

September 2000

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M. Stuart Madden

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Recommended Citation

M. Stuart Madden, *Federal Preemption of Inconsistent State Safety Obligations*, 21 Pace L. Rev. 103 (2000)

DOI: <https://doi.org/10.58948/2331-3528.1249>

Available at: <https://digitalcommons.pace.edu/plr/vol21/iss1/2>

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Federal Preemption of Inconsistent State Safety Obligations

M. Stuart Madden*

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Abstract

The reach of Federal statutory preemption of inconsistent state law obligations has extended to numerous products liability subject matters, including most notably tobacco products, agricultural pesticides, medical devices and automobile air bags. The Supreme Court decision in Cipollone v. Liggett Group, Inc. countenanced a broad application of federal preemption when the subject statute contained an express preemption clause. Eight years later the Court appeared to back away from Cipollone, and held in Geier v. American Honda Motor Co. that even as to statutes with express preemption clauses, the simultaneous presence of a savings clause might trigger a narrow reading of the preemption provision. The potential effect of Geier upon lower court decisions in liability suits involving pesticides, medical devices, or even tobacco products, will necessarily be played out in litigation before lower courts for years to come.

I. INTRODUCTION

The significance of federal statutory preemption of inconsistent state tort law obligations was branded on the hind-quarters of products liability law in the 1992 Supreme Court decision of *Cipollone v. Liggett Group, Inc.*¹ *Cipollone's* emphasis on textual express preemption was followed by numerous lower court decisions holding that federal health and safety rules in product subject categories ranging from pesticides to

1. 501 U.S. 504 (1992).

prostheses to propellers should be given sway over inconsistent state common law liability or statutory obligations.

The *Cipollone*-sparked romp over the historical federal hesitance to impose federal regulation in areas of health, safety and welfare traditionally ceded to the individual states was brought to a pause, if not a halt, by the Supreme Court's 2000 decision in *Geier v. American Honda Motor Co.*² In *Geier*, an air bag case, the Court gave new vitality to the application of ordinary preemption principles even in the context of a federal safety statute that contained an express preemption provision clause, should such statute also contain a "savings" clause provision essaying to preserve common law damage claims from any preemptive consequences. The implications of *Geier* and its explicit distancing from *Cipollone* will surely roil the waters of products liability litigation for years to come.

II. TYPES OF PREEMPTION

A. *Express preemption*

Perhaps the most important emerging issue in modern products liability law is the role of the federal statutory preemption of private civil suits brought under state statutory or common law. Characteristically, the question of the appropriateness of federal preemption is implicated when such state law claims for damages or equitable remedies trench upon the same safety objectives, which Congress has addressed directly, or indirectly through federal statute or administrative regulation. As discussed below, the Supreme Court's 1992 decision in *Cipollone v. Liggett Group, Inc.*³ gave new definition to the constitutional doctrine of federal legislative preemption, and provided a basis for modern application of the tenets of that doctrine in a range of accident law and regulatory settings.

In general terms, federal safety-related statutes, or regulations pursuant to those statutes, that pertain to a particular field or subject matter may be deemed to preempt state regulation or common law that would impose design, performance, or informational requirements upon a seller that are inconsistent with the federal standard. Federal law may also preempt suits

2. ___ U.S. ___, 120 S. Ct. 1913 (2000).

3. 505 U.S. 504 (1992).

brought under state common law or state codification of common law principles that create the risk that a seller who has satisfied federal safety-related requirements might nevertheless be found liable in money damages, or subject to equitable relief, in a products liability suit.⁴ The primacy of federal law in such subject areas as Congress may elect to regulate is grounded in the Supremacy Clause of Article VI of the Constitution, which provides that the laws of the United States "shall be the supreme Law of the Land; and . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."⁵

Preemption may be either express or implied, and "is compelled whether Congress's command is explicitly stated in the statute's language or implicitly contained in its structure and purpose."⁶ Issues of express preemption are textual, while questions of implied preemption are contextual. By this it is meant that the question of whether federal law expressly preempts inconsistent or additional state common law, statutory or regulatory requirements may be deduced from the explicit language of a federal statute.⁷ Implied preemption, in contrast, must ordinarily be inferred from an evaluation of not only the language of the statute, which may or may not contain a preemption clause, but also from an assessment of the overall statutory objectives. As to the latter, a full understanding of statutory objectives will frequently be informed by pertinent

4. Where applicable, federal preemption precludes coequally state statutes, regulations or common law enforcement claims. *Cf. Gilbert v. Burlington Indus., Inc.*, 765 F.2d 320, 327-28 (2d Cir. 1985), *aff'd*, 477 U.S. 901 (1986)(ERISA), referenced with approval in *Oglesby v. Delaware & Hudson R.R. Co.*, 180 F.3d 458 (2d Cir. 1999) (held: railroad employee personal injury claim against employer and manufacturer of engineer cab seat impliedly preempted by Locomotive Boiler and Inspection Act, 49 U.S.C. § § 20701-20903).

Also, the application of preemption principles to state statutory/regulatory and common law pursuits alike is explained by the Supreme Court's observation in *San Diego Building Trades Council v. Garmon*, 359 U.S. 236, 247 (1959), that awards of money damages in suits for civil liability can act as a "potent method of governing conduct and controlling policy."

5. U.S. CONST. art. VI, § 2.

6. *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977); *See generally Oja v. Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997) (held: negligent failure to warn claim in hip prosthesis products liability action is not preempted under 1976 Medical Device Act Amendments). Preemption issues associated with medical devices are discussed below in § II(H).

7. *See generally Cipollone*, 505 U.S. 504 (1992), discussed in detail at II(A) below.

legislative history and the interpretation of the statute given it by the regulatory agency charged with its effectuation.⁸

The approach taken by the Supreme Court in its interpretation of the Supremacy Clause as applicable to state law preemption “starts with the assumption that the historic police powers of the States [are] not to be superseded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress.”⁹ Express preemption is properly found “[w]hen Congress has considered the issue of preemption and has included in the enacted legislation a provision explicitly addressing that issue, and when that provision provides a ‘reliable indicium of congressional intent with respect to state authority[.]’”¹⁰ In the words of one court concerning express preemption:

Federal preemption is a relatively simple concept, especially when Congress has explicitly provided the terms of preemption. It provides order. Instead of having 50 or more standards with respect to a given human pursuit, there is one. When a preemptive federal standard is applied evenhandedly, it further provides both the protection of the federal standard and some leeway to develop state standards where the federal standard does not apply.¹¹

A party advancing the defense of federal preemption must overcome an established presumption against federal preemption of state law. Thus any statutory provision forming the basis of a preemption defense will be narrowly construed,¹² consistent with the tenet that state police powers, particularly state regulations relating to health and safety, should not be

8. Implied preemption of state common law or statutory products liability litigation is discussed in § I(B) below.

9. *Cipollone*, 505 U.S. at 516 (citing *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

10. *Id.* at 517.

11. *Steele v. Collagen Corp.*, 54 Cal. App. 4th 1474 (1997) (citations omitted) (personal injury claims arising from administration of *Zyderm*).

12. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 484 (1996), interpreted in *Ryan v. Brunswick Corp.*, 557 N.W.2d 541, 546 (Mich. 1997) (federal decision not to require boat propeller guards found to preempt state law personal injury claims grounded in argument that propeller guards would have prevented or lessened decedent's injury).

superseded without a demonstration that such preemption is the "clear and unequivocal intent of Congress."¹³

B. *Implied preemption*

i. *General implied preemption*

Where a federal safety-related statute does not contain language providing expressly for its preemptive effect, and, where pertinent, the preemptive effect of regulations or standards promulgated pursuant thereto, the products liability defendant will attempt to argue that the language of the statute, the context of the federal regulatory interest, and the wishes of the congressional authors, read together, require the conclusion that inconsistent or additional state law claims or requirements are impliedly preempted.¹⁴ This subsection and the two to follow describe briefly the three principal theories underlying the doctrine of implied preemption.¹⁵

Defendant's defense of general implied preemption may succeed upon a showing that the scope of the safety-related statute, including a fact-specific appreciation of its comprehen-

13. *Ryan*, 557 N.W.2d at 546 (citing *Cipollone*, 505 U.S. 504, 516 (1992)). See *Hillsborough Co. v. Automated Medical Labs, Inc.*, 471 U.S. 707, 715 (1985).

As stated by the Supreme Court in *Medtronic*, matters of the citizenry's health and safety "are primarily and historically matters of local concern[.]" and therefore "the States traditionally have a great latitude under their police powers to legislate as to the protection of the lives, limbs, comfort and quiet of all persons." *Medtronic*, 518 U.S. at 475.

14. See, e.g., Carter H. Dukes, Comment, *Alcohol Manufacturers and the Duty to Warn: An Analysis of Recent Case Law in Light of the Alcoholic Beverage Labeling Act of 1988*, 38 EMORY L.J. 1189 (1989) (27 U.S.C.A. §§ 201-210 (West 1988) expressly preempts claims against alcohol manufacturers for failure to warn, but neither expressly nor impliedly precludes plaintiffs' cause of action for promotional and advertising activities).

