonidentical state performance and safety standards\textsuperscript{148} as well as a savings clause preserving tort liability.\textsuperscript{149} Citing the airbag decisions as persuasive authority, many courts have held that the Act preempts design defect claims for failure to install propeller guards by virtue of the United States Coast Guard's decision not to mandate them.\textsuperscript{150} In contrast, courts generally have rejected

\begin{footnotesize}


\textsuperscript{148} The FBSA states:

\begin{quote}
Unless permitted by the Secretary under section 4305 of this title, a State or political subdivision of a State may not establish, continue in effect, or enforce a law or regulation establishing a recreational vessel or associated equipment performance or other safety standard or imposing a requirement for associated equipment (except insofar as the State or political subdivision may, in the absence of the Secretary's disapproval, regulate the carrying or use of marine safety articles to meet uniquely hazardous conditions or circumstances within the State) that is not identical to a regulation prescribed under section 4302 of this title.
\end{quote}

\textsuperscript{149} Id. § 4306 (1988).

\end{footnotesize}
preemption defenses to design defect claims premised on the installation of faulty equipment.\(^{151}\)

**B. Differentiating Between Various Degrees of Preemption**

Although courts have generally accepted, at least under some circumstances, preemption of common-law claims under these various statutory provisions, important questions remain unresolved. One of the most immediate quandaries concerns the practical consequences of a finding that a federal statute preempts one or more claims in a particular case. For instance, does preemption mean that failure-to-warn or other tort claims may never be brought against companies, or, instead, may a plaintiff sustain such a claim by introducing evidence of noncompliance with agency regulations? If the latter is true, then who bears the burden of proof if the plaintiff alleges noncompliance? Must the defendant prove compliance as a predicate for invoking a preemption defense, or does it become an element of the plaintiff's burden when attempting to assert a claim in the face of such a defense? More fundamentally, is such a defense even properly characterized as one based on “preemption,” or have the courts converted these express preemption provisions into nothing more than a “government standards” defense?

The lower courts have offered varied answers to these questions, suggesting three different conceptions of federal preemption as applied in the context of tort litigation. As more fully developed in the sections that follow, one may differentiate between strong, intermediate, and weak versions of the preemption defense, based in part on whether compliance with federal safety standards is relevant and which party shoulders the burden of proof on that issue.\(^{152}\) A court's choice of approaches from among these three competing conceptions of the preemption defense may have profound consequences for litigants in

---


152. A chart comparing these three versions appears in Table 1. See infra p. 959.
tort cases.

1. The Strong Version: Foreclosing Tort Remedies Altogether

In the wake of Cipollone, several lower courts have suggested that preemption would completely cut off common-law claims whenever federal safety requirements apply, whether or not a particular company has strictly complied with those requirements. This view is most noticeable in recent medical device cases. For example, in Reeves v. AcroMed Corp., the United States Court of Appeals for the Fifth Circuit declined the plaintiff's "invitation to create an unwieldy exception to [preemption] in cases where manufacturers attempt to mislead the FDA or violate FDA regulations." One possible explanation for the

153. See, e.g., Gile v. Optical Radiation Corp., 22 F.3d 540, 544 (3d Cir.) ("[O]nly the government has a right to take action with respect to adulterated products."); cert. denied, 115 S. Ct. 429 (1994); Mendes v. Medtronic, Inc., 18 F.3d 13, 19 n.4 (1st Cir. 1994). In Mendes, the First Circuit stated:

One way to ensure that a factfinder applies a standard not adding to or differing from FDA regulations is to supplant the common law standard with FDA's requirements. We find nothing to support that Congress intended such a radical, unwieldy form of preemption, however, particularly where Congress did not intend to create a private right of action under the [FD&C] Act.

Mendes, 18 F.3d at 19 n.4. One should note, however, that the courts' precise resolution of this question is unclear because the plaintiffs in many of these cases never alleged a failure to comply with agency requirements. See, e.g., id. at 19-20; see also English v. Mentor Corp., 67 F.3d 477, 481 (3d Cir. 1995), petition for cert. filed, 133 L. Ed. 2d 594 (1995).


155. Id. at 307 ("Allowing a jury or court to second-guess the FDA's enforcement of its own regulations contravenes Congress' expressly stated intent in § 360k(a) to eliminate attempts by states to impose conflicting requirements on medical device manufacturers."); see also Lohr v. Medtronic, Inc., 56 F.3d 1335, 1343 (11th Cir. 1995) (holding that "preemption under the MDA cannot be defeated by a common-law suit alleging a violation of the statutory standards"); cert. granted, 116 S. Ct. 806 (1996); Stamps v. Collagen Corp., 984 F.2d 1416, 1425 (5th Cir.) ("If defendant is correct, [plaintiff] has no cause of action."); cert. denied, 114 S. Ct. 84 (1993); King v. Collagen Corp., 983 F.2d 1130, 1139 (1st Cir.) ("If defendant is correct, [plaintiff] has no cause of action."); cert. denied, 114 S. Ct. 84 (1993); Richman v. W.L. Gore & Assocs., 881 F. Supp. 895, 902 (S.D.N.Y. 1995) ("This Court must leave to the FDA an investigation of an alleged failure to comply with FDA standards, because otherwise it might create a requirement in addition to the mandates of the MDA."); Powers v. Optical Radiation Corp., 44 Cal. Rptr. 2d 485, 490-92 (Ct. App.
strong version of preemption is that an agency's approval of a specific product's labeling and design provides seemingly unsailable evidence of compliance with applicable safety standards.\textsuperscript{156} Courts have not, however, restricted their application of the strong version of the preemption defense to situations in which a federal administrative agency has given its actual approval.\textsuperscript{157}

In \textit{Talbott v. C.R. Bard, Inc.},\textsuperscript{158} a device manufacturer successfully invoked the preemption defense in a wrongful death action notwithstanding the fact that it had pled guilty to numerous charges of violating FDA requirements and had paid more than $60 million in penalties.\textsuperscript{159} As the court explained, the MDA's preemption provision "manifests a decision by Congress to replace completely the private rights of action usually available under state law with civil and criminal enforcement by the federal government."\textsuperscript{160} Although recognizing that this was "a particularly poignant case," the court in \textit{Talbott} felt compelled to

\begin{itemize}
  \item \textsuperscript{156} See \textit{Welchert v. American Cyanamid, Inc.}, 59 F.3d 69, 73 (8th Cir. 1995) ("To hold otherwise would be to allow state courts to sit, in effect, as super-EPA review boards that could question the adequacy of the EPA's determination of whether a pesticide registrant successfully complied with the specific labeling requirements of its own regulations."); \textit{National Bank of Commerce v. Kimberly-Clark Corp.}, 38 F.3d 988, 998-99 (8th Cir. 1994) (Loken, J., concurring) (concluding that "the agency's finding of substantial equivalence necessarily reflected a determination that the labels comply with" the FDA's tampon labeling regulation and rejecting Judge Heaney's contention, \textit{id.} at 996, that plaintiff's expert created a genuine issue of material fact for the jury about whether the product actually complied with that regulation); \textit{id.} at 994 n.4 ("[Actual agency approval eliminates any possible claims under state tort law for failure to comply with federal requirements.").
  
  \item \textsuperscript{157} See, e.g., \textit{Mendes}, 18 F.3d at 17-19 (holding that FDA premarket clearance would suffice); \textit{Ouellette v. Union Tank Car Co.}, 902 F. Supp. 5, 9 (D. Mass. 1995) ("All plaintiff's claims against UTC are preempted by the FRSA regardless of whether the placement of the handrail was in compliance with the federal regulations."); \textit{Kennan v. Dow Chem. Co.}, 717 F. Supp. 799, 809-10 (M.D. Fla. 1989) (in holding that plaintiff's failure-to-warn claims were expressly preempted under FIFRA, court viewed proffered evidence concerning EPA approval as irrelevant).
  
  \item \textsuperscript{158} 865 F. Supp. 37 (D. Mass. 1994), \textit{aff'd}, 63 F.3d 25 (1st Cir. 1995), \textit{petition for cert. filed}, 64 U.S.L.W. 3593 (U.S. Feb. 16, 1996) (No. 95-1321); \textit{see supra} part I.
  
  \item \textsuperscript{159} \textit{Talbott}, 865 F. Supp. at 39.
  
  \item \textsuperscript{160} \textit{id.} at 40 (adding that "[t]he government has vigorously enforced the applicable criminal and civil laws").
\end{itemize}
effectuate what it regarded as the "clearly expressed" belief of Congress that "the public interest will best be served by relying exclusively on the FDA to strike the proper balance between reasonably assuring safety and promoting innovation with regard to new devices that have the potential both to enhance and to injure human health."

Under the strong version of preemption, even fraud claims, framed as an allegation that agency approval was secured by the submission of incomplete or inaccurate data, would be unavailable. In Michael v. Shiley, Inc., for example, the Third Circuit decided that such a fraud-on-the-agency claim was preempted, even though the plaintiff had "produced substantial evidence that [the manufacturer] misled the FDA with false or misleading information when it applied for Premarket Approval." Noting that such a claim would require a court "to per-

161. Id. (conceding that its decision "may cause some, including those who enacted the law, to question whether complete preemption of private rights of action is the most fair" outcome); see also id. at 53 ("[B]alancing the cost to the few against the benefit to the public in deciding whether preemption is appropriate is a discretionary decision concerning public policy which is, in our democracy, committed to the politically accountable branches of government."); Ouellette, 902 F. Supp. at 10 ("While federal preemption often means that there is no remedy available to a claimant, in many instances unfortunately this result is necessary to vindicate the intent of Congress."). The First Circuit fully concurred in this analysis. See Talbott v. C.R. Bard, Inc., 63 F.3d 25, 31 (1st Cir. 1995), petition for cert. filed, 64 U.S.L.W. 3593 (U.S. Feb. 16, 1996) (No. 95-1321).

162. See, e.g., Shots v. CSX Transp., Inc., 38 F.3d 304, 308 (7th Cir. 1994) (agreeing "that the preemptive effect of a safety requirement laid down by the Secretary [of Transportation] cannot be challenged in a tort suit by arguing to the court that he made a mistake" because it would amount to an inappropriate "collateral challenge" to the agency's action); Papas v. Upjohn Co., 985 F.2d 516, 519 (11th Cir.) (per curiam) ("It is for the EPA Administrator, not a jury, to determine whether labelling and packaging information is incomplete or inaccurate . . . . FIFRA leaves states with no authority to police manufacturers' compliance with the federal procedures."); cert. denied, 114 S. Ct. 300 (1993); King v. Collagen Corp., 983 F.2d 1130, 1139-40 (1st Cir.) (Aldrich, J., concurring) (concluding that plaintiff's allegation of fraud in procuring FDA approval was inappropriate for judicial resolution); cert. denied, 114 S. Ct. 84 (1993); Reutzel v. Spartan Chem. Co., 903 F. Supp. 1272, 1283-84 (N.D. Iowa 1995) (FIFRA).


164. Id. at 1328 ("Because of the conflict with the FDA's own efforts to monitor and control its PMA application process, we conclude that Michael's claims for Shiley's knowing misrepresentation to the FDA, even if provable, are pre-empted.").
form the same functions initially entrusted to the FDA," the Third Circuit concluded that the MDA "does not permit such a searching state inquiry into the inner workings of FDA procedures." Although the statute's preemption provision is broader than that applicable to cigarettes, this position is difficult to reconcile with Cipollone's treatment of fraud claims.

Apart from the question of whether fraud on the agency might provide a separate basis for recovery that is not preempted, courts abiding by the strong version of preemption have squarely rejected the argument that allegations of fraud in procuring approval should defeat an otherwise applicable preemption defense.

After noting that the Agency could impose civil or criminal penalties for the submission of fraudulent information, the court in Reeves concluded that "the FDA is in the

165. Id. at 1329.
166. Id. ("This inquiry could ultimately require that a court determine whether the information Shiley submitted was truthful, whether it was complete, whether FDA procedures sufficed to avoid a material misrepresentation, and whether the FDA should have or would have approved the device despite the misrepresentations."); see also In re Orthopedic Bone Screw Prods. Liab. Litig., 1995 WL 273600, at *2 (E.D. Pa. Mar. 2, 1995) (dismissing fraud claims as preempted by the MDA).
167. See Cipollone v. Liggett Group, Inc., 505 U.S. 504, 528 (1992) (plurality opinion) (finding that the preemption provision would not foreclose recovery on a fraud claim alleging a failure "to disclose material facts about smoking and health to an administrative agency" if state law created a duty to disclose such information); id. at 555 (Scalia, J., concurring in the judgment in part and dissenting in part) (conceding that "the hypothetical law requiring disclosure to a state regulatory agency would seem to survive" even his more sweeping interpretation of the preemption provision). Because the other Justices would have found no claims preempted, the Court was unanimous in regard to this dictum.
best position to decide whether AcroMed withheld material information from the agency and, if so, the appropriate sanction." For the same reason, the court in Michael rejected the plaintiff's argument that "we should not permit Shiley to invoke the cloak of federal pre-emption when it obtained that cloak through the fraudulent manipulation of the regulatory process," concluding that this would present an even "greater interference with the FDA's decisions" than recognition of a separate fraud-on-the-agency claim.

---

170. Reeves v. AcroMed Corp., 44 F.3d 300, 307 (5th Cir.), cert. denied, 115 S. Ct. 2251 (1995); see also Michael, 46 F.3d at 1329 ("If Shiley knowingly misled the FDA in its PMA application, it is for the FDA to remedy that situation . . . ."); Talbott, 865 F. Supp. at 45 ("Congress did not intend to establish a fraud on the FDA exception to the express preemption established by § 360k(a) of the MDA.").

171. Michael, 46 F.3d at 1329 ("If a medical device manufacturer's claim that the MDA pre-empts a plaintiff's cause of action depends in the first instance upon proof that its Premarket Approval was not fraudulently obtained, courts would have to engage in the intrusive inquiry which we have just demonstrated is forbidden."). In short, a plaintiff cannot "revive the pre-empted fraud claim by characterizing it as a defense to pre-emption." Id.; see also Taylor AG Indus. v. Pure-Gro, 54 F.3d 555, 561 (9th Cir. 1995) (rejecting as "irrelevant" plaintiff's argument that the EPA's review of defendant's pesticide labeling had not been adequate).

Courts also have hesitated to entertain arguments that the federal regulation being given preemptive effect in a tort suit was not lawfully promulgated by the agency. See Busch v. Graphic Color Corp., 644 N.E.2d 839, 842 (Ill. App. Ct. 1995) (rejecting plaintiff's argument that CPSC methylene chloride warning rule had been adopted in violation of required rulemaking procedures), aff'd, No. 78662, 1996 Ill. LEXIS 23 (Ill. Feb. 15, 1996); cf. Adamo Wrecking Co. v. United States, 434 U.S. 275, 285 (1978) ("The narrow inquiry to be addressed by the court in a criminal prosecution is not whether the Administrator has complied with appropriate procedures in promulgating the regulation in question, or . . . any of the other familiar inquiries which arise in the course of an administrative review proceeding."); United States v. Fleetwood Enters., 702 F. Supp. 1082, 1090 (D. Del. 1988) ("It was [defendant's] responsibility to marshall its challenges to the validity of the standards
Moreover, to recognize any such exceptions to preemption would make allegations of fraud on the agency routine in products liability litigation and difficult to dispose of short of a trial.\textsuperscript{172} As explained in another court’s opinion:

Were the court to decide that an allegation of fraud on an agency would save all state tort claims against Class III devices, then the provisions of the MDA and the intent of Congress would be rendered a nullity. Such a decision would circumvent the preemptive effect of section 360k, and Congress’s intent to protect manufacturers of highly innovative and risky medical devices would be severely undermined.\textsuperscript{173}

Indeed, preemption would apply even if the agency itself determines that it was misled, as happened in the Talbott case,\textsuperscript{174} though the FDA has expressed its pronounced disagreement and even dismay with the court’s conclusion.\textsuperscript{175}
Under this extreme approach, a plaintiff could not seek compensatory damages for injuries allegedly resulting from a manufacturer's failure to abide by federal requirements. Courts consistently have rejected arguments that a private right of action exists under any of the federal safety statutes. Similarly, a number of courts have rejected negligence per se claims premised on violations of federal requirements because, otherwise, they conclude, plaintiffs could circumvent Congress's intent not to provide a private right of action under these federal statutes. Even under the strong version of preemption, however, state common law would continue to provide both a remedy and the applicable standard of care for aspects of products or activities outside of the preempted domain.


178. See King v. Collagen Corp., 993 F.2d 1130, 1135 (1st Cir.), cert. denied, 114 S. Ct. 84 (1993); Slater v. Optical Radiation Corp., 961 F.2d 1330, 1334 (7th Cir.) (stating that medical malpractice claims alleging improper implantation or removal of intraocular lenses would not be preempted), cert. denied, 506 U.S. 917 (1992).
The strong conception of the preemption defense resembles so-called "complete" preemption, a doctrine that has developed under the federal labor statutes. Complete preemption means that the displacement of state law by federal statute is so extraordinary that a defendant could remove an action from state court under federal question jurisdiction, creating an exception to the well-pleaded complaint rule that would otherwise ignore federal issues raised defensively. In other words, because of the comprehensive federal regulation of labor-management relations, a court may treat an employee's state law claims as necessarily arising under federal law and, therefore, properly removable to federal court. Although courts originally regarded the existence of a parallel federal remedy as a prerequisite for complete preemption of a state law claim, such substitution apparently is no longer necessary to support removal. Courts generally have rejected arguments that federal safety statutes establish complete preemption, but a few have granted removal petitions on such a theory.

179. See Avco Corp. v. Aero Lodge No. 735, Int'l Ass'n of Machinists, 390 U.S. 557, 559-60 (1968); see also supra note 66.
181. See, e.g., Caterpillar Inc. v. Williams, 482 U.S. 386, 391 n.4 (1987); Deford v. Soo Line R.R., 867 F.2d 1080, 1086 (8th Cir.), cert. denied, 492 U.S. 927 (1989); see also Moss, supra note 180, at 1618-25.
Similarly, according to some courts, preemption deprives them of subject matter jurisdiction over any tort actions within the preempted domain,\textsuperscript{184} apparently in the sense that a federal agency has been given exclusive jurisdiction over the matter.\textsuperscript{185} This effect is similar to the impact of preemption under the National Labor Relations Act.\textsuperscript{186} Because Congress assigned exclusive jurisdiction over unfair labor practice claims to the NLRB, federal preemption strips state courts of their subject matter jurisdiction to hear claims of this sort.\textsuperscript{187} The Supreme Court has emphasized, however, that Congress's decision to vest exclusive jurisdiction in the NLRB "does not apply to pre-emption claims generally but only to those pre-emption claims that go to the State's actual adjudicatory or regulatory power as


\textsuperscript{185} See Talbott v. C.R. Bard, Inc., 865 F. Supp. 37, 40 (D. Mass. 1994), aff'd, 63 F.3d 25, 29-30 (1st Cir. 1995), petition for cert. filed, 64 U.S.L.W. 3593 (U.S. Feb. 16, 1996) (No. 95-1321). Although he did not address subject matter jurisdiction over preempted tort claims, Professor Gardbaum has argued quite persuasively that true preemption is a "jurisdiction-stripping" concept. Gardbaum, \textit{supra} note 7, at 771 ("Whereas supremacy resolves a conflict resulting from the exercise by two or more entities of their concurrent powers, preemption implies that one entity (the federal) has attained exclusive power on the issue."); cf. Merrell Dow Pharmaceuticals Inc. v. Thompson, 478 U.S. 804, 816 & n.13 (1986) (suggesting that drug manufacturer's argument concerning federal question jurisdiction over negligence per se claim under state law could have been, but was not, recast as a claim that the federal statute "pre-empts state court jurisdiction over the issue in dispute"). Preemption of tort claims in this sense, however, may be a misnomer. See International Paper Co. v. Ouellette, 479 U.S. 481, 499-500 (1987) ("Simply because a cause of action is preempted does not mean that judicial jurisdiction over the claim is affected as well; the \textit{Clean Water} Act pre-empts laws, not courts.").