15. The three analytically distinct types of implied preemption that courts have recognized are (1) general implied preemption, (2) field preemption, and (3) conflict preemption. Ordered differently, the factor analysis employed by many courts in adopting these distinctions were summarized by the Supreme Court in this way: (1) "Congress' intent to supersede state law altogether may be found from a 'scheme of federal regulation so persuasive as to make reasonable the inference that Congress left no room to supplement it;'" (2) an act of Congress may touch a field in which the federal interest is "so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject;" or (3) because "the object sought to be obtained by the federal law and the character of obligations imposed by it may reveal the same purpose." *Fidelity Fed. Sav. & Loan Assoc. v. de la Cuesta*, 458 U.S. 141, 153 (1982).

siveness and its particularity, taken together with the observations of its congressional authors and its regulatory legal experts, demonstrates that toleration of inconsistent or additional state common law or statutory requirements would frustrate the purpose of the federal act.¹⁶ As the Supreme Court has explained, in the absence of language revealing “an explicit congressional intent to preempt state law,” courts examining the potential that federal law impliedly preempts state statutory or common law claims should consider “whether the federal statute’s ‘structure and purpose,’ or nonspecific statutory language, reveal a clear, but implicit, pre-emptive intent.”¹⁷

ii. *Field preemption*

Even though concepts of federalism preserve a constitutional reluctance to permit federal law to supplant state regulatory prerogative, particularly in matters associated with the health, safety and welfare of citizens of that state, there are two additional theories by which a federal safety-related statute may be deemed to impliedly preempt an additional or inconsistent state claim or requirement. A second means of implied preemption is termed “field preemption.” A conclusion that state statutory or common law remedies are preempted by a federal statutory initiative may be warranted when examination of the federal statute and allied regulations permit the conclusion that in passing the statute and creating the regulatory authority of the pertinent federal agency or agencies, Congress intended that federal law and regulation effectively and functionally occupy the safety field that the state law or regulation would purport to enter. Field preemption may be found when Congress or its administrative delegees have “so thoroughly occupied a legislative field ‘as to make reasonable the inference that Congress left no room for the states to supplement it.’”¹⁸

A finding of field preemption of state statutory enforcement or common law liability claims does not turn upon whether the federal agency has actually initiated regulation in the pertinent

16. See *Phillip Morris, Inc., v. Harshbarger*, 122 F.3d 58, 66-67 (1st Cir. 1997).

17. *Barnett Bank of Marion County v. Nelson*, 517 U.S. 25, 30-31 (1996).

18. *Cipollone*, 505 U.S. at 516. Compare with *Merrell Dow Pharm. v. Orendine*, 649 A.2d 825 (D. C. Cir. 1994) (held: FDA regulations did not implicitly preempt state common law claims in Bendectin-related litigation).

subject matter, but rather upon whether it is empowered to do so.¹⁹ The Supreme Court so confirmed in *Napier v. Atlantic Coast Line R. Co.*²⁰ in which, interpreting the Locomotive Boiler Inspection Act,²¹ it wrote: "The fact that the [Interstate Commerce] Commission has not seen fit to exercise its authority to the full extent conferred, has no bearing on the construction of the act delegating the power."²²

iii. *Conflict preemption*

Third, additional or inconsistent state safety common law or statutory obligations or requirements may be deemed to be impliedly preempted where the obligations or prohibitions imposed by state statute or regulation "actually conflic[t] with federal law,"²³ which is to say, in instances in which "compliance with both state and federal law is a 'physical impossibility,' or where state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'"²⁴ This type of implied preemption is described as "conflict" preemption.

As is true in matters of potential express preemption, courts have adopted a rebuttable presumption against all types of implied preemption that would supplant state legislative authority, particularly where such preemption is urged in actions implicating accident law. In one court's words: "Where the state laws at issue affect health and safety issues, there is a presumption against implied preemption by congressional enactments."²⁵

19. See *Oglesby*, 180 F.3d 458, 461 (2nd Cir. 1999) ("[T]he relevant question is not whether the federal government has exercised its authority but whether it possesses the power in the first place.").

20. 272 U.S. 605 (1926).

21. See 49 U.S.C. §§ 20701-20903.

22. *Napier*, 272 U.S. at 613.

23. *Cipollone*, 505 U.S. at 516.

24. *Philip Morris, Inc.*, 122 F.3d 58, 68 (1st Cir. 1997). Accord *Oxendine*, 649 A.2d 825, 828 (D.C. Cir. 1994) (stating "Third, preemption results if state law directly conflicts with a federal law in one of two ways: compliance with both federal and state law is impossible, or state law obstructs the federal purpose.")

25. *Oxendine*, 649 A.2d at 828 (citing *Hillsborough County v. Automated Medical Labs, Inc.*, 471 U.S. 707, 715 (1985)). Accord *Mazur v. Merck & Co.*, 742 F. Supp. 239, 245 (E.D. Pa. 1990) (suit against manufacturer of measles, mumps and rubella vaccine brought by parents of a child who contracted subacute sclerosing panencephalitis (SSPE)).

III. PREEMPTION AND REGULATORY ISSUES

A. Tobacco Product Labeling

Preemption analysis as it relates to tobacco product matters derives almost exclusively from the Supreme Court decision in *Cipollone v. Liggett Group, Inc.*²⁶ In *Cipollone*, the Court reiterated that “Congress’ intent may be ‘explicitly stated in the statute’s language or implicitly contained in the structure and purpose.’”²⁷ Consistent with the discussion of implied preemption, the Court confirmed that even absent express or explicit preemption, state law may be preempted where “that law actually conflicts with federal law, or if federal law so thoroughly occupies a legislative field ‘as to make reasonable the inference that Congress left no room for the States to supplement it.’”²⁸

The suit in *Cipollone* was filed in the New Jersey federal trial court by Rose Cipollone, who would die of lung disease one year later, and her husband. The plaintiffs alleged that cigarette manufacturers: (1) sold a product that was defectively designed, in that there were safer alternative designs for cigarettes, and because the social utility of cigarettes was vastly outweighed by the dangers inhering in their use; (2) failed to provide adequate warnings; (3) “were negligent in the manner [that] they tested, researched, sold, promoted and advertised” cigarettes; (4) breached express warranties as to the lack of health risks from smoking; (5) fraudulently misrepresented health risks, thereby neutralizing federally mandated warnings; (6) “ignored and failed to act upon” scientific and medical data showing the health risks of cigarette smoking; and (7) by “conspiracy to defraud” combined with other manufacturers to deny the public of medical and scientific information.²⁹

Section 5 of the 1965 Cigarette Labeling and Advertising Act (“1965 Act”), captioned “Preemption,” provided “(a) No statement relating to smoking and health, other than the [Section 4] statement . . . shall be required on any cigarette package,” and “(b) no [such] statement . . . shall be required in the

26. 505 U.S. 504 (1992).

27. *Id.* at 516.

28. *Id.*

29. *Id.* at 509-10. The *Cipollone* decision itself did not address the issue of product defectiveness. See *Richardson v. Phillip Morris, Inc.*, 950 F.Supp 700 (D. Md. 1997).

advertising of any cigarettes the packages of which are labeled in conformity with" Section 4.³⁰ Section 5 (b) was amended by the Public Health Cigarette Smoking Act of 1969 ("1969 Act") to specify that: "No requirement or prohibition based on smoking and health shall be imposed under state law with respect to the advertising and promotion of any cigarette the packages of which are [lawfully] labeled."³¹

The Third Circuit Court of Appeals held that Congress "had impliedly pre-empted . . . claims challenging the adequacy of warnings on labels or in advertising or the propriety of [the manufacturers'] advertising and promotional activities."³² The Supreme Court reversed in part and affirmed in part.³³ The Court found that the preemptive scope of the 1965 Act and the 1969 Act was governed entirely by the express language of § 5 of each Act,³⁴ and that, therefore, no justification existed for evaluating the possibility of implied preemption.³⁵

At the same time, the *Cipollone* Court determined that the appellate court erred in concluding that the preemptive language of the two respective Acts was operatively indistinguishable. In the Court's view, § 5 of the 1965 Act "only preempted state and federal rule-making bodies from mandating particular cautionary statements and did not preempt state common law damages actions."³⁶ The Court reasoned that (1) the presumption against the preemption of state police power regulations required a narrow reading of the 1965 preemption provision;³⁷ (2) label warning mandated by the 1965 Act's § 4

30. Federal Cigarette Labeling and Advertising Act, 15 U.S.C.A. §§ 1331-1340 (West 1965).

31. Public Health Cigarette Smoking Act of 1969, 15 U.S.C.A. §§ 1331-1340 (West 1969).

32. *Cipollone*, 505 U.S. at 517 (citing the Third Circuit Court of Appeals ruling in *Cipollone v. Liggett Group Inc.*, 789 F.2d 181, 187 (3d Cir. 1986)). In so doing, the Court observed that the Third Circuit had placed unwarranted reliance upon the fact that the 1969 Act did not alter the statement of purpose from the 1965 Labeling Act. *Id.* at 517 n. 13.

33. *Cipollone*, 505 U.S. 504 (1992); see Richard C. Ausness, *The Impact of the Cipollone Case on Federal Preemption Law*, 15 J.PROD. & TOX.LIAB. 1 (1993).

34. See *Cipollone*, 505 U.S. at 517.

35. See *id.*

36. *Id.* at 519-20. Elsewhere in its opinion the court uses the terminology "positive enactment" synonymously with a "mandat[e] [as to] particular cautionary statements[.]" *Id.* at 520.

37. See *id.* at 518-19.

“does not by its own effect foreclose additional obligations imposed under state law,”³⁸ because the mere fact “that Congress requires a particular warning does not pre-empt a regulatory field;”³⁹ and (3) “there is no general, inherent conflict between federal preemption of state warning requirements and the continued viability of state common law damages actions.”⁴⁰ All of these considerations led the Court to conclude that § 5 of the 1965 Act “superseded only positive enactments by legislatures or administrative agencies that mandate particular warning labels.”⁴¹

Disagreeing with the Third Circuit, the Supreme Court found that the preemptive language in the 1969 Act was materially different—and substantially broader in application—than the preemptive language in the 1965 Act. The Court explained:

First, the [1969] Act bars not simply ‘statement[s]’ but rather ‘requirement[s] or prohibition[s] . . . imposed under State law.’ Second, the later Act reaches beyond statements ‘in the advertising’ to ‘obligations with respect to the advertising or promotion’ of cigarettes.⁴²

The Supreme Court continued by noting that this broader reading was justified, in part, on the basis that the 1969 Act substantially altered the 1965 Act by “rewriting the label warning, banning broadcast advertising, and allowing the FTC to regulate print advertising.”⁴³

In addition, the Court found that the phrase “imposed under state law” is not limited to “positive enactments” obligating manufacturers to employ particular cautionary language or symbols.⁴⁴ Focusing on the 1969 Act’s broader language of “requirements or prohibitions,”⁴⁵ the Supreme Court considered whether or not personal injury claims brought under state law might operate as a de facto imposition of a requirement or a prohibition. The question the Court posed could be put this way: “Does imposition of or vulnerability to a plaintiff’s verdict

38. *Id.* at 518.

39. *Cipollone*, 505 U.S. at 518.

40. *Id.*

41. *Id.* at 518-19.

42. *Id.* at 520.

43. *Id.*

44. *Cipollone*, 505 U.S. at 522.

45. *Id.* at 521-24.

arising from a claim that the manufacturer should have provided warnings in addition to those required by the 1969 Act impose an obligation upon the manufacturer that can be considered a requirement or a prohibition within the meaning of the 1969 Act?" The Supreme Court answered its own question affirmatively.⁴⁶

The Court stated that "the central inquiry" in the matter before it was straightforward: "We ask whether the legal duty that is the predicate of the common-law damages action constitutes a 'requirement or prohibition based on smoking and health . . . imposed under State law with respect to . . . advertising or promotion,' giving that clause a fair but narrow reading."⁴⁷ Applying this "straightforward" analysis to the common law claims advanced by Mrs. Cipollone and her husband, the Supreme Court held that a products liability action alleging failure to provide adequate warnings was in essence a claim that the manufacturer's "post-1969 advertising or promotions should have included additional, or more clearly stated, warnings[.]"⁴⁸ Such a failure to warn claim was, by the terms of the 1969 Act, preempted.⁴⁹

A different result was appropriate, however, for such tort claims as were not associated with the advertising or promotion of cigarettes. Thus, the Supreme Court made clear that the 1969 Act did not operate to preempt claims in tort that might be based upon "the testing or research practices [of a defendant,] or other actions unrelated to advertising or promotion [of cigarettes.]"⁵⁰ Further, the Supreme Court continued, the plaintiffs' claims for breach of an express warranty were not precluded insofar as they derived from the contractual nature of the relationship between the seller and buyer, rather than being imposed by state law.⁵¹ Thus, the *Cipollone* Court concluded "a common law remedy for a contractual commitment voluntarily

46. *See id.* at 524.

47. *Id.* at 523-24.

48. *Id.* at 524.

49. *Cipollone*, 505 U.S. at 524.

50. *Id.* at 524-25.

51. *See id.* at 525-26. The Court's evaluation regarding express warranties is of limited modern significance, as today, unlike the era in which Mrs. Cipollone began to smoke, no tobacco manufacturer is so incautious as to plump the health virtues of smoking.

undertaken should not be regarded as a 'requirement . . . imposed under State law' within the meaning of § 5(b)."⁵²

The plaintiffs alleged that the manufacturer had engaged in two distinct types of misrepresentation. Taking each misrepresentation claim in turn, the Court found that a claim for fraudulent misrepresentation premised upon an allegation that the advertising practices of the cigarette manufacturers neutralized the effect of federally-mandated warning labels was preempted by the 1969 Act.⁵³ Noting the interrelationship between regulatory prohibitions on advertising that downplay dangers of smoking and the associated statutory requirements for warnings, the Court found that such a theory of fraudulent misrepresentation was inextricably related to a theory of failure to warn and was similarly preempted.⁵⁴

The Supreme Court recognized, however, an important distinction between fraudulent misrepresentation claims associated with advertising and other forms or venues of misrepresentation. An example of the former might be a billboard with an image of young vibrant persons engaged in vigorous physical activity, serving to convey the message that cigarette smoking is compatible with cardiovascular fitness. Examples of the latter type of misrepresentation such as evidence that the cigarette manufacturers concealed material facts from administrative agencies, or that they included false statements of material fact, e.g., carbon monoxide or tar levels, in their advertising, would not be preempted by the 1969 Act.⁵⁵ The Court reasoned that this second type of fraudulent misrepresentation claim was predicated on state law duties to disclose material facts, rather than on advertising and promotion. To further clarify the distinction, the Supreme Court stated that in the former type of alleged fraudulent misrepresentation, such as billboards, print media and the like, state laws obligating manufacturers to disclose safety or health risks to administrative agencies were "obligations with respect to advertising or promotion" and a state law claim premised upon the breach of

52. *Id.* at 526.

53. *See id.* at 527.

54. *Cipollone*, 505 U.S. at 528.

55. *See id.*

that duty would be preempted.⁵⁶ Claims that an advertisement contains a false statement of a material fact, in contrast, are not “predicated upon a duty based on smoking and health, but rather on a more general obligation—the duty not to deceive.”⁵⁷ Regarding plaintiff’s conspiracy claims, the Court found these, too, were not preempted, as the duty not to conspire to commit fraud is not a prohibition “based on smoking and health.”⁵⁸

In summarizing its holding, the Court wrote:

The 1965 Act did not pre-empt state law damages actions; the 1969 Act pre-empts petitioner’s claims based on a failure to warn and the neutralization of federally mandated warnings to the extent that those claims rely on omissions or inclusions in respondents’ advertising or promotions; the 1969 Act does not pre-empt petitioner’s claims based on express warranty, intentional fraud and misrepresentation, or conspiracy.⁵⁹

Mr. Justice Blackmun, joined by Justices Kennedy and Souter, concurred in part and dissented in part, arguing that the modified language of § 5(b) in the 1969 Act did not clearly exhibit the necessary congressional intent to preempt state common law damage actions.⁶⁰ The three Justices concluded, therefore, that the plaintiffs’ various failure to warn and fraudulent misrepresentation claims, as well as express warranty and conspiracy claims, should not be preempted by the 1969 Act.⁶¹ Conversely, Justices Scalia and Thomas argued that all of petitioner’s common law claims were preempted by the 1969 Act.⁶²

i. *Warnings or misrepresentation claims regarding second-hand smoke or nicotine addiction*

The legislative history is ambiguous as to whether Congress, in either the 1965 or the 1969 Acts, contemplated that the labeling provisions should cover risks that were then unknown, or as to which the scientific and medical data were in-

56. *Id.* at 528.

57. *Id.* at 528-29.

58. *See id.*

59. *Cipollone*, 505 U.S. at 530-31.

60. *See id.* at 531-44.

61. *See id.*

62. *See id.* at 544-56.

cipient, or as it is sometimes put, “immature.” *Cipollone* did not address the issue of whether the 1969 Act should be interpreted to preempt warning or misrepresentation claims regarding risks allegedly associated with second-hand smoke or nicotine addiction. Read together, the statements of purpose and the committee reports underlying the 1965 and the 1969 Acts permit no confident conclusion. Evaluation of whether the 1969 Act ought properly to preempt claims that the manufacturers fraudulently concealed or purposefully misrepresented information regarding claimed risks of injurious exposure to second-hand smoke or nicotine addiction requires examination of the legislative tradeoffs, or bargained-for exchanges, if any, that were involved in the consideration of and drafting of the 1969 Act. In this connection, the legislative history of the 1965 Act also enjoys a role, as the metes and bounds of congressional consideration in both the 1965 and the 1969 Acts may, to a cautious extent, be considered collectively.

Section 2 of the 1965 Act declared that the statute’s two purposes were “(1) adequately informing the public that cigarette smoking may be hazardous to health, and (2) protecting the national economy from the burden imposed by diverse, nonuniform, and confusing cigarette labeling and advertising regulations.”⁶³ Both the statement of the 1965 Act’s purpose, and the language comprising its required labeling, make it clear that Congress intended the warnings to convey to the public only that cigarette “smoking” could be hazardous to health. Section 2 further states that the goal of the mandated warning language is that of “informing the public that cigarette smoking can be hazardous to health,” while Section 4 of the 1965 Act required a specific label stating, among other things: “Caution: Cigarette Smoking May Be Hazardous To Your Health.”⁶⁴ Nowhere referenced in the statute’s statement of purpose or its required labeling is the suggestion that a message was intended to be conveyed to nonsmokers, i.e., information suggesting that smoking by others could be hazardous to nonsmokers. It appears, therefore, that in the absence of any arguable revelation of congressional intent that this too was an objective of the 1965 or 1969 Acts, neither Act can logically be construed to apply to

63. *Id.* at 514.

64. *Cipollone*, 505 U.S. at 514.

the health claims arising from the health risks of exposure to secondhand smoke.

The legislative history for the 1969 Act contains several references to the Congressional authors' awareness of (1) the risks of inhalation of environmental smoke and (2) the potential that with the passage of time, additional health risks of tobacco would be discovered and proved. Senate Report 91-566⁶⁵ and the accompanying Conference Report to Public Law 91-222,⁶⁶ otherwise known as the Public Health Cigarette Smoking Act of 1969,⁶⁷ contains several references to cigarette-related health risks. The fair inference of this is that, in passing the 1969 Act, (1) Congress was aware of health dangers other than the orthodox litany, i.e., respiratory disease, lung disease, pulmonary disease; and (2) Congress was further aware of health risks posed to individuals other than the smokers themselves.

As to the issue of nicotine dependence, the Conference Report to the 1969 Act cited conspicuously a 1967 FTC Report, filed pursuant to the 1965 Act § 5(d)(2), which stated that the very fact that "cigarette smoking is so strongly habit forming" was a basis for its statement that "it is unlikely that a mildly phrased cautionary statement will have any effect on confirmed cigarette smokers."⁶⁸ The Senate Report later reiterated the FTC's observations that "another aspect of cigarette smoking that is . . . ignored, and has vital implications in terms of health hazard, is the fact that cigarette smoking is strongly habit forming."⁶⁹ As a result of the reports, the FTC recommended the listing of nicotine content on cigarette packages.

Further reflective of Congress's awareness that not only tar levels, but also nicotine levels, contributed to the health risks, S. Rep. No. 91-566 referenced the Department of Health, Education and Welfare's (HEW) recommendation, filed pursuant to the 1965 Act, that "levels of 'tar' and nicotine in cigarette smoke should be published on cigarette packages[.]"⁷⁰ That the 1969 Act contemplated the potential of new discernible health risks

65. S. REP. NO. 91-566, (1970), *reprinted in* 1970 U.S.C.C.A.N. 2652, 2653

66. H.R. REP. NO. 91-897 (1970), *reprinted in* 1970 U.S.C.C.A.N. 2676.

67. *See id.* *See also* 15 U.S.C.A. §§ 1331-1340 (West 1997).