\textsuperscript{187} See International Longshoremen's Ass'n v. Davis, 476 U.S. 380, 391 (1986) ("If there is pre-emption under \textit{Garmon}, then state jurisdiction is extinguished."). The Court decided, therefore, that the defense was not waivable, but it added that "those claiming pre-emption must carry the burden of showing at least an arguable case before the jurisdiction of a state court will be ousted." \textit{Id.} at 396. Justice Blackmun noted that this burden may pose difficulties because preemption normally is raised in a motion to dismiss, "before facts have been developed or discovery has occurred." \textit{Id.} at 407 n.4 (Blackmun, J., concurring in part and dissenting in part).
opposed to the State's substantive laws." Nonetheless, some lower courts have accorded a comparable effect to preemption provisions in federal safety statutes, treating these provisions as divesting them of subject matter jurisdiction over tort claims against products or activities that are subject to regulation by federal agencies.

Of course, even if not properly regarded as an objection to jurisdiction, the strong version of preemption would support a defendant's motion to dismiss for failure to state a claim, and no set of proffered evidence or amended allegations could save any claims that fall within the preempted domain. The strong version thus effectively forecloses tort remedies altogether.

2. An Intermediate Version: Displacing Tort Standards

Under a less extreme view, federal preemption of tort claims would not completely cut off actions for damages, at least not in the event of noncompliance with federal standards. For ex-

188. Id. at 391 n.9 ("The nature of any specific pre-emption claim will depend on congressional intent in enacting the particular pre-empting statute.").
190. See, e.g., Lowe v. Sporicidin Int'l, 47 F.3d 124, 130 (4th Cir. 1995) ("The central preemption question presented by this case is whether Lowe has alleged a 'breach of a FIFRA-created duty' . . . that could form the 'basis for a state remedy' and . . . not be preempted."); Worm v. American Cyanamid Co., 5 F.3d 744, 748 (4th Cir. 1993) (same); Moss v. Parks Corp., 985 F.2d 736, 740 (4th Cir.) ("[I]n an area of limited Congressional preemption such as the FHSA, a common law tort action based upon failure to warn may only be brought for non-compliance with existing federal labeling requirements."); cert. denied, 113 S. Ct. 2999 (1993); Jenkins v. James B. Day & Co., 634 N.E.2d 998, 1003-05 (Ohio 1994) (following Moss). But
ample, several courts in earlier medical device cases explained that only the substantive duties imposed under the common law are preempted: "The question...is not the preemption of a remedy, but whether the federal government can impose upon a manufacturer a binding, uniform standard of conduct. The remedy is available to plaintiff, but compliance with federal law protects the defendant from the vagaries of each state's judicial system."

Under this view, preemption does not foreclose the availability of compensatory damages for personal injuries or other common-law remedies, but it does mean that federal regulatory standards will trump common-law standards such as the general duty of care under negligence. Plaintiffs would not see

---

see Talbott v. C.R. Bard, Inc., 63 F.3d 25, 29 (1st Cir. 1995) (rejecting what the court characterized as a "theory of cooperative preemption"), petition for cert. filed, 64 U.S.L.W. 3593 (U.S. Feb. 16, 1996) (No. 95-1321); Kennan, 717 F. Supp. at 808 (finding that FIFRA's express preemption "defense tends to annul the cause of action and not merely provide a different legal standard").


be able to invite judges and juries to second-guess, under the guise of applying a manufacturer's duty of care, an agency's safety and utility determinations for products whose design and labeling the agency has either dictated by regulation or individually reviewed and approved. Although admittedly beyond its scope, the recently approved Restatement (Third) of Torts embraces this more moderate form of federal preemption.\(^{193}\)

Because many of the preemption provisions cover only non-identical state requirements, courts reason that state tort claims premised on noncompliance with federal standards impose an identical obligation and, therefore, are not preempted.\(^ {194}\) The possibility that a company may be liable for violating federal standards has provided courts with one way of reconciling statutory savings clauses, which preserve existing rights or remedies at common law, with express preemption provisions.\(^ {195}\) Indeed,

\(^{193}\) See Restatement (Third) of Torts: Prods. Liab. § 7 cmt. e (1995), at 198 ("[W]hen federal preemption is found, the legal effect is clear. Federal preemption replaces the tort law of all states with a uniform body of federal law regulating the relevant area of product safety."). Although this passage also could be read to support the strong version of preemption, the new Restatement clearly evinces a more limited notion of federal preemption in its discussion of the special liability rules governing pharmaceutical products. See id. § 8 cmt. b, at 213 ("Where such preemption is found as a matter of law, liability cannot attach when the manufacturer has complied with the applicable regulatory standard.").

\(^{194}\) See, e.g., Mitchell v. Collagen Corp., 67 F.3d 1268, 1282 (7th Cir. 1995) (declining to hold "that an adulteration claim based on a product's failure to meet PMA standards—standards that have been explicitly set forth by the FDA—does not survive MDA preemption"), petition for cert. filed, 64 U.S.L.W. 3593 (U.S. Feb. 20, 1996) (No. 95-1323); National Bank of Commerce v. Kimberly-Clark Corp., 38 F.3d 988, 993 (8th Cir. 1994) ("[W]hen a statute only preempts state requirements that are different from or in addition to those imposed by federal law, plaintiffs may still recover under state tort law when defendants fail to comply with the federal requirements."); Moss, 985 F.2d at 740-41 (FHSA); Blanchard v. Collagen Corp., 909 F. Supp. 427, 436-37 (E.D. La. 1995) (MDA); cf. Worm, 5 F.3d at 748 ("Allowing such actions, however, is substantially distinguishable from accepting the argument that the state common law duty to warn is not 'in addition to or different from' the federally defined duty."). The counterargument, drawing on complete preemption decisions, posits that an award of damages for injuries allegedly caused by violations of federal standards is "in addition to" the federal choice of sanctions and should, therefore, be preempted. Cf. Amalgamated Ass'n of Street, Elec. Ry. & Motor Coach Employees v. Lockridge, 403 U.S. 274, 288-89 n.5 (1971) (NLRA). But cf. Note, Getting Away with Murder: Federal OSHA Preemption of State Criminal Prosecutions for Industrial Accidents, 101 Harv. L. Rev. 535, 541-53 (1987) (criticizing suggestions that federal sanctions would preempt state criminal law).

one of these savings clauses preserves only "remedies" at common law,\textsuperscript{196} supporting an interpretation of preemption as affecting the content of tort law duties but not altering the availability of damages for any breach of these duties.

The intermediate version of preemption may therefore be understood as nothing more than a choice-of-law principle,\textsuperscript{197} directing courts to select federal, rather than state, standards when resolving tort claims.\textsuperscript{198} Although a failure to state a (suggesting that the FBSA's "savings clause would include claims for failure to meet regulatory standards"); Timothy Wilton, \textit{Federalism Issues in "No Airbag" Tort Claims: Preemption and Reciprocal Comity}, 61 \textit{NOTRE DAME L. REV.} 1, 21-27 (1986); see also Pauline E. Calande, Note, \textit{State Incorporation of Federal Law: A Response to the Demise of Implied Federal Rights of Action}, 94 \textit{YALE L.J.} 1144, 1159-60 (1985) (discussing whether Congress has prohibited the states from using federal law as the applicable duty of care).


Federal preemption is not, by its nature, an affirmative defense to a state law cause of action. . . . It is wiser to view the preemption doctrine as being analogous to a choice-of-law principle. That is, preemption analysis simply tells the court what law, state or federal, should be referred to in order to determine the plaintiff's right to relief in a given case.


claim objection may be made as late as the trial on the merits, preemption understood merely as a choice-of-law objection would represent an affirmative defense that may be waived if not raised in a timely fashion.

Plaintiffs would be able to recover under state law for injuries in the event that a manufacturer violated the conditions contained in any applicable product license or regulation. Indeed, in many jurisdictions, violations of federal requirements may constitute negligence per se, although not all jurisdic-
tions recognize this rule. Under the intermediate version of preemption described in this section, courts essentially allow only such negligence per se claims to go forward. Although it would not defeat a defense under the intermediate version of preemption, a fraud-on-the-agency claim, like a negligence per se claim, also might remain available under state law.

Preemption would not depend on compliance with the federal standard; instead, a jury may find a defendant liable only in the event (and only to the extent) that the plaintiff can demonstrate noncompliance with that standard. Preemption of common-law claims suggested in the tampon cases, for example, evidently would not depend on a defendant's first proving compliance with FDA requirements. After all, preemption of positive state enactments does not vary depending on each manufacturer's

203. See, e.g., Sheridan v. United States, 969 F.2d 72, 75 (4th Cir. 1992) (holding that violation of government regulation barring servicemen from having a weapon on base does not constitute negligence per se); Swift v. United States, 866 F.2d 507, 508-09 (1st Cir. 1989) (finding violation of safety statute not negligence per se); Eimers v. Honda Motor Co., 785 F. Supp. 1204, 1208 (W.D. Pa. 1992) (holding that violation of administrative rule or regulation is never negligence per se). Others may be disinclined to use federal, as opposed to state, standards in this fashion. See, e.g., R.B.J. Apartments, Inc. v. Gate City Sav. & Loan Ass'n, 315 N.W.2d 284, 290 (N.D. 1982) (stating that "principles of federalism" prevent states from adopting a federal statute as the standard of care in state negligence actions when no private cause of action exists under the federal statute); supra note 177 (citing decisions rejecting negligence per se claims when Congress failed to provide a private right of action under the statute).

204. See, e.g., Evraets v. Intermedics Intraocular, Inc., 34 Cal. Rptr. 2d 852, 858 (Ct. App. 1994) ("[T]here is no evidence of a congressional intent to exonerate from liability manufacturers who engage in deceit to obtain approval to market their product."). But see Mitchell v. Collagen Corp., 67 F.3d 1268, 1283 (7th Cir. 1995) (rejecting fraud-on-the-agency claim as preempted even though it would have entertained a noncompliance claim), petition for cert. filed, 64 U.S.L.W. 3593 (U.S. Feb. 20, 1996) (No. 95-1323); Michael v. Shiley, Inc., 46 F.3d 1316, 1328-29 (3d Cir.) (holding that fraud-on-the-agency claim was preempted and that evidence of any fraud could not be used to defeat preemption under the MDA), cert. denied, 116 S. Ct. 67 (1995).