68. S. REP. NO. 91-566 (1969), *reprinted in* 1970 U.S.C.C.A.N. 2652, 2655.

69. *Id.*, *reprinted in* 1970 U.S.C.C.A.N. 2652, 2656.

70. *Id.*, *reprinted in* 1970 U.S.C.C.A.N. 2652, 2655.

of tobacco use was reflected in § 8 of the Act, “continu[ing] the requirement that the Secretary of [HEW] . . . transmit reports to Congress . . . providing current information on the health consequences of smoking[.]”⁷¹ In addition, the Senate Bill confirmed that the preemption entailed “is narrowly phrased to preempt only state action based on smoking and health. . . . It would in no way,” the Report points out, “affect the power of any state . . . [regarding] the prohibition of smoking in public buildings[.]”⁷²

Commentators have urged that in the specific context of second-hand smoke claims, the labeling and advertising requirements do not extend to nonsmokers subjected to second-hand smoke; “reliance on the notice given to smokers via the labeling act[s] . . . cannot apply to nonsmokers, as they are not the ones who are warned through the contents of the cigarette label.”⁷³ To further the argument that the warning provisions apply to smokers and not to nonsmokers is the fact that the language of the 1965 Act references the relationship between cigarette “smoking” and health, rather than a reference to the effects of “smoke” and health, a usage equally available to the legislative authors of the Act.

As to the question of whether at the very time of passing the 1969 Act Congress visualized that additional tobacco use health risks might be discovered, as previously noted, the pertinent Conference Report noted the inclusion of a new § 8 to the Act that directed HEW to report to Congress “current information on the health consequences of smoking . . .”⁷⁴ One potential interpretation of this provision is that the congressional authors imagined that yet undiscovered health risks tied to tobacco use might be unearthed in the future and that Congress should not be considered to have preempted that which has not visualized. However, preemption advocates might respond that warnings or misrepresentation state law claims associated with such new risks would bear the unmistakable earmarks of “requirements or prohibitions relating to advertising or promotion

71. *Id.*, reprinted in 1970 U.S.C.C.A.N. 2652, 2662.

72. *Id.*, reprinted in 1970 U.S.C.C.A.N. 2652, 2663.

73. Cindy L. Pressman, *No Smoking Please: A Proposal for Recognition of Non-Smokers' Rights Through Torts Law*, 10 N.Y.L. SCH. J. HUM. RTS. 595 (1993).

74. *Id.* at 33, 34.

of cigarettes” as those terms of art have been constructed by the *Cipollone* Court.⁷⁵

Various state disclosure laws have been held not to trammel preemption provisions under comparable tobacco-related acts.⁷⁶ For example, the Court of Appeals for the Fifth Circuit affirmed the district court’s ruling that a state Disclosure Act was not preempted by either the 1969 Act or the Smokeless Tobacco Act.⁷⁷ At issue was the Massachusetts Disclosure Act,⁷⁸ that required “manufacturers of tobacco products to disclose the additives and nicotine yield ratings of their products to the state’s public health department.”⁷⁹ The court in *Philip Morris, Inc. v. Harshbarger*⁸⁰ held that the Disclosure Act did not ‘relate to’ advertising or promotion because it lack[ed] the requisite ‘reference to’ or ‘connection with’ the preempted realm.”⁸¹ The appellate court also declared that there existed no evidence to support defendant’s contention that Congress had intended to impose “national uniformity” with respect to disclosure or ingredient reporting regulations.⁸² To be compared is the decision of an Alabama federal trial court in *Lacey v. Lorillard Tobacco Co. Inc.*,⁸³ in which the court held that common law claims regarding disclosure of cigarette ingredients were preempted by the 1969 Act.

B. *Pesticide, Herbicide and Rodenticide Labeling*

In the Federal Insecticide, Fungicide and Rodenticide Act (“FIFRA”), Congress established a comprehensive regulatory system for the registration and labeling of pesticides.⁸⁴ Prior to being placed into the market, a manufacturer must register a

75. *Cipollone*, 505 U.S. at 506.

76. *Philip Morris, Inc. v. Harshbarger*, 122 F.3d 58 (1st Cir. 1997).

77. *See id.*

78. *See* MASS. GEN. LAWS ch. 94, § 307(B) (West 1996).

79. *Harshbarger*, 122 F.3d at 58 (citing MASS GEN. LAWS ch. 94, 307(B)).

80. *Id.* at 74.

81. *See id.*

82. *Id.* at 85.

83. 956 F. Supp. 956 (N.D. Ala. 1997).

84. *See* 7 U.S.C.A. §§ 136-136y (West 1999). *See also* *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 990-91 (1984); *Love v. Thomas*, 858 F.2d 1347, 1350 (9th Cir.1988), *cert. denied*, 490 U.S. 1035 (1989) (FIFRA is “an elaborate framework for registration of pesticide use in United States”).

pesticide with the Environmental Protection Agency ("EPA").⁸⁵ As part of the registration process, the manufacturer must submit a proposed label to the EPA for approval.⁸⁶ FIFRA requires that the label be "adequate to protect health and the environment"⁸⁷ and be "likely to be read and understood."⁸⁸ For purposes of this discussion, the preemption issues associated with FIFRA are limited to the ability of a state to permit common law damage actions based upon product labeling. The Supreme Court held in *Wisconsin Public Intervenor v. Mortier (Ralph)*⁸⁹ that FIFRA does not preempt local governmental regulation of pesticide use.

FIFRA expressly prohibits states from imposing "any requirements for labeling or packaging in addition to or different from those required" under the Act.⁹⁰ Although a state is permitted to regulate the sale or use of a registered pesticide to the extent that such regulation does not permit a sale or use prohibited by the Act, it is precluded from imposing labeling or packaging requirements which alter, in any way, those imposed by the EPA.⁹¹

i. *Decisional law prior to Cipollone v. Liggett Group*

Prior to the Court's decision in *Cipollone*, the lower courts were divided with regard to the preemptive effect of FIFRA registration and labeling requirements upon suits brought under state common or statutory law for compensatory damages. In a pre-*Cipollone* decision finding no preemption, *Ferebee v. Chevron Chemical Co.*,⁹² a trial verdict was rendered against Chevron in favor of an agricultural worker who died from pulmonary fibrosis allegedly contracted through long-term inhalation of and dermal exposure to the herbicide Paraquat. Plaintiff claimed that the decedent's injuries were caused by Chevron's

85. See 7 U.S.C.A. § 136a(a) ("Except as provided in this Subchapter, no person in any state may distribute or sell to any person any pesticide that is not registered under this Subchapter").

86. See 7 U.S.C.A. § 136a(c)(1)(C) (West 1999).

87. 7 U.S.C.A. §§ 136(q)(1)(F), 136a(d) (West 1999).

88. 7 U.S.C.A. § 136(q)(1)(E) (West 1999).

89. 501 U.S. 597 (1991).

90. 7 U.S.C.A. § 136v(b) (West 1999).

91. 7 U.S.C.A. §§ 136v(a) and 136v(b) (West 1999).

92. 736 F.2d 1529 (D.C. Cir. 1984)

failure to adequately label Paraquat to warn against the possibility that chronic inhalation and skin exposure could lead to lung disease and death. The Court of Appeals for the District of Columbia Circuit held that in FIFRA and its accompanying regulations (1) there was no express preemption of state common law actions; (2) there was no implied field preemption of such claims, as there was no evidence of Congressional intent to occupy the field; and (3) there was no conflict preemption, as compliance with both federal and state law was not mutually exclusive.

In holding that FIFRA § 136v(b) did not expressly preempt state tort recovery, the Court of Appeals stated:

While FIFRA does not allow states directly to impose additional labeling requirements, the Act clearly allows states to impose more stringent constraints on the use of EPA approved pesticides than those imposed by the EPA Given this provision, Maryland might well have the power to ban Paraquat entirely [I]f a state chooses to restrict pesticide use by requiring that the manufacturer compensate for all injuries or for some injuries resulting from the use of a pesticide, federal law stands as no barrier.⁹³

In concluding that there was neither field nor conflict preemption, the court interpreted FIFRA as having primarily a regulatory aim—to ensure that, from a cost-benefit point of view, Paraquat, as labeled, does not produce “unreasonable adverse effects on the environment.”⁹⁴ The federal appeals court reasoned that state tort law had both a regulatory and a “broader, compensatory goal, [and that] conceivably, a label may be inadequate under state law if that label, while sufficient under a cost-benefit standard, nonetheless fails to warn against any significant risk.”⁹⁵ Although, the court continued, an award of damages for failure to warn imposed a dual obligation upon the manufacturer, Chevron could comply with both federal and state law by continuing to use the EPA approved label and by paying damages.⁹⁶ The court also stated that tort recovery could promote legitimate regulatory aims by leading manufac-

93. 736 F.2d at 1541.

94. *Id.* at 1540; see 7 U.S.C.A. § 136(bb) (West 1999) (defining “unreasonable adverse effects”).

95. 736 F.2d at 1540.

96. *See id.*

turers to petition EPA to allow more detailed labeling of their products, or by influencing the EPA to require revised labels in light of the new information brought to light through common law litigation.⁹⁷ Several courts adopted the *Ferebee* rationale and held that state common law remedies are not expressly preempted by FIFRA. For example, in *Riden v. ICI Americas, Inc.*,⁹⁸ the court held that FIFRA did not expressly or impliedly preempt state tort claims, that state common law remedies did not conflict with FIFRA's purposes, and that FIFRA falls short of requiring uniform labeling.⁹⁹

In contrast, a Michigan federal trial court rejected the *Ferebee* analysis in *Fitzgerald v. Mallinckrodt, Inc.*,¹⁰⁰ and held that the common law claims for failure to warn were preempted. The *Fitzgerald* court was not persuaded that a manufacturer had an authentic choice with respect to altering a pesticide's label in response to an adverse jury award. The court stated that the *Ferebee* "choice of reaction" analysis "seems akin to the free choice of coming up for air after being underwater. Once a jury has found a label inadequate under state law, and the manufacturer liable for damages for negligently employing it, it is unthinkable that any manufacturer would not immediately take steps to minimize its exposure to continued liability."¹⁰¹

In reaching its conclusion that FIFRA expressly preempted any state labeling or packaging requirements different from or additional to those mandated in FIFRA, the *Fitzgerald* court relied heavily on *Palmer v. Liggett*¹⁰² and the *Palmer* court's pur-

97. See *id.* at 1541.

98. 763 F. Supp. 1500 (W.D.Mo. 1991).

99. See *Roberts v. Dow Chem. Co.*, 702 F. Supp. 195, 199 (N.D.Ill. 1988) (adopting *Ferebee* rationale and concluding that legislative history indicates FIFRA regulations not intended to be so comprehensive as to occupy field). See also *Evenson v. Osmose Wood Preserving Inc.*, 760 F. Supp. 1345 (S.D.Ind. 1990); *Stewart v. Ortho Consumer Prods.*, 1990 WL 36129 (E.D.La. 1990); *Whitener v. Reilly Indus., Inc.*, No. 87-5224, slip op. at 4 (D.Ill. 1989); *Cox v. Velsicol Chem. Corp.*, 704 F. Supp. 85, 87 (E.D.Pa. 1989).

100. 681 F. Supp. 404 (E.D.Mich. 1987).

101. *Id.* at 407 (quoting *Palmer v. Liggett Group, Inc.*, 825 F.2d 620, 627-28 (1st Cir. 1987)).

102. 825 F.2d 620 (1st Cir. 1987).

ported rejection of *Ferebee*.¹⁰³ The *Fitzgerald* court held that whereas federal statute preempts any state regulation of labels, any recovery in tort is precluded. To hold otherwise "would have effectively authorized the state to do through the back door exactly what it cannot do through the front."¹⁰⁴ Several courts criticized the *Fitzgerald* court's reliance on *Palmer*,¹⁰⁵ but followed its conclusion and held that FIFRA preempts common law failure to warn claims.¹⁰⁶

103. Although the *Palmer* court noted its dissatisfaction with the *Ferebee* "choice of reaction" analysis as it applied to the 1969 Act, it did not question or criticize its application to FIFRA.

104. *Fitzgerald v. Mallinckrodt*, 681 F. Supp. 404, 407 (E.D. Mich. 1987).

105. *Riden v. ICI Americas, Inc.*, 763 F. Supp. 1500, 1507 n.13 (W.D.Mo. 1991); *Fisher v. Chevron Chem. Co.*, 716 F. Supp. 1283 (W.D.Mo. 1989). *Palmer*, 825 F.2d at 628, distinguished the *Ferebee* analysis on the basis that:

FIFRA, which applies to some 40,000 different herbicide and pesticide formulations, imposes upon an entirely different type of regulatory scheme from that established under the [1969] Act. Under FIFRA, each manufacturer drafts a warning label for each product for EPA approval. Thus, two manufacturers of the same regulated product may use different labels of their own choosing, provided only that they obtain prior EPA approval In contrast, the [1969] Act explicitly (i) applies to cigarettes only; (ii) mandates the precise language of the label; and (iii) prohibits any state from regulating any aspect of cigarette warnings.

106. *See Yowell v. Chevron Chemical Co.*, 836 S.W.2d 62 (Mo.App. 1992) (FIFRA preempted state wrongful death claim based upon alleged inadequacy of pesticide labeling); *Hurt v. Dow Chem. Co.*, 759 F. Supp. 556 (E.D.Mo. 1990); *Fisher v. Chevron Chem. Co.*, 716 F. Supp. 1283 (W.D.Mo. 1989); *Kennan v. Dow Chem. Co.*, 717 F. Supp. 799 (M.D.Fla. 1989); *Little v. Dow Chem. Co.*, 559 N.Y.S.2d 788 (1990). *See also Jenkins v. Anchem Products Inc.*, 886 P.2d 869 (Kan. 1994) (held: FIFRA preempted common law failure to warn claims as such claims constituted "requirement[s] for labeling or packaging [.]"); *Compare Hurt v. Dow Chem. Co.*, 759 F. Supp. 556 (E.D.Mo. 1990), where the court stated that § 136v(a) specifically allowed states to regulate the sale or use of any federally registered pesticide and that there was no conflict with regard to claims based upon the sale or application of a defective product.

See also Fisher v. Chevron Chem. Co., 716 F. Supp. 1283, 1284 (W.D.Mo. 1989), in which the federal trial court held that the claim that Paraquat was sold in an unreasonably dangerous, defective condition when put to its reasonably anticipated use was not preempted, in that there was no Congressional intent to "occupy the field" relating to pesticides and injuries arising from their use. Neither, the *Fisher* court held further, was plaintiff's claim that the aerial spraying of Paraquat was an inherently or abnormally dangerous activity.

In *Villari v. Terminix Int'l, Inc.*, 692 F. Supp. 568 (E.D.Pa. 1988), the court held that FIFRA's prohibition of state labeling and packaging requirements did not preempt state law tort action against an exterminator and a manufacturer based on the exterminator's alleged failure to warn of dangers associated with termiticides used in the home. The plaintiff's injuries did not result from the de-

ii. *Decisional law after Cipollone v. Liggett Group*

The Court of Appeals for the Eleventh Circuit's decisions in *Papas I* and *Papas II* provide a temporal bridge between a pre-*Cipollone* FIFRA analysis and the post-*Cipollone* approach that seemingly governs today. In *Papas v. Upjohn Co. (Papas I)*,¹⁰⁷ the court noted that the language in FIFRA, as well as its legislative history, could support a determination that state common law actions based upon inadequate labeling are expressly preempted, but declined to reach the issue.¹⁰⁸ Instead, the court found that federal preemption of common law tort claims based upon labeling deficiencies could be implied from FIFRA and the labeling regulations promulgated pursuant thereto.¹⁰⁹ The court reasoned (1) that FIFRA occupied the entire field of labeling regulation, leaving no room for the states to supplement federal law, even by means of state common law tort actions;¹¹⁰ (2) that "jury awards of damages in such tort actions would result in direct conflict with federal law";¹¹¹ and (3) that "allowing state common law tort suits for inadequate labeling would stand as an obstacle to the accomplishment and execution of the full objectives of Congress."¹¹² The court stated further that permitting common law tort actions based on labeling claims "would permit state court juries to do what state legislatures and state administrative agencies were forbidden to do: impose requirements for labeling pesticides."¹¹³ In the subsequent proceeding before the Supreme Court, the Court vacated *Papas I*

fendants' failure to comply with federal regulations, but rather from their breach of a duty to ensure that an appropriate warning reached not only the employees handling the pesticides but to the ultimate consumers of the pesticide product.

107. 926 F.2d 1019 (11th Cir. 1991), *cert. granted and judgment vacated*, 505 U.S. 1215 (1992), *on remand*, 985 F.2d 516 (11th Cir. 1993) (held: FIFRA expressly preempts state law claims based upon inadequate labeling or packaging). *See also Papas v. Upjohn Co.*, 985 F.2d 516 (11th Cir. 1993) (*Papas II*), *cert. denied*, *Papas v. Zoecon Corp.*, 505 U.S. 1215 (1993) (state law action for damages expressly preempted to extent dependent upon showing pesticide labeling or packaging failed to meet standards in addition to or different from those required by FIFRA).

108. *See Papas I*, 926 F.2d at 1023-24.

109. *See id.* at 1024.

110. *See id.* at 1025.

111. *Id.*

112. 926 F.2d 1019, 1025 (11th Cir. 1991). *See also Lescs v. Dow Chem. Co.*, 976 F. Supp. 393, 400 (W.D.Va. 1997).

113. *Id.* at 1026.

and remanded for reconsideration in light of its recent decision in *Cipollone*.¹¹⁴ With the *Cipollone* decision now before it, the Eleventh Circuit entered its ruling in *Papas II*, and held that FIFRA expressly preempted claims based upon inadequate labeling or packaging.¹¹⁵ A similar conclusion was reached in *MacDonald v. Monsanto Co.*,¹¹⁶ in which the Fifth Circuit Court of Appeals concluded that state common law judgments, including those predicated on a failure to warn theory, are "requirements" for the purposes of preemption.¹¹⁷

In *Shaw v. Dow Brands, Inc.*,¹¹⁸ the Court of Appeals for the Seventh Circuit compared the preemption provisions in both the 1969 Act and FIFRA and found them sufficiently alike to compel the conclusion that FIFRA expressly preempted inconsistent state common law demands.¹¹⁹ To like effect, in *King v. E.I. du Pont de Nemours & Co.*,¹²⁰ a Maine federal trial court considered whether FIFRA's mandate barring states from imposing requirements on herbicide labels precludes state common law tort claims. After reviewing the legislative history of FIFRA, the regulations promulgated to govern the registration of pesticides, and guidance of *Cipollone*, the *King* court held:

[FIFRA § 136v(b)] says that states 'shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter Since the 1969 Cigarette Act, which prohibits states from imposing 'requirements' on cigarette advertising, was held to preempt com-

114. 985 F.2d 516 (11th Cir. 1993).

115. *Id.* See also *Clubine v. American Cyanamid Co.*, 534 N.W.2d 385 (Iowa 1995) (discussed and limited in *Ackerman v. American Cyanamid Co.*, 586 N.W.2d 208 (Iowa 1998)) (held: claims associated with label-based warranties preempted by FIFRA as such claims constituted additional or different requirements than those imposed by FIFRA).

116. 27 F.3d 1021, 1025 (5th Cir. 1994).

117. *Id.* *Accord* *Deshotel v. Rhone-Poulenc, Inc.*, 969 F. Supp. 397 (W.D. La. 1997) (held: label-based claims brought against pesticide manufacturer by farmer who experienced failure of sweet potato crop preempted). See also *Ackles v. Luttrell*, 561 N.W.2d 573 (Neb. 1997) (held: claims based upon either failure to warn or fraudulent labeling claims against pesticide manufacturer preempted by FIFRA).

118. 994 F.2d 364 (7th Cir.1993).

119. *Id.* (citing *Cipollone v. Liggett Group*, 505 U.S. 504 (1992)).