205. See, e.g., Rinehart, 688 F. Supp. at 477-78; Evraets, 34 Cal. Rptr. 2d at 859 ("State actions which echo or attempt to enforce federal standards are not preempted. . . . In applying a negligence per se theory, the state's requirements are equal to the federal requirements; in fact, they simply adopt the federal standard of conduct."). But see Powers v. Optical Radiation Corp., 44 Cal. Rptr. 2d 485, 490-91 (Ct. App. 1995) (disagreeing with Evraets), withdrawn, 1995 Cal. LEXIS 6773 (Nov. 2, 1995).
proof of compliance with federal law. Instead, plaintiffs attempting to sustain claims affected by this type of preemption would have to prove any alleged failures to comply with federal requirements. Rather than supporting either an objection to subject matter jurisdiction or a removal petition, preemption in these cases is a ground for either a motion to dismiss for failure to state a claim or a motion for summary judgment.

With the proliferation of more or less detailed (and often ambiguous) regulatory requirements, gauging compliance may be difficult. Courts can resolve questions of compliance with the statutory labeling requirements for cigarettes with relative ease, but efforts to determine whether a device manufacturer has complied fully with the requirements found in a premarket approval and any generally applicable regulations could present serious difficulties. The matter would, of course, be simple if an agency successfully had prosecuted the defendant for a regulatory infraction. As a general matter, litigants may be able to use formal agency decisions to estop collaterally the other party from relitigating a previously decided issue. Although less

206. Cf. 45 Fed. Reg. 67,326, 67,328 (1980) (noting that the MDA preempts state requirements when they are different from, or in addition to, FDA requirements, not only when they directly conflict with FDA requirements).


208. See Talbott v. C.R. Bard, Inc., 865 F. Supp. 37, 39-41 (D. Mass. 1994) (describing criminal prosecution of a manufacturer of cardiac catheters), aff'd, 63 F.3d 25 (1st Cir. 1995), petition for cert. filed, 64 U.S.L.W. 3593 (U.S. Feb. 16, 1996) (No. 95-1321). Even in such a case, however, whether the charges relate directly to the device at issue in the tort action may be unclear. See id. at 47 ("The parties dispute whether Bard admitted fraud on the FDA concerning the three lumen Mini Profile catheter used in Mrs. Beavers' angioplasty in connection with its guilty plea in the criminal case.").

209. See Astoria Fed. Sav. & Loan Ass'n v. Solimino, 501 U.S. 104, 107 (1991) ("We have long favored application of the common-law doctrines of collateral estoppel . . . to those determinations of administrative bodies that have attained finality."); cf. Jetcraft Corp. v. FlightSafety Int'l, Inc., 781 F. Supp. 687, 694 (D. Kan. 1991) ("In addition to the lack of mutuality, and the informal nature of the FAA proceedings, Jetcraft's arguments of collateral estoppel must fail . . . because the FAA's finding of a violation of § 61.57(c) related solely to record-keep-
clearly probative of noncompliance, formal citations alleging a violation also may support a negligence per se claim.\textsuperscript{210}

At the other extreme, a plaintiff may argue that, notwithstanding the agency's silence on the matter, the defendant has failed to comply with an applicable regulation. In some situations, a court will experience little difficulty resolving such questions,\textsuperscript{211} but

\begin{itemize}
  \item For instance, FDA warning letters will express the Agency's opinion that a company has violated a regulation and threaten formal enforcement actions, such as product seizures, if the manufacturer fails to bring itself into prompt compliance. \textit{Compare Professionals & Patients for Customized Care v. Shalala}, 847 F. Supp. 1359, 1365 (S.D. Tex. 1994) (holding that warning letters do not constitute final agency action but instead "merely establish a dialogue between the FDA and the pharmacist and do not necessarily lead to further sanctions"), \textit{aff'd}, 56 F.3d 592, 599 (5th Cir. 1995) \textit{with Den-Mat Corp. v. United States}, 1992 U.S. Dist. LEXIS 12233 (D. Md. Aug. 17, 1992) (holding that issuance of FDA warning letter was agency action ripe for judicial review). Informal concerns expressed by agency employees, however, should be given no special solicitude on the matter of noncompliance. \textit{See, e.g.}, 21 C.F.R. \textsuperscript{\textcircled{212}} § 10.85(j)-(k) (1995) (stating that advisory opinion may not be used to illustrate a legal requirement and that statements made by FDA employees are informal communications that do not constitute advisory opinions).

\item See, \textit{e.g.}, \textit{Moss v. Parks Corp.}, 985 F.2d 736, 741-42 (4th Cir.) (affirming summary judgment for manufacturer of paint thinner, agreeing that the product complied with all applicable CPSC labeling regulations notwithstanding plaintiff's argument that FHSA required stronger warnings), \textit{cert. denied}, 113 S. Ct. 2999 (1993); \textit{Sloman v. Tambrands, Inc.}, 841 F. Supp. 699, 703 (D. Md. 1993) (finding "no genuine issue of fact concerning Tampax's compliance with federal labeling regulations"); \textit{cf. National Bank of Commerce v. Kimberly-Clark Corp.}, 38 F.3d 988, 996 (8th Cir. 1994) ("I cannot say that the label in question complied with the FDA requirements as a matter of law, and I would instead leave this question for the factfinder."); \textit{Jenkins v. James B. Day & Co.}, 634 N.E.2d 998, 1004-05 (Ohio 1994) (rejecting motion for summary judgment because plaintiff's expert raised genuine issues of material fact concerning compliance with FHSA requirements).
\end{itemize}
often the inquiry will be quite complicated. Not surprisingly, courts sometimes get it wrong.

Because of such difficulties, courts generally recognize that agencies should exercise primary jurisdiction over regulatory matters within their special expertise. Indeed, this is one of the premises underlying the strong version of preemption discussed in the previous section. Short of avoiding the compliance issue altogether through complete preemption, however, courts should differentiate between situations in which a regulatory infraction is apparent, as when the agency undertakes an enforcement action, and other cases in which the plaintiff has alleged only some failure to comply with an ambiguous requirement. In

212. See, e.g., Lowe v. Sporicidin Int'l, 47 F.3d 124, 130 (4th Cir. 1995) (noting that a comparison of claims made in labeling and advertising "does not clearly establish—one way or the other—whether the advertisement claims" violate FIFRA but deciding that the court "need not resolve this knotty question" because summary judgment for the manufacturer could be affirmed on grounds other than preemption); Bammerlin v. Navistar Int'l Transp. Corp., 30 F.3d 898, 900 (7th Cir. 1994) (finding that the trial judge made a "serious mistake" by leaving jury to interpret the meaning of ambiguous motor vehicle safety standards); Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc., 902 F.2d 222, 231 (3d Cir. 1990) (declining to decide, in private trademark litigation, how the FDA might interpret and apply its ambiguous drug labeling regulations); In re Air Crash Disaster at Detroit Metro. Airport, 791 F. Supp. 1204, 1223 (E.D. Mich. 1992) ("[T]o a lay person who is not versed in the FAA regulatory scheme, the FAA orders and regulations for airport improvement projects contain vague, confusing, and, at times, seemingly inconsistent language . . . ."); Paul H. Rubin, Are Pharmaceutical Ads Deceptive?, 49 FOOD & DRUG L.J. 7, 10-11 (1994).

213. For example, in Mendes v. Medtronic, Inc., 18 F.3d 13, 17-18 (1st Cir. 1994), the court opined that a design modification to a pacemaker previously cleared by the FDA would not require the submission of a new premarket notification, an interpretation that is clearly incorrect, see Noah, supra note 104, at 208-10 & n.135. Similarly, in Reeves v. AcroMed Corp., 44 F.3d 300, 305-06 (5th Cir.), cert. denied, 115 S. Ct. 2251 (1995), the court found no violation of FDA restrictions on the promotion of unapproved uses, also representing an error in comprehending the full import of the agency's applicable regulations. See 59 Fed. Reg. 59,820, 59,821-25 (1994) (describing the FDA's policy on off-label uses of drugs and devices); Lars Noah, Constraints on the Off-Label Uses of Prescription Drug Products, 16 J. PROD. & TOXICS LIAB. 139, 146, 153-56 & n.80 (1994).

214. See, e.g., Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645, 654 (1973) ("Threshold questions within the peculiar expertise of an administrative agency are appropriately routed to the agency, while the court stays its hand."); Biotics Research Corp. v. Heckler, 710 F.2d 1375, 1376 (9th Cir. 1983) (stating that the basis for granting primary jurisdiction to the FDA is the agency's technical and scientific expertise); 21 C.F.R. § 10.25(b) (1995) (asserting primary jurisdiction for the FDA).
any case, under the intermediate version, claims premised on noncompliance would provide plaintiffs with their sole avenue for relief.

3. The Weak Version: Compliance As a Predicate

Under the weakest version of preemption suggested by courts in the wake of Cipollone, defendants would shoulder the burden of proving compliance as a predicate for successfully invoking the preemption defense.\textsuperscript{215} Rather than serving either as a subject matter jurisdiction objection or as grounds for dismissal or summary judgment for failure to state a claim, litigants would frame preemption arguments as an affirmative defense. Because otherwise the public would be left unprotected,\textsuperscript{216} plaintiffs might be able to defeat the weak version of the preemption defense altogether by demonstrating noncompliance. This conception of preemption differs from the intermediate version described in the previous section, which only forecloses recovery on tort claims premised on state law duties other than the duty to comply with any applicable (federal) safety standards.