120. 806 F. Supp. 1030 (D.Me. 1992), *aff'd*, *King v. E.I. DuPont de Nemours & Co.*, 996 F.2d 1346 (1st Cir. 1993), *cert. dismissed*, 510 U.S. 985 (1993) (FIFRA expressly preempts state tort law claims based upon alleged failure to provide adequate herbicide warning labels).

mon law damage actions with respect to inadequate warnings in *Cipollone*, we hold that the prohibition of 'requirements' under FIFRA preempts common law damage actions for failure to warn in the herbicide labeling context.¹²¹

Other courts having the opportunity to consider the preemptive effect of FIFRA in light of *Cipollone*¹²² have interpreted the Supreme Court's decision more restrictively. For example, in *Burke v. Dow Chemical Co.*,¹²³ the court undertook a detailed analysis of the statutory language of FIFRA to determine whether failure to warn claims would amount to a state imposed "requirement for labeling or packaging in addition to or different from those required [under FIFRA] and would therefore be expressly preempted."¹²⁴ The court found that the preemption provision in FIFRA lies "somewhere in between the [1965 Act] and [1969 Act] provisions."¹²⁵ The court stated that the prohibition upon the state imposing any "requirements" "for labeling or packaging" "different from" the EPA requirements, when viewed in conjunction with the general savings clause explicitly authorizing each state to regulate the sale or use of pesticides, "indicate[s] a congressional design to leave the states with expansive powers to 'regulate' pesticides."¹²⁶ Finding the doctrine of express preemption to be narrow in its scope and, moreover, that the failure to warn claims were not implicitly prohibited by FIFRA,¹²⁷ the court wrote:

Applying the somewhat subtle distinctions of *Cipollone*, we hold that, if EPA-approved labels were in fact affixed to the relevant containers, plaintiffs may not claim that defendants' products were mislabeled. If, however, warnings to the trade, warnings apart from labels or packaging, limitation on sales to professionals, or other protections falling generally within the ambit of warnings [which] should have been used when the content of the

121. 806 F. Supp. at 1036. See also *Casper v. E.I. Du Pont De Nemours & Co.*, 806 F. Supp. 903 (E.D.Wash. 1992); *Brennan v. Dow Chem. Co.*, 613 So.2d 131 (Fla. Ct.App. 1993).

122. 505 U.S. at 504.

123. 797 F. Supp. 1128 (E.D.N.Y. 1992).

124. *Id.* at 1140.

125. *Id.* at 1140; see 7 U.S.C.A. §§ 136v(a)-(b) (West 1999).

126. 797 F. Supp. at 1140.

127. See *id.* at 1141.

label was fixed by EPA there remains a liability question for the trier of fact.¹²⁸

Similarly, in *Couture v. Dow Chemical*,¹²⁹ the court held that "the narrow construction mandated by the preemption analysis utilized in *Cipollone*"¹³⁰ supported an earlier interpretation of FIFRA in which the court had followed *Ferebee*, and held that states are "free to regulate, through common law remedies, the use and sale of pesticides."¹³¹

It is seen that most courts considering the matter have concluded that FIFRA expressly preempts state law claims that manufacturers should have used labels or warnings different from or in addition to those required by federal statute.¹³² Importantly, however, FIFRA's preemptive effects are limited to claims related to labeling or packaging. Other common law products liability or warranty claims may remain viable.¹³³

128. *Id.* at 1140.

129. 804 F. Supp. 1298 (D.Mont. 1992).

130. *Id.* at 1302.

131. *Id.* at 1302. See also *Montana Pole & Treating Plant v. I.F. Laucks*, 775 F. Supp. 1339 (D.Mont. 1991), *aff'd*, 993 F.2d 676 (9th Cir. 1993) (common law tort claims not preempted by FIFRA).

132. See *DerGazarian v. Dow Chemical Co.*, 836 F. Supp. 1429 (W.D.Ark. 1993) (FIFRA preempts state common law insecticide warning or labeling claim); *Kolich v. Sysco Corp.*, 825 F. Supp. 959 (D.Kan. 1993) (held: warning and labeling claim against manufacturer of aerosol insecticide labeled in accordance with FIFRA labeling requirements preempted); *Levesque v. Miles, Inc.*, 816 F. Supp. 61 (D.N.H. 1993) (FIFRA expressly preempts common law failure to warn claim arising from leakage and ignition of a container of insect repellant leaked and ignited); *June v. Carmel Chem. Corp.*, 602 N.Y.S.2d 778 (1993) (FIFRA preempts firefighter's failure to warn claim arising from pesticide exposure); *Moody v. Chevron Chem. Co.*, 505 N.W.2d 900 (1993) (failure to warn claim preempted by FIFRA); *Brennan v. Dow Chem. Co.*, 613 So.2d 131 (Fla.Ct. App. 1993) (FIFRA preempts plaintiff's claims only to extent those claims were based upon finding that the product's labeling was inadequate).

133. See *DerGazarian*, 836 F. Supp. at 1429 (FIFRA did not preempt common law action premised upon insecticide manufacturer's alleged failure to use ordinary care in formulation, inspection and testing of insecticide); *Levesque v. Miles, Inc.*, 816 F. Supp. 61 (D.N.H. 1993) (FIFRA did not preempt statutory cause of action for breach of warranty); *Bingham v. Terminix Int'l Co.*, 850 F. Supp. 516 (S.D.Miss.1994) (preemptive scope of FIFRA extends only to claims relating to labeling and packaging; claims involving a failure to test or inspect product, non-labeling claims for breach of warranty, and claims for defective design or formulation not preempted).

C. Motor vehicle safety

In *Geier v. American Honda Motor Company*,¹³⁴ the Supreme Court retreated from its *Cipollone*-grounded focus on express preemption, but in so doing the Court did not necessarily ease the complexity of federal preemption issues as they affect motor vehicle safety statutes and regulations. In *Geier*, the Court was asked to analyze the effect of the express preemption provision in the National Traffic and Motor Vehicle Safety Act (“NTMVSA” or “Safety Act”) on a lawsuit alleging that a 1987 Honda was defective in design because it did not have a driver’s side air bag. The NTMVSA, under which the Department of Transportation issued a federal motor vehicle safety standard (“FMVSS”) which permitted automobile manufacturers in the late 1980s to choose among three options for passenger safety restraints, does contain a preemption provision, but also has a savings clause, described below.

Automobile design defect claims have been examined under the lens of federal law preemption for many years, and certain automobile design defect claims have been held preempted by the NTMVSA.¹³⁵ The NTMVSA delegates to the Secretary of Transportation the authority to establish motor vehicle safety standards, and the Secretary of Transportation has in turn delegated the duty of standard promulgation to the National Highway Transportation Safety Administration (“NHTSA”).¹³⁶ The NTMVSA contains a preemption clause that reads:

(b) Preemption.

(1) When a motor vehicle safety standard is in effect under this chapter, a State or a 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 in this chapter.¹³⁷

While the Safety Act by its terms precludes state safety standards with respect to “any motor vehicle or item of motor vehi-

134. ___ U.S. ___, 120 S. Ct. 1913 (2000).

135. See 49 U.S.C. § 30103(b)(1) (1996). The NTMVSA was previously codified at 15 U.S.C. § 1381, but in 1994 was recodified.

136. See 49 C.F.R. § 1.50 (current through September 29, 2000); See 49 C.F.R. § 501.2 (current through September 29, 2000).

137. 49 U.S.C. § 30103(b)(1) (West 1996).

cle equipment of any safety standard . . . which is not identical to the Federal standard,”¹³⁸ it contains a savings clause that reads: “(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.”¹³⁹

i. *Decisional law preceding Geier v. American Honda Motor Co.*

Prior to the entry of the Supreme Court’s decision in *Geier*, courts in several jurisdictions had held that compliance with the criteria for one of the multiple passive restraint options set forth in the regulations impliedly preempted a tort claim targeting the manufacturer’s election not to install airbags.¹⁴⁰ For example, in *Taylor v. General Motors, Corp.*¹⁴¹ the Court of Appeals for the Eleventh Circuit ruled that plaintiff’s state law claims against the manufacturer of an automobile for failure to install an airbag was impliedly preempted by the NTMVSA insofar as the manufacturer had sold a product equipped with one of the other passive restraint options available to it. Because no Florida appellate court had been presented with such an issue, the role of the Eleventh Circuit was to predict the outcome should the matter be heard by the State’s highest court.¹⁴² The federal appeals court focused on Supreme Court cases involving federal law preempting, by implication, state law claims, in which the Supreme Court had ruled that “under the principles of implied preemption, a state cannot impose common law damages on individuals for doing what a federal act or regulation ‘authorized them to do.’”¹⁴³ Insofar as personal injury claims brought under state law could, hypothetically but foreseeably, conflict with the passive restraint system approach permitted

138. 15 U.S.C.A. § 1392(d) (West 1974).

139. 49 U.S.C. § 30103(e) (West 1996). *See also* 15 U.S.C. § 1397(k) (West 1974).

140. 49 C.F.R. § 571.208 S5.1(a)-(b) (current through September 29, 2000).

141. 875 F.2d 816 (11th Cir. 1989).

142. *See id.*

143. *Id.* at 827 (citing *Chicago & N.W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 318 (1981)).

by the Safety Act, to permit such claims would "take away the flexibility provided by a federal regulation."¹⁴⁴

In *Taylor*, the Eleventh Circuit held that even absent express preemption, standards published by the NHSTA preempted, by implication, a common law claim for defect in design. The court held that the NHSTA as amended and regulations thereunder, authorizing the manufacturer a choice of three different methods for occupant crash protection, one of which being manual seat belts, impliedly preempted a common law claim of design defect for the manufacturer's conscious design choice not to equip an automobile with airbags.¹⁴⁵

A Wisconsin court of appeals also held that a state law claim for failure to install airbags in a 1980 Plymouth Horizon was preempted in circumstances of the defendant's compliance with the NTMVSA standard.¹⁴⁶ Observing that the phrase

144. *Id.* (citing *Fidelity Federal Savings & Loan Ass'n v. de la Cuesta*, 458 U.S. 141 (1982)). See also *Wood v. General Motors Corp.*, 865 F.2d 395, 412-414 (1st Cir. 1988); *Montag v. Honda Motor Co.*, 75 F.3d 1414, 1417 (10th Cir. 1996).