Because the reported cases poorly elaborate the weak version, though perhaps Cipollone itself is an example,\textsuperscript{217} one must summarize it by comparison to the other conceptions of the preemption defense described previously.\textsuperscript{218} If compliance is undisputed, the outcome will be indistinguishable from the result under the other two versions of preemption. Under both the strong and intermediate versions, the preemption defense is not dependent on proof of compliance. Courts abiding by the intermediate version recognize negligence per se claims, but no color-
able basis would exist for pursuing such claims in the event that compliance is undisputed. Similarly, even if the defense is predicated on proof of compliance, a defendant would escape potential tort liability when no party disputes that it complied with the applicable federal requirements.

In the event of a dispute over compliance, however, the weak version differs from the intermediate version by placing the burden of proof on the defendant. Because the intermediate version of preemption does not make the defense hinge on compliance but, rather, preserves negligence per se claims, plaintiffs would carry the frequently difficult burden of establishing non-compliance in order to recover damages for their injuries. Under the weak version, in contrast, preemption does not even come into play until the defendant has proven compliance with federal requirements. In light of the potential complexities posed by questions of compliance,219 this difference in the allocation of the burden may be quite important. Although the plaintiff still shoulders the burden of proof on the underlying tort claims, the defendant’s failure to carry the burden with regard to questions of compliance would entirely remove federal preemption from the case (and perhaps invite a negligence per se claim by the plaintiff).

219. See supra notes 208-14 and accompanying text.
PREEMPTION TYPOLOGIES

<table>
<thead>
<tr>
<th>Characterization:</th>
<th>STRONG VERSION</th>
<th>INTERMEDIATE</th>
<th>WEAK VERSION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete preemption (jurisdiction objection or possible grounds for a removal petition)</td>
<td>Motion to dismiss for failure to state claim; choice-of-law issue (waivable)</td>
<td>Affirmative defense (subject to waiver)</td>
<td></td>
</tr>
<tr>
<td>Noncompliance:</td>
<td>Irrelevant</td>
<td>Basis for a negligence per se claim (plaintiff's burden)</td>
<td>Eliminates defense (defendant's burden)</td>
</tr>
<tr>
<td>Agency Fraud:</td>
<td>Irrelevant</td>
<td>Irrelevant (though may provide separate claim)</td>
<td>Allows plaintiff to defeat preemption</td>
</tr>
</tbody>
</table>

Furthermore, under the weak version of preemption, even if the defendant establishes compliance, plaintiffs may be able to escape the defense by alleging fraud on the agency.\(^{220}\) As noted previously,\(^{221}\) courts applying the stronger versions of preemp-

---


221. See supra part III.B.1.
tion have rejected such allegations as an impermissible collateral attack on an agency's decisions.222

Finally, if noncompliance is fairly apparent, the weak version may differ from the intermediate version, in the sense that the federal safety standards completely drop out of sight, even if noncompliance is only partial. For example, failure to abide by FDA labeling requirements in a premarket approval may expose the manufacturer to both failure-to-warn and design defect claims, even if no evidence demonstrates that the device deviated from design specifications in the product license. Under the intermediate version, in contrast, plaintiffs could only pursue a negligence per se failure-to-warn claim under these circumstances. Second, under the weak version, the defendant's conduct may be judged against a more stringent common-law standard of care in the event of noncompliance, so that even trivial deviations from federal requirements may be regarded as sufficiently extreme departures from the state law standard of reasonable care to support the imposition of punitive damages.223

IV. PREEMPTION RECONCEPTUALIZED

In the face of such confusion over the proper application of statutory preemption provisions in tort litigation, one might favor the simplicity of a clear statement rule, demanding that Congress specifically enumerate tort claims as preempted before displacing common-law remedies.224 We are not, however, writ-

222. See King v. Collagen Corp., 983 F.2d 1130, 1139-40 (1st Cir.) (Aldrich, J., concurring) (declining to follow the suggestion in Hurley that a jury was the appropriate factfinder for allegations that information was withheld), cert. denied, 114 S. Ct. 84 (1993); Papas v. Upjohn Co., 926 F.2d 1019, 1026 n.8 (11th Cir. 1991) (rejecting the approach suggested in Hurley, at least as applied to FIFRA-regulated pesticides), vacated sub nom. Papas v. Zoecon Corp., 505 U.S. 1215 (1992), modified, 985 F.2d 516, 519 (11th Cir.) (per curiam), cert. denied, 114 S. Ct. 300 (1993); supra notes 162-75 and accompanying text.


224. See Ferebee v. Chevron Chem. Co., 736 F.2d 1529, 1543 (D.C. Cir.), cert. denied, 469 U.S. 1062 (1984); Hernandez-Gomez v. Leonado, 884 P.2d 183, 190 (Ariz. 1994) (“Such a rule transfers the decision about preemption and its reach from the post-hoc speculation of lawyers to the forum where it should be argued: the legislature, where the competing interests may be reconciled before the statute is passed.”),
ing on a clean slate. Because the plurality’s judgment in *Cipollone* has been embraced fully by the Supreme Court, a clear statement rule seems unrealistic at this juncture.

Alternatively, courts might reconsider implied private rights of action under federal statutes that they have given sweeping preemptive effect. In a sense, however, this approach would attempt to fix one arguable error in construing congressional intent—namely, the recent tendency to find express preemption of tort claims notwithstanding congressional silence—with what might well be a second error. Instead, by understanding preemption of tort claims as the government standards defense, courts could make sense of *Cipollone* without giving it the extreme effect suggested by the strong version of preemption.

### A. Revisiting Implied Private Rights of Action

As one possible solution to the growing recognition of broad preemption in tort litigation, courts could be more willing to imply private rights of action in statutes with preemption provisions. Indeed, plaintiffs sometimes include federal statutory

---


225. *See* CSX Transp., Inc. v. Easterwood, 113 S. Ct. 1732, 1737 (1993); *see also* *Freightliner*, 115 S. Ct. at 1488 (acknowledging the possibility that tort claims may be impliedly preempted even if not expressly preempted under an applicable statutory provision); cf. Chatowski, *supra* note 101, at 801 (arguing that *Cipollone* embraced a type of clear statement rule).

claims in complaints in which preemption may be raised as a defense to the state law claims. Nonetheless, apparently feeling bound by long-standing precedent rejecting implied private rights of action under these federal statutes, courts have denied such claims at the same time that they have found preemption of plaintiffs' remedies under state law.

In *Cort v. Ash*, the Supreme Court announced a four-factor test for determining whether to find an implied private right of action under a federal statute. The test questions whether (1) the plaintiff is a member of the class for whose benefit the statute was enacted, (2) there is any indication of congressional intent to create a private remedy, (3) a private remedy would be consistent with the underlying purposes of the legislative scheme, and (4) the cause of action is one traditionally reserved for state law, so that it would be inappropriate to infer one based solely on federal law. In more recent decisions, the Court has placed primary emphasis on the second question, the

from violations of federal statutory standards cannot be redressed in any forum" as the scope of preemption expands while implied private rights of action contract). The refusal to recognize the creation of a federal cause of action, coupled with a finding of federal preemption, may result in the elimination of any private cause of action for injuries suffered as a result of a defendant's conduct. The state cause of action in tort is eliminated, and not replaced by any federal action. . . . [T]his is clearly not the intent of Congress in adopting the overwhelming majority of statutes in the consumer protection area.

*Id.* at 906-07.

227. *See, e.g.*, Hodges v. Delta Airlines, Inc., 44 F.3d 334, 340 n.13 (5th Cir. 1995) (en banc) (describing negligence per se theory as plaintiff's "fallback position").

228. *See, e.g.*, Gile v. Optical Radiation Corp., 22 F.3d 540, 544 (3d Cir.), cert. denied, 115 S. Ct. 429 (1994); Kemp v. Pfizer, Inc., 835 F. Supp. 1015, 1022 & n.5 (E.D. Mich. 1993); *see also supra* note 177 (citing decisions rejecting negligence per se claims when Congress provided no private right of action under the statute).


230. *Id.* at 78.
intent of Congress.\textsuperscript{231} Even so, courts still apply the \textit{Cort v. Ash} test in instances in which that intent is ambiguous.\textsuperscript{232}

As indicated earlier, courts have not found implied private rights of action under federal safety statutes.\textsuperscript{233} Nonetheless, a reexamination of these decisions in light of the growing acceptance of preemption could lead to a different result today because preemption would appear to alter the analysis significantly.\textsuperscript{234} For example, if courts interpret a federal statute as completely foreclosing tort remedies under state law, then it is no longer inappropriate to infer a federal cause of action merely because the cause of action was one traditionally available under state law. The intermediate version of preemption, which allows tort claims to proceed if premised on negligence per se for violations of federal requirements, would have much the same effect as implying a private right of action.\textsuperscript{235} Even then, recognizing a federal right of action might be preferable because the tort laws of some jurisdictions do not accept claims solely premised on violations of federal safety standards.\textsuperscript{236}

\begin{footnotesize}
\begin{enumerate}
\item \textsuperscript{232} See, e.g., \textit{Suter v. Artist M.}, 503 U.S. 347, 363-64 & n.16 (1992); \textit{Daily Income Fund, Inc. v. Fox}, 464 U.S. 523, 536 (1984); \textit{Texas Indus.}, 451 U.S. at 639 (“Congressional intent may be discerned by looking to the legislative history and other factors: e.g., the identity of the class for whose benefit the statute was enacted, the overall legislative scheme, and the traditional role of the states in providing relief.”).
\item \textsuperscript{233} See supra note 176 (citing decisions rejecting arguments that private causes of action exist under federal safety statutes).
\item \textsuperscript{234} See \textit{Starry}, supra note 226, at 689 (“Those courts were not operating under the assumption that all state tort claims relating to air carrier operations were preempted. Surely, if they had been, their analysis under \textit{Cort v. Ash} would have been different.”).
\item \textsuperscript{235} Indeed, this similarity has inclined some courts against allowing negligence per se claims for violations of federal requirements when there is no private right of action under the statute. See supra note 177 (citing cases).
\item \textsuperscript{236} See supra note 203 (citing cases).
\end{enumerate}
\end{footnotesize}
Courts, however, could use a finding of express preemption as further support for the conclusion that Congress did not intend to create a private remedy.²³⁷ Courts also hesitate to imply private rights of action to avoid providing litigants with federal question jurisdiction. Unlike the intermediate version of preemption, recognition of a private right of action might burden the federal courts unnecessarily with fairly routine personal injury claims. For these and other reasons, although courts rejected implied private rights of action in cases predating the widespread acceptance of the preemption defense to tort claims, courts will not likely revisit these decisions.

B. Adopting the Government Standards Defense

Instead of revisiting the possibility of recognizing implied private rights of action, courts should view preemption provisions as nothing more than a decision by Congress to give companies a defense to state tort liability if they have complied with federal safety standards. Of the three different conceptions of preemption, Cipollone supports only the weak version. Although denoted “preemption,” this version of preemption more closely resembles the government standards or approval defense. First, one must review the traditional rule that compliance provides no defense to tort liability.

1. Regulatory Compliance Is Rarely Dispositive

In most jurisdictions, evidence of compliance with a government safety standard is relevant but rarely dispositive in assessing allegations that a product is defective or that the defendant’s conduct was negligent. Several courts argue that government standards establish only minimum requirements,

requirements that a jury can find a reasonable person should have exceeded in certain situations. The hesitancy to recognize a compliance defense is of even older vintage than is the negligence per se rule. The statutory safety standards in many of the earliest cases were quite limited in scope, often lacked an enforcement mechanism, and sometimes expressly preserved common-law tort remedies. In the century since the development of the common-law rule against recognizing a regulatory compliance defense, however, the complexity of government regulation has increased profoundly. Courts, however, continue to give little or no weight to compliance with today's far more intricate regulatory regimes, frequently dismissing the defense out of hand with the oft-repeated and largely unexamined premise that government safety standards are nothing more than minimum requirements.

Although some federal statutes and agency regulations really have only such limited purposes, modern regulatory systems more typically represent legislative or administrative efforts to set optimal, not minimal, safety standards. A few jurisdictions

239. See, e.g., Grand Trunk Ry. v. Ives, 144 U.S. 408, 421 (1892) (holding that giving signals required by law does not always render railroad free from negligence).
240. See Paul Dueffert, Note, The Role of Regulatory Compliance in Tort Actions, 26 HARV. J. ON LEGIS. 175, 182 (1989). "The perspective of the Second Restatement . . . is based upon the simple statutory schemes and railroad crossing accidents of the nineteenth century." Id. at 208.
241. Id. at 217. "Against such complex regulatory schemes, the rule that regulatory compliance cannot shield a defendant from liability seems archaic." Id. at 218.
242. See, e.g., Cleveland v. Piper Aircraft Corp., 985 F.2d 1438, 1445 (10th Cir.) (emphasizing that federal airworthiness regulations only purport to represent "minimum standards"), cert. denied, 114 S. Ct. 291 (1993); Perry, 957 F.2d at 1264-65 (noting that NHTSA regulations are only "minimum standards"). But see Wood v. General Motors Corp., 865 F.2d 395, 414 (1st Cir. 1988) ("Although the standards are 'minimum' in the sense that a manufacturer may make a vehicle safer than required by federal law, the standards are not 'minimum' in relation to state law."); cert. denied, 494 U.S. 1065 (1990); Wilson v. Piper Aircraft Corp., 577 P.2d 1322, 1333 (Or. 1978) (en banc) (Linde, J., concurring) (noting that FAA regulation "represents a more deliberate, technically intensive program to set and control a given level of safety . . . than is true of many run-of-the-mill safety regulations"); cf. Ray v. Atlantic Richfield Co., 435 U.S. 151, 165-69 (1978) (finding that state statute governing oil tanker design would have been preempted by federal law, even though the latter referred only to "minimum standards of design").
have recognized a government standards defense in limited circumstances, either as a matter of judicial decision or in connection with recent codifications of state tort rules, and the Restatement (Second) of Torts accepted judicial authority to decide that compliance with particular government standards would provide a defense to tort liability.

243. See Lorenz v. Celotex Corp., 896 F.2d 148, 152 (5th Cir. 1990) ("[C]ompliance with government safety standards . . . constitutes strong and substantial evidence that a product is not defective."); Hurley v. Lederle Lab. Div. of Am. Cyanamid Co., 863 F.2d 1173, 1179 (5th Cir. 1988); O'Gilvie v. International Playtex, Inc., 821 F.2d 1438, 1442 (10th Cir. 1987) (approving jury instruction that included presumption of nondefectiveness for compliance with FDA tampon labeling requirement unless plaintiff proved that a reasonable person would have done more), cert. denied, 486 U.S. 1032 (1988); Coley v. Commonwealth Edison Co., 768 F. Supp. 625, 629 (N.D. Ill. 1991) (compliance with Nuclear Regulatory Commission's radiation exposure regulations provided conclusive proof of non-negligence); Dentson v. Edds & Lee Bus Sales, Inc., 491 So. 2d 942, 944 (Ala. 1986) (holding conclusive as to defectiveness of a bus a state law that did not require passenger seat belts); Ramirez v. Plough, Inc., 25 Cal. Rptr. 2d 97, 102 (Cal. 1993) ("[T]here is some room in tort law for a defense of statutory compliance."); Jefferson County Sch. Dist. v. Gilbert, 725 P.2d 774, 777-80 ( Colo. 1986) (finding no liability when intersection conformed to city manual); Josephson v. Meyers, 429 A.2d 877, 880-81 (Conn. 1980) (deciding that bus driver complied with all statutory requirements regarding safe discharge of passengers); McDaniel v. McNeil Lab., Inc., 241 N.W.2d 822, 828 (Neb. 1976) (finding FDA approval of drug "not necessarily conclusive" as to whether drug was safe, but safety should not be challenged simply because some experts may differ); Montgomery v. Royal Motel, 645 P.2d 968, 970 (Nev. 1982) (stating that, when motel met required standard, there was no liability for criminal assault on guests by unknown assailant).


245. RESTATEMENT (SECOND) OF TORTS § 288C cmt. a (1965) ("Where there are no such special circumstances, the minimum standard prescribed by the legislation or regulation may be accepted . . . by the court as a matter of law, as sufficient for the occasion . . . ."); see also Model Uniform Prod. Liab. Act § 108, 44 Fed. Reg. 62,714, 62,730 (1979) (noting relevance of legislative or regulatory standards); 2 ALI REPORTERS' STUDY, ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY 95-101 (1991) (describing rationales for recognizing a compliance defense); Dueffert, supra note 240, at 217 ("Regulatory compliance most often stands as a defense where the governing statute (1) tightly controls the defendant's conduct, (2) obviously reflects a careful balancing of the interests usually gauged in determining negligence at common law, and (3) carries substantial sanctions for failure to comply.").
Nonetheless, rejection of the government standards defense remains by far the prevailing rule. The American Law Institute's project to restate products liability law in the Restatement (Third) of Torts does not recognize a rebuttable presumption of nondefectiveness in cases in which a defendant has complied with comprehensive government safety standards that were intended to provide an optimal level of safety. The new Restatement also distinguishes between federal preemption and the government standards defense by noting that the former cuts off tort liability as a matter of law under the Supremacy Clause, while the latter might simply provide a common-law defense to tort liability. As argued in the next section, this suggested distinction may overstate the real difference between these two notions.

2. Preemption As the Government Standards Defense

Although compliance with federal safety standards traditionally has not protected companies from tort liability, under the strong version of preemption, companies are now immunized from liability even if they violated these standards. Surely, this is a remarkable situation. As this section will conclude, preemption of tort claims should, at most, be understood as adopting the government standards defense. The weak version of preemption, which seems closely akin to the compliance defense, shows greater fidelity to recent Supreme Court deci-

246. See Restatement (Third) of Torts: Prods. Liab., supra note 193, § 7 & cmt. e.
247. See id. § 7 cmt. e, at 197-98 ("[A] determination that there is preemption nullifies otherwise operational state law. . . . Judicial deference to federal product safety statutes or regulations occurs not because the court concludes that compliance with the statute or regulation shows the product to be nondefective; the issue of defectiveness under state law is never reached.").
248. See supra part III.B.3; see also State ex rel. Jones Chems., Inc. v. Seier, 871 S.W.2d 611, 614 n.1 (Mo. Ct. App. 1994) ("The parties have approached this matter as pre-emption of the common law cause of action of inadequate or improper labeling. It might also be approached as a question of duty wherein compliance with the federal labeling mandate serves as a matter of law to establish no further duty or no breach . . . ."). Compare Wood v. General Motors Corp., 865 F.2d 395, 401 n.8 (1st Cir. 1988) ("Preemption is a concept both narrower and different from an ordinary [compliance] defense."), cert. denied, 494 U.S. 1065 (1990) with id. at 426 (Seyla, J., dissenting) ("It would be a strange 'savings clause' indeed which could
Several aspects of *Cipollone* undergird the weak version of preemption. First, the statutory provision at issue in the case made compliance a predicate for invoking the defense. This element of the preemption provision has received little or no attention, however, in part because the tobacco companies have conscientiously used the mandatory warning statements in their labeling. Although the statutory provision is entitled “Preemption,” by demanding compliance as a prerequisite for preemption, the cigarette labeling law more closely resembles other federal statutes adopting a compliance defense. Second, because the statute itself specifies the text of these statements, compliance should be simple to determine. Presumably, in the event of noncompliance, a plaintiff alleging injuries from cigarettes would be free to pursue failure-to-warn and related tort claims on theories other than noncompliance with the federal labeling requirement. Arguably, this weak version is not really preemption at all.

---

salvage an action on the merits in this fashion but be impuissant to stop preemption, when the effect on uniformity of regulation and manufacture would be precisely the same in either case.”) and Ferebee v. Chevron Chem. Co., 736 F.2d 1529, 1540 (D.C. Cir.) (“Unless FIFRA preempts a state from making these choices, a state jury may find a product inadequately labeled despite EPA's determination that, for purposes of FIFRA, the label is adequate.”), cert. denied, 469 U.S. 1062 (1984).

249. 15 U.S.C. § 1334(b) (1994) (preempting imposition of requirements or prohibitions under state law with respect to cigarettes “labeled in conformity with the provisions of this chapter”). The possibility that a state could enact legislation mandating more stringent warning statements and enforcement sanctions for any cigarettes that the manufacturer did not label in conformity with the federal statute seems somewhat odd, but nothing in the legislative history sheds further light on this aspect of the preemption provision.