145. 875 F.2d at 822 n.13 ("[W]e conclude that a state common law rule that would, in effect, remove the element of choice authorized in Safety Standard 208 would frustrate the federal regulatory scheme."). See also *Myrick v. Freuhauf Corp. (Myrick I)*, 795 F. Supp. 1139 (N.D. Ga. 1992) (held: state statutory or common law claims would impose stricter safety standards than established by federal regulations and were, therefore, preempted).

Accord *Loulos v. Dick Smith Ford, Inc.*, 882 SW.2d 149 (Mo. Ct. App. 1994). In *Loulos*, a motorist's claim against Ford, among others, for failure to equip a 1979 vehicle with airbags, the court held that plaintiff's claim was preempted by the NTMVSA. The court noted specifically that regulations promulgated pursuant to the NTMVSA authorized manufacturers to adopt one of four permissible passive restraint system options, and that to permit a state tort law cause of action would, in effect, permit punishment of manufacturers for making a choice Congress specifically countenanced.

See also *Gills v. Ford Motor Co.*, 829 F. Supp. 894 (W.D.Ky. 1993) (FMVSS 208, adopted pursuant to NTMVSA, preempted common law claim seeking damages for failure to install airbags); *Pokorny v. Ford Motor Co.*, 902 F.2d 1116 (3d Cir. 1990). In *Pokorny* the Third Circuit held that state common law claims for failure to provide either air bags or automatic seatbelts were impliedly preempted by federal regulations authorizing the manufacturers their choice of safety mechanisms to be installed into the motor vehicle. However, the court held that common law claims for failure to install additional passive restraint systems not included among the options listed in Standard 208 were not preempted. See *id.* at 1126.

146. See *Boyle v. Chrysler Corp.*, 501 N.W.2d 865 (Wis. 1993); see *Panarites v. Williams*, 629 N.Y.S.2d 359 (N.Y. App. Div. 1995) (state law claims arising from a manufacturer's election of a passive restraint system other than airbags both expressly and impliedly preempted insofar as judgment against manufacturer would impose safety requirements different from and in addition to those required by

“state law’ . . . include[s] common law as well as statutes and regulations[.]”¹⁴⁷ The state appellate court held that because the defendant complied with the federal act, state law claims, including common law claims, were preempted. To hold otherwise, the Wisconsin court noted, would have required judicial entertainment of state law claims that would have created a conflict with the federal standards. Lastly, the court applied a conservative interpretation to the Safety Act’s saving clause, and held that “[t]he savings clause does not operate to preserve common-law liability claims that conflict with the federal safety standards. Rather, the savings clause preserves only those common-law liability claims that do not conflict with the automobile safety equipment standards that Congress enacted.”¹⁴⁸

A harmonious conclusion was reached in the appeal of a suit bringing state law claims against a manufacturer for failure to install lap seat belts. A Minnesota state appeals court found the state law claims were impliedly preempted by the NTMVSA,¹⁴⁹ reasoning that maintenance of potential state law liability, in effect, would have conflicted with the manufacturer’s prerogative under federal regulation to pick one from among a group of federally-approved passive restraint systems.¹⁵⁰

A limited preemption province was defined by the Seventh Circuit in *Gracia v. Volvo Europa Truck, N.V.*,¹⁵¹ a claim against a truck manufacturer alleging that its windshield retention system was inadequate to prevent windshield ejection during collision. The federal appeals court stated the proposition broadly that the savings provision of the Safety Act “was not to preserve common law claims when they conflict with NHTSA standards, but to prevent a manufacturer from having

federal government); *Dykema v. Volkswagenwerk AG*, 525 N.W.2d 754 (Wis. Ct. App. 1994) (state law claims preempted because they would have subjected manufacturers to different safety standards than established by the NTMVSA).

147. *Id.* (quoting *Cipollone*, 505 U.S. at 521).

148. *Boyle*, 501 N.W.2d at 869; *see also* *Gills v. Ford Motor Co*, 829 F. Supp. 894 (W.D. Ky. 1993) (FMVSS 208, adopted pursuant to NTMVSA, preempted common law claim seeking damages for failure to install airbags); *Cellucci v. General Motors Corp.*, 706 A.2d 806 (Pa. 1998).

149. *See* *Scholtz v. Hyuandai Motor Co.*, 557 N.W.2d 613 (Minn. Ct. App. 1997).

150. *See id.*

151. 112 F.3d 291 (7th Cir. 1997).

a complete defense to a common law action not addressed by a NHTSA standard by merely stating that it is in full compliance with all federal safety standards.”¹⁵² Observing that the Safety Act’s savings provision¹⁵³ should not be interpreted as “preserv[ing] conflicting or non-identical state common law actions from preemption,”¹⁵⁴ the court held that common law claims were not to be preempted by the NHTSA if, and only if, they were identical to the federal standards.¹⁵⁵

Regarding the windshield retardation standard specifically, the court noted that in this instance, the agency had specifically concluded that “given the design of forward control vehicles it was both technically impracticable to design windshields which would comply with the standards and impracticable to apply the standard’s barrier crash tests to these vehicles.”¹⁵⁶ Given the NHTSA particularized conclusion that the standard would not apply, the court held that “a state common law standard on windshield retention would, accordingly, be a standard that is not identical to the federal one[,]” and was thus preempted.¹⁵⁷

Thus, even without backdrop of a specific standard, the NHTSA dormant authority to create a safety standard may preempt a personal injury claim brought under state law. Be the question one of passive restraint systems or another vehicle component within the NHTSA’s NTMVSA purview, the agency’s decision to forego application of a standard to a particular type of product may still be given preemptive effect. For example, regarding the safety standard for windshield retention systems, and the exclusion from that standard of forward control vehicles with a gross vehicle weight exceeding 10,000 pounds, at issue in *Garcia*, the Ninth Circuit Court of Appeals explained:

[H]ere there is a specific federal standard addressing windshield retention for the truck at issue, in which the NHTSA determined that this type of vehicle should be exempt from the affixing requirement. The Supreme Court has held that “a federal decision

152. *Id.* at 298.

153. *See* 49 U.S.C. § 30102(a)(9) (West 1996).

154. 112 F.3d at 298.

155. *See id.*

156. *Id.* at 297.

157. *Id.* at 296.

to forego regulation in a given area may imply an authoritative federal determination that the area is best left unregulated, and in that event would have as much preemptive force as a decision to regulate."¹⁵⁸

In *Loulos v. Dick Smith Ford, Inc.*,¹⁵⁹ a motorist's claim against Ford, among others, for failure to equip a 1979 vehicle with airbags, the Missouri appellate court held that plaintiff's claim was not preempted, and refused to consider an implied preemption theory, reasoning, according to *Cipollone*, an express preemption provision was "a reliable indicium of congressional intent," terminating implied preemption analysis.¹⁶⁰

Regarding Safety Act regulations for illumination, the Court of Appeals for the Third Circuit in *Buzzard v. RoadRunner Trucking, Inc.*¹⁶¹ held that the plaintiff's state common law tort claims of inadequate lighting were not preempted. The court, in its decision, noted the defendant's burden to overcome the generally applicable rebuttable presumption against a finding of Congressional intent to preempt state law or regulation.¹⁶² Emphasizing Congress's stated goal of increasing transportation safety and the potential value of permitting states to enact more stringent regulations than are federally imposed to achieve that goal, the Third Circuit held that plaintiff's claims were not preempted, and wrote:

Buzzard's action could encourage increased safety by enhancing motorists' ability to take in at a glance the size, location and movement of tractor-trailers encountered at night on the public highways. Encouraging manufacturers to act in a way that increases safety does not frustrate the primary purpose of the Safety Act. Nor does it make it impossible to comply with both federal and state law, as it does not suggest that illumination equipment mandated by state common law be used instead of that required by federal law, but only in addition to that specified in Standard 108.¹⁶³

158. *Id.* at 296 (emphasis added by appellate court).

159. 882 S.W.2d 149 (Mo. Ct. App. 1994). *See also* *Minton v. Honda of America Mfg., Inc.*, 684 N.E.2d 648 (1997).

160. *Id.* at 152.

161. 966 F.2d 777 (3d Cir. 1992).

162. *See id.* at 780.

163. *Id.* at 785.

A federal trial court in *Byrnes v. Honda Motor Co., Ltd.*,¹⁶⁴ held that a products liability claim against the manufacturer of the 1990 Honda motorcycle's lighting system was not impliedly preempted by the NTMVSA, and explained that in the absence of any reference to the subject matter in the Safety Act, much less in its preemption provision, no further evaluation of implied preemption was necessary. Also finding no implied preemption is the decision of the Court of Appeals for the Eleventh Circuit in *Doyle v. Volkswagenwerk Aktiengesellschaft*,¹⁶⁵ in which the plaintiffs challenged the restraint design of a Volkswagen Jetta. The model at issue had an automatic shoulder belt, but no lap belt for either the driver or front seat passenger. Rather, the design employed knee bolsters to restrain the driver or passenger from sliding beneath the belt upon collision. The Eleventh Circuit affirmed the trial court's determination that standards promulgated under the NTMVSA do not preempt common-law claims, citing the Supreme Court's decision in *Freightliner Corp. v. Myrick*,¹⁶⁶ which noted specifically that there existed no federal safety standard creating a conflict of compliance.

In *Collazo-Santiago v. Toyota Motor Corp.*,¹⁶⁷ a suit brought by a motorist claiming that deployment of her vehicle's airbag caused her facial injuries, a federal trial court found that the federal standards were not design standards at all, but rather constituted performance standards. As such, the court reasoned:

Manufacturers are apparently free to choose any air bag design, as long as the design meets the performance criteria[.] Thus, there is no conflict between the provisions of [federal law] nor its implementing regulations, on the one hand, and tort liability for defective design, on the other, because such liability "[does] not remove or require any particular choice, or otherwise frustrate 'flexibility' that the federal scheme provides."¹⁶⁸

164. 845 F. Supp. 875 (S.D. Fla. 1994).

165. 114 F.3d 1134 (11th Cir. 1997).

166. 514 U.S. 280 (1995).

167. 957 F. Supp. 349 (D.P.R. 1997).

168. *Id.* at 354 (quoting *Perry v. Mercedes Benz*, 957 F.2d 1257, 1264-65 (5th Cir. 1992); 49 U.S.C.A. § 30103(e) (West 1996)).

ii. *Geier v. American Honda Motor Company*

In the years following the Supreme Court's 1992 *Cipollone*¹⁶⁹ decision, some courts and commentators have referred to the Court's preemption analysis as "schizophrenic"¹⁷⁰ or "shaky."¹⁷¹ In *Geier v. American Honda Motor Company*,¹⁷² the Court seemed to retreat from its *Cipollone* focus on express preemption, but in so doing did not necessarily simplify matters for litigants and trial judges seeking the proper doctrinal analysis by which to answer preemption questions.

In *Geier*, the review of a lawsuit alleging that a 1987 Honda was defective in design because it did not have a driver's side air bag, the Court was asked to identify the specific species and phylum of the NTMVSA preemption provision. As noted earlier, the NTMVSA authorizes the NHTSA to promulgate and implement FMVS standards. The NHTSA did so, implementing a standard that permitted automobile manufacturers during the applicable time period to choose among three options for passenger safety restraints, while stating further that compliance with federal safety standards would not "exempt any person from any liability under common law."¹⁷³ In *Grier*, the Court held that this statutory provision does not expressly preempt state common law damages actions, but, rather, that "ordinary preemption principles" do.¹⁷⁴

The express preemption clause of the NTMVSA provides that states may not maintain "motor vehicle safety standards" which conflict with federal performance standards on the same topic. In *Freightliner Corp. v. Myrick*,¹⁷⁵ which involved the effect of the absence, at that time, of a federal standard pertaining to anti-lock brakes, the Court, in a unanimous opinion written by Justice Thomas, concluded that since there was no federal standard in issue on the topic for eighteen-wheel trucks,

169. 505 U.S. 504 (1992).

170. Betsy J. Grey, *Make Congress Speak Clearly: Federal Preemption of State Tort Remedies*, 77 B.U. L. REV. 559, 627 (1997).

171. *Wilson v. Bradlees of New England, Inc.*, 96 F.3d 552, 556 (1st Cir. 1996) (the Supreme Court's preemption analysis makes its application "shaky" in "a changing legal climate.").

172. ___ U.S. ___, 120 S. Ct. 1913 (2000).

173. *Id.* at 1915

174. *Id.* at 1913.

175. 514 U.S. 280 (1995).

there was no express or implied preemption of state design defect claims based on the absence of such brakes. The Court did not reach the question of whether the Safety Act would preempt such claims if a federal standard did exist, but in the course of its opinion, the Court raised a question about the scope of *Cipollone's* express preemption analysis:

The fact that an express definition of the pre-emptive reach of a statute 'implies'—i.e., supports a reasonable inference—that Congress did not intend to pre-empt other matters does not mean that the express clause entirely forecloses any possibility of implied pre-emption. . . . At best, *Cipollone* supports an inference that an express preemption clause forecloses implied preemption; it does not establish a rule.¹⁷⁶

The unanimous decision in *Myrick*, it is seen, foreshadowed a potential reinvigoration of the doctrine of implied preemption. Some commentators noted that the Court's preemption analysis after *Cipollone*, *Myrick*, and its 1996 decision in *Medtronic*,¹⁷⁷ was less and less a true express preemption analysis and more and more a veiled implied preemption analysis.¹⁷⁸ *Geier*¹⁷⁹ proved this observation to be true. Justice Breyer, writing for the majority in *Geier*, articulated a three-part preemption analysis: Does the express preemption provision explicitly preempt the lawsuit? If not, "do ordinary preemption principles nonetheless apply?"¹⁸⁰ If so, does the lawsuit "actually conflict" with the federal statute? Of primary importance was how the Court answered the second question because if "ordinary," also known as "implied," preemption principles applied in the face of an express provision to the contrary, then the continued influence of *Cipollone* and *Medtronic* beyond their precise subject matter precincts—tobacco labeling and medical devices respectively—would arguably be ripe for recalibration.

176. *Id.* at 289.

177. *Medtronic v. Lohr*, 518 U.S. 470 (1996).

178. See e.g. Susan Raeker-Jordan, *The Pre-emption Presumption That Never Was: Pre-emption Doctrine Swallows the Rule*, 40 ARIZ. L. REV. 1379, 1418-1419 (1998).

179. ___ U.S. ___, 120 S. Ct. 1913 (2000). *Geier* was a five to four opinion. Justice Breyer, writing for the majority, was joined by Chief Justice Rehnquist, Justices O'Connor, Scalia and Kennedy. Justice Stevens, the author of both the *Cipollone* and *Medtronic* plurality opinions, dissented in an opinion in which Justices Souter, Thomas and Ginsberg joined.

180. *Id.* at 1918.

Neither in its analysis of the NTMVSA preemption provision nor the Safety Act's preemption clause did the majority expend the time necessary to provide lower courts with such guidance as has been characteristic of the Court's prior preemption decisions. The *Grier* Court declined to focus upon the meaning of the language of the NTMVSA preemption provision to determine its scope, including, without limitations, the question of what is meant by "standard," as distinct from the term "requirement" emphasized in the *Cipollone* line of decisions. Instead, the Court concluded, with little fanfare, that the "savings clause" made that exercise unnecessary, and explained its reticence to interpret the term "standard" as based upon its conclusion that it should be read to include common law damages actions because the savings clause assumes "that there are some significant number of common-law liability cases to save."¹⁸¹ In essence, the Court found that the presence of the savings clause triggered a narrow reading of the express preemption provision, and that further, in order to give meaning to the savings clause, it operated to exclude common law damages actions from the preemption clause's reach.¹⁸²

D. *Foods, Drugs and Cosmetics*

Manufacturers of pharmaceuticals are subject to the labeling and formulation standards articulated by the Food, Drug and Cosmetic Act ("FDCA").¹⁸³ Also, pharmaceutical sellers and manufacturers may be held strictly liable for injuries that result from their failure to warn of product dangers that are known or knowable within the scientific field.¹⁸⁴

In the realm of pharmaceuticals, the FDCA contains no language expressly preempting claims brought under state law.¹⁸⁵ Moreover, courts considering the issue have held generally that with regard to health and safety issues, the statutory language

181. *Id.*

182. *See id.* stating, "We have found no convincing indication that Congress wanted to preempt not only state statutes and regulations, but also common-law tort actions." *Id.* at 1918.

183. 21 U.S.C. § 301-394 (1988 & Supp. III 1991).

184. *See Carlin v. Superior Court*, 920 P.2d 1347 (Cal. 1996) (citing *Anderson v. Owens-Corning Fiberglass Corp.*, 810 P.2d 549 (1991)).

185. *See Merrell Dow Pharm., Inc. v. Oxendine*, 649 A.2d 825 (D.C. Cir. 1994); *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293, 1299 (D. Minn 1988).

does not evince a congressional objective to so occupy the field of pharmaceutical regulation as to impliedly preempt state claims.¹⁸⁶ Support for this conclusion can be found in *MacDonald v. Ortho Pharmaceutical Corp.*,¹⁸⁷ in which the court rejected the manufacturer's preemption defense.¹⁸⁸ The *MacDonald* court held that "[t]he regulatory history of the FDA requirements belies any objective to cloak them with preemptive effect."¹⁸⁹

The Supreme Court has held that where Congress has not expressly preempted state tort law claims, there exists a strong presumption against implied preemption unless there are exceptional circumstances involved.¹⁹⁰ The District Court in *Mazur v. Merck & Co., Inc.*¹⁹¹ inferred from the absence of express preemption that Congress, via the FDCA, had not intended to preempt state regulations imposed upon a vaccine's manufacture, distribution and labeling.¹⁹²

As stated by the District of Columbia Court of Appeals in *Merrell Dow Pharmaceuticals v. Oxendine*,¹⁹³ a Bendectin suit, "FDA prescription drug regulations and safety determinations are intended to be minimum standards which 'do not conflict with state law which sets higher standards for due care and safety in the manufacture of drugs.'"¹⁹⁴ One federal trial court described the underlying rationale for finding no necessary conflict between state tort remedies and FDA regulation in terms of the differing objectives of regulation and actions in tort:

[F]ederal regulation serves a very different purpose than state tort law. Essentially, federal regulation serves a deterrent pur-

186. See *Reese v. Payless Drug Stores Northwest, Inc.*, 40 Cal. Rptr. 2d 75 (1995), review granted, 34 Cal. App. 4th 19, 39 Cal. App. 4th 160, 43 Cal. App. 4th 1317. Special issues concerning medical devices and the statutory and regulatory treatment pertinent thereto are discussed in § III(D). See Richard C. Ausness, *Federal Preemption of State Products Liability Doctrines*, 44 S.C.L. REV. 218-225 (1993).

187. 475 N.E.2d 65 (Mass. 1985).

188. See Ausness, *supra* note 186, at 218-25.

189. *Id.* at 219 (quoting *MacDonald*, 475 N.E.2d at 70).

190. See *Mazur v. Merck & Co., Inc.*, 742 F. Supp. 239, 246 (E.D. Pa. 1990) (citing *Maryland v. Louisiana*, 451 U.S. 725, 726 (1981)).

191. 742 F. Supp. 239 (E.D. Pa. 1990).

192. See *id.* at 248.

193. 649 A.2d 825 (D.C. App. 1994).

194. *Id.* at 828 (citations omitted).

pose by limiting the manufacture of inherently dangerous products to those applicants who meet stringent safety standards, while state tort law serves the equally important purpose of compensating individuals injured by those very same products. Since compliance with FDA regulations will not insure that a manufacturer's products will not cause injury, compliance will not necessarily exempt a manufacturer from liability. When those products do cause injuries, the state tort system provides a means of compensation. State tort law is intended to supplement federal regulation by providing a vehicle for compensation of vaccine-related injuries.¹⁹⁵

Many individuals have brought actions