250. Id.

251. For example, the National Childhood Vaccine Injury Act provides a limited compliance defense against failure-to-warn and manufacturing defect claims. See 42 U.S.C. §§ 300aa-22(b), 300aa-23(d) (1988 & Supp. V 1993).

252. See Gardbaum, supra note 7, at 773 (“Under any version of the principle of supremacy, a finding of conflict applies only to the specific state measure at issue, whereas preemption applies to every measure in the given field. In other words, supremacy necessitates case-by-case analysis on an ex post basis.”); see also id. at 805 (“In short, preemption eliminates the need to consider the content of state laws on the subject, to lay the two laws side by side to ascertain whether or not they conflict.”). This contrast seems overdrawn, however, because Congress may choose a limited scope of preemption that requires some evaluation of the terms or effect of
Cipollone certainly cannot support the strong version of preemption, in part because of the plurality's distinction between pre- and post-1969 failure-to-warn claims. If the 1969 amendments were understood as completely preempting failure-to-warn claims, then the preemption provision would foreclose any tort actions founded on such claims brought after 1969, whether or not some of the defendant's alleged negligence pre-dated enactment of the statute. Instead, of course, the Cipollone plurality distinguished between claims grounded on conduct occurring before and after passage of the preemption provision. Finally, by differentiating among numerous tort claims and only finding preemption of a limited class that was based on a failure to warn, the plurality's decision in Cipollone left a number of alternative grounds for recovery available to plaintiffs. The practical result of preemption, therefore, was not particularly harsh in that case.

---

state law. See, e.g., 7 U.S.C. § 136v(b) (1994) (preempting any state "requirements for [pesticide] labeling or packaging in addition to or different from those required under this subchapter").

253. Although retroactive application of statutes generally is disfavored, see Landgraf v. USI Film Prods., 114 S. Ct. 1483, 1496-1505 (1994), complete preemption, operating as a jurisdictional rule, see id. at 1501-02, would foreclose claims filed after enactment, even if premised on conduct pre-dating the statute, see Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc., 959 F.2d 158, 160-61 (10th Cir.) (holding that FIFRA preempted failure-to-warn claims even though defendant's allegedly negligent conduct entirely pre-dated enactment of the preemption provision), vacated, 506 U.S. 910 (1992), reinstated, 981 F.2d 1177, 1178 (10th Cir.), cert. denied, 114 S. Ct. 60 (1993); Kennan v. Dow Chem. Co., 717 F. Supp. 799, 811 (M.D. Fla. 1989) (same).

254. See Cipollone v. Liggett Group, Inc., 505 U.S. 504, 522-24 (1992) (plurality opinion); see also Kotler v. American Tobacco Co., 685 F. Supp. 15, 18 (D. Mass. 1988) (holding that postenactment claims against cigarette manufacturer alleging negligence prior to 1966 were not preempted), aff'd, 926 F.2d 1217 (1st Cir. 1990), vacated, 505 U.S. 1215 (1992). Such an approach is also consistent with the intermediate version of preemption, in the sense that courts would judge pre-enactment conduct against any then prevailing tort-law standards of care rather than the subsequently announced uniform federal standard. See Landgraf, 114 S. Ct. at 1506-07; Mojica v. Gannett Co., 7 F.3d 552, 558 (7th Cir. 1993), cert. denied, 114 S. Ct. 1643 (1994); Desmarais v. Dow Corning Corp., 712 F. Supp. 13, 15 (D. Conn. 1989) (noting that failure-to-warn claims would have been preempted had plaintiff's breast prostheses been implanted after enactment of the MDA but not in a case in which they were implanted before the date of enactment).

255. Cipollone, 505 U.S. at 524-31; see also Slater v. Optical Radiation Corp., 961 F.2d 1330, 1334 (7th Cir.) (listing alternatives to products liability claims preempted
Although preemption provisions in other statutes are broader than that applicable to cigarettes, Cipollone does not clearly dictate the recognition of more sweeping preemption defenses in those cases. None of the other federal safety statutes includes a similar compliance prerequisite in the text of the preemption provision, and compliance with requirements imposed under those statutes is also harder to determine, but these are reasons for narrowing or distinguishing Cipollone rather than for unthinkingly giving it even greater effect under those other statutes. In particular, the absence of substitute remedies should incline courts against finding preemption of tort law

by the MDA), cert. denied, 506 U.S. 917 (1992); Jenkins v. Amchem Prods., Inc., 886 P.2d 869, 884 (Kan. 1994) ("Plaintiff still has viable causes of action to remedy the harm he allegedly suffered by defendants' products even though one theory of liability [i.e., failure to warn] is preempted [under FIFRA]."), cert. denied, 116 S. Ct. 80 (1995); cf. Michael v. Shiley, Inc., 46 F.3d 1316, 1326 (3d Cir.) (holding that express warranty claim survived because otherwise the MDA would eliminate "all legal remedies to the purchaser"), cert. denied, 116 S. Ct. 67 (1995); Lohr v. Medtronic, Inc., 56 F.3d 1335, 1342-43 (11th Cir. 1995) (same), cert. granted, 116 S. Ct. 806 (1996). But cf. William T. Smith, III & Kathryn M. Coonrod, Cipollone's Effect on FIFRA Preemption, 61 UMKC L. Rev. 489, 501 (1993) (suggesting that federal preemption of failure-to-warn claims against pesticide manufacturers will have a significant impact on plaintiffs because design defect and other claims are more difficult to pursue); Junda Woo, Tobacco Firms Still Are Facing Many Lawsuits, WALL ST. J., Nov. 9, 1992, at A3 (reporting that the plaintiffs in Cipollone voluntarily dismissed their remaining claims after remand from the Supreme Court because their counsel had withdrawn for financial reasons).

256. See, e.g., 21 U.S.C. § 360k(a) (1994) (preempting all state and local medical device requirements that differ or add to a safety or effectiveness requirement or any other requirement under the MDA).


258. See Richard C. Ausness, Federal Preemption of State Products Liability Doctrines, 44 S.C. L. Rev. 187, 258-59 (1993); Lyndon, supra note 173, at 140 ("The courts seem drawn to the preemption doctrine in part out of exasperation with the shortcomings they perceive in tort law. When the statutory bases for preemption are less than compelling, the sense that tort law itself is dysfunctional may tip the balance against liability."); Weinberg, supra note 197, at 1751 ("The current majority, appointees of the Reagan and Bush administrations, . . . might want corporate defendants to have the benefit of a defense of compliance with some federal requirement. One majority might relish a new federal [preemption] defense, but another equally conservative majority might scruple to fashion one at common law.").
claims unless congressional intent to foreclose such claims is unmistakable. Of course, the plurality in *Cipollone* and the majority in *Easterwood* did not construe the respective statutes so narrowly, but then only the weaker versions of preemption discussed above seem appropriate. Interpreting preemption provisions as establishing a government standards defense would promote the goal of federal uniformity without foreclosing tort remedies when federal safety standards have been violated.

In a sense, courts would be recognizing a federal common-law defense against state tort claims when a product or activity is subject to regulation under a federal statute that contains a preemption provision. In *Boyle v. United Technologies Corp.*, the Supreme Court recognized an analogous defense against products liability claims for government contractors, specifically in the context of military equipment. Although there was no conflict with any particular federal law, the Court decided that the threat of liability for design defects under state law could conflict with important federal interests, so it elected to displace

---

259. See, e.g., Hodges v. Delta Airlines, Inc., 44 F.3d 334, 338 & n.8 (5th Cir. 1995) (en banc) (noting that “neither the ADA nor its legislative history indicates that Congress intended to displace the application of state tort law to personal physical injury inflicted by aircraft operations, or that Congress even considered such preemption,” and contrasting “the ADA with ERISA legislation, in which Congress provided several federal causes of action to replace the preempted state causes”); Abbot v. American Cyanamid Co., 844 F.2d 1108, 1112 (4th Cir.) (noting that the presumption against preemption is particularly strong when there is no federal remedy), cert. denied, 488 U.S. 908 (1988); Ministry of Health v. Shiley Inc., 858 F. Supp. 1426, 1440 (C.D. Cal. 1994) (“If the intent of Congress were to nullify an entire body of state consumer protection law, and leave the victims without a remedy, it would have specifically said so.”); Margolis v. United Airlines, Inc., 811 F. Supp. 318, 324 (E.D. Mich. 1993) (“Preemption under [the ADA] was not intended to be an insurance policy for air carriers against their own negligence. . . . [Otherwise] injured plaintiffs would be left without any remedy for serious physical injuries.”); Burke v. Dow Chem. Co., 797 F. Supp. 1128, 1132, 1140-41 (E.D.N.Y. 1992) (FIFRA); Callan v. G.D. Searle & Co., 709 F. Supp. 662, 665 (D. Md. 1989) (MDA); Kociemba v. G.D. Searle & Co., 680 F. Supp. 1293, 1300 (D. Minn. 1988) (MDA).

260. In *Easterwood*, for example, the Court affirmed preemption of the plaintiff’s excessive speed claim when the defendant had not exceeded the DOT’s 60 mph limit. See *CSX Transp., Inc. v. Easterwood*, 113 S. Ct. 1732, 1742 (1993). Because the parties did not dispute compliance, however, the Court did not have any occasion to rule on the possible effect of noncompliance on the preemption defense.


262. Id. at 509.
state law by crafting the government contractor defense as a matter of federal common law.\textsuperscript{263} The majority found that "the procurement of equipment by the United States is an area of uniquely federal interest,"\textsuperscript{264} which made it necessary to determine next whether state law might conflict with this interest.\textsuperscript{265}

The Court in Boyle conceded that tort claims would not always pose a sufficiently serious conflict with the federal interest to justify the displacement of state law.\textsuperscript{266} In searching for a limiting principle, the majority relied on the discretionary functions exception of the Federal Tort Claims Act (FTCA),\textsuperscript{267} even though it only preserves sovereign immunity for government officials under limited circumstances, to frame the appropriate scope of this defense under federal common law.\textsuperscript{268} As formu-

\begin{itemize}
\item \textsuperscript{263} \textit{Id.} at 510.
\item \textsuperscript{264} \textit{Id.} at 507. The Court noted that "uniquely federal interests" included the rights and obligations of the United States under its contracts as well as civil liability of federal officials for actions taken in the course of their duties, both of which were implicated indirectly by liability rules applicable to independent government contractors. \textit{See id.} at 504-05. In particular, the majority speculated that the "imposition of liability on Government contractors will directly affect the terms of Government contracts: either the contractor will decline to manufacture the design specified by the Government, or it will raise its price." \textit{Id.} at 507; \textit{see also id.} at 511-12 (arguing that the cost of judgments against contractors will be passed on to the government through higher prices). \textit{But see id.} at 521 (Brennan, J., dissenting) ("The relationship at issue is at best collateral to the Government contract.").
\item \textsuperscript{265} The Court stated:
\begin{quote}
The conflict with federal policy need not be as sharp as that which must exist for ordinary pre-emption . . . . Or to put the point differently, the fact that the area in question is one of unique federal concern changes what would otherwise be a conflict that cannot produce pre-emption into one that can.
\end{quote}
\textit{Id.} at 507-08 (footnote omitted). In other cases, however, the Court also has inquired about the desirability of uniformity before deciding to displace state law with a federal common-law rule. \textit{See, e.g.}, United States v. Kimbell Foods, Inc., 440 U.S. 715, 739-40 (1979).
\item \textsuperscript{266} \textit{See Boyle}, 487 U.S. at 509 ("No one suggests that state law would generally be pre-empted in this context."). For example, if "a federal procurement officer orders, by model number, a quantity of stock helicopters that happen to be equipped with escape hatches opening outward, it is impossible to say that the Government has a significant interest in that particular feature." \textit{Id.}
\item \textsuperscript{267} Ch. 753, tit. IV, 60 Stat. 842 (1946) (codified as amended in scattered sections of 28 U.S.C.).
\item \textsuperscript{268} \textit{See Boyle}, 487 U.S. at 511 (finding that permitting plaintiffs to second-guess military equipment design judgments "through state tort suits against contractors
lated by the majority, the defense provides that:

Liability for design defects in military equipment cannot be imposed, pursuant to state law, when (1) the United States approved reasonably precise specifications; (2) the equipment conformed to those specifications; and (3) the supplier warned the United States about the dangers in the use of the equipment that were known to the supplier but not to the United States. 269

As in the weak version of preemption, a contractor would have to identify the government requirements that trigger the defense, demonstrate compliance with those specifications,270 and not be guilty of fraud or misrepresentation in its dealings with the government.271 Although the defense originated in the context of military equipment, a few courts have extended the defense to other products purchased by the federal government.272
Commentators have criticized the *Boyle* decision on a number of different grounds. Even so, the case for recognizing a government standards defense for compliance with federal safety requirements is stronger than the argument for the contractor defense in *Boyle*. Under the government standards defense, courts can interpret the express preemption provisions in the relevant statutes to justify the recognition of such a defense as a matter of federal common law, rather than relying on the FTCA's discretionary functions exception, as did the majority in *Boyle*. Although courts generally reserve the development of
federal common-law rules for extraordinary circumstances, such interstitial lawmaking is preferable to the tortured feats of statutory construction that courts engage in when finding sweeping express preemption of tort claims.

The theoretical difference between interpreting such provisions as dictating preemption of tort claims or as authorizing courts to fashion a government standards defense may be inconsequential. Even so, courts could decide that a provision preempting state law demonstrates a sufficiently strong interest in uniformity (but not exclusivity) to support application of the government standards defense against tort claims. Regardless of whether courts style the defense recognized in Cipollone as preemption or government standards, courts should articulate more clearly the prerequisites for invoking the defense. The three-part government contractor defense suggests one useful formulation that could be readily adapted to this end.

To be sure, significant controversy surrounds use of the government standards defense. Critics make a number of cogent arguments against the recognition of such a defense to liability. For example, the tort system has the virtue of encouraging product manufacturers to discover and address health and

---


276. See Martha A. Field, Sources of Law: The Scope of Federal Common Law, 99 HARV. L. REV. 881, 893-94 (1986) (offering a definition that "leaves no clear-cut line between federal common law and federal interpretational law"); see also id. at 895 ("My thesis is not affected by including cases of interpretation, because the scope of federal common law power is not a problem in those cases. The problem cases for federal common law power are the cases in which it is difficult to pass off judicial lawmaking as interpretation . . . ").

277. See Boyle, 487 U.S. at 512.

safety risks before they result in serious injuries, whereas regulators generally can react only after such injuries have come to light.\(^{279}\) Opponents of the defense also question whether administrative agencies reliably protect public health and safety,\(^{280}\) and they add that, in any event, government standards may be quite difficult to discern and apply.\(^{281}\) Finally, of course, the federal government generally offers no direct system of compensation for persons who are injured.\(^{282}\)

Conversely, supporters offer several justifications for the government standards defense. For instance, allowing recovery of tort damages notwithstanding conscientious adherence to carefully crafted safety standards is both inefficient and unfair, and lay jurors are not qualified to second-guess the safety determinations made by federal regulators.\(^{283}\) Proponents argue that the

---


281. See Schwartz, supra note 278, at 1130-35; see also supra notes 208-14 and accompanying text (discussing the difficulties of gauging compliance).


283. See, e.g., Richard C. Ausness, The Case for a "Strong" Regulatory Compliance Defense, 55 MD. L. REV. (forthcoming 1996); James A. Henderson, Jr. & Aaron D. Twerski, Doctrinal Collapse in Products Liability: The Empty Shell of Failure To Warn, 65 N.Y.U. L. REV. 265, 320 (1990) ("[F]or reasons that we find difficult to understand, courts have not deferred to the determinations of product safety agencies . . . . The analysis usually begins and ends with the statement that agency
traditional assumptions underlying the hesitancy to accept a
government standards defense are open to serious question in
light of the radical changes in the regulatory state. 284

Ultimately, this Article must sidestep the debate, in part
because the propriety of the government standards defense may
well vary across different product categories. 285 Nonetheless,
even critics of the defense should agree that a government stan-
dards interpretation of express preemption provisions is far
better than the stronger versions of preemption that a number
of courts have adopted. The government standards defense may
be harder for defendants to establish and more easily overcome
than preemption in any particular case, in the same way in
which the weak version of preemption differs from the two
stronger versions. 286 Moreover, by deciding that preemption
translates into the government standards defense when raised
in the context of tort litigation, courts could decouple the defense

\[\begin{align*}
\text{standards are minimum, not maximum, standards and that courts are therefore free}
\text{to disregard them.}; \text{James A. Henderson, Jr., } \text{Manufacturers' Liability for Defective}
\text{Product Design: A Proposed Statutory Reform, 56 N.C. L. REV. 625, 639 (1978) (urg-
\text{ing recognition of a rebuttable presumption that products that comply with federal}
\text{regulations are not defectively designed); Peter Huber, } \text{Safety and the Second Best:}
\text{The Hazards of Public Risk Management in the Courts, 85 COLUM. L. REV. 277, 333-
\text{35 (1985) (suggesting that courts should defer to the expert opinions of agencies); W.}
\text{Kip Viscusi, Toward a Diminished Role for Tort Liability: Social Insurance, Govern-
\text{ment Regulation, and Contemporary Risks to Health and Safety, 6 YALE J. ON REG.}
\text{65 (1989) (arguing that regulations generate superior risk reduction incentives).}
\end{align*}\]

284. See, e.g., Huber, supra note 283, at 334.

285. See Lars Noah, The Imperative To Warn: Disentangling the "Right to Know" from the "Need to Know" About Consumer Product Hazards, 11 YALE J. ON REG. 293, 334 n.187, 337-38, 399-400 (1994). Products regulated by the FDA are the most
frequently mentioned as deserving the protections of a government standards de-
ference. See, e.g., STEVEN GARBER, PRODUCT LIABILITY AND THE ECONOMICS OF
PHARMACEUTICALS AND MEDICAL DEVICES xxxii (1993); Richard A. Epstein, Legal
Liability for Medical Innovation, 8 CARDOZO L. REV. 1139 (1987) (urging a safe har-
bor for compliance with FDA warning standards); W. Kip Viscusi et al., Deterring
Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory
Compliance Defense, 24 SETON HALL L. REV. 1437 (1994). But see Margaret
Gilhooley, Innovative Drugs, Products Liability, Regulatory Compliance, and Patient
Choice, 24 SETON HALL L. REV. 1481, 1488-93 (1994) (expressing concerns about ade-
quate funding and public accountability).

286. See supra part III.B.3; see also Atwell, supra note 191, at 227-29 (arguing that
courts should be more hesitant to find preemption of tort claims but adding that
compliance with federal standards should provide a more limited defense to punitive
or excessive compensatory damages).
and arguments about its desirability from the conceptually different issue of federal preemption of positive state enactments.

V. CONCLUSION

The Supreme Court decided *Cipollone* under the rubric of federal preemption. Perhaps this was an unfortunate choice of terminology because it has caused great mischief in other contexts. Before 1992, the Supreme Court did not accept preemption as a defense to tort liability, at least not unless the statute provided a substitute remedy or otherwise granted exclusive jurisdiction to a federal agency. The plurality's judgment in *Cipollone*, as refined in a pair of subsequent decisions by the Court, signalled a new willingness to accept preemption as a defense to common-law tort claims.

A number of lower courts have read *Cipollone* and its progeny as an invitation to cut off plaintiffs' access to tort remedies, even in extreme situations in which a company has not complied with the federal requirements that are being given preemptive effect. This strong version of preemption represents the least defensible reading of *Cipollone*. The intermediate version, which does not preempt claims if they are premised on violations of federal requirements, is somewhat more sensible but arguably still more protective than *Cipollone* demands. Instead, the weak version of preemption, which is really indistinguishable from the government standards defense, may be more in keeping with what the Supreme Court actually decided in that case. Under this approach, proof of compliance is a predicate for invoking this affirmative defense, and evidence of fraud on the responsible agency might defeat it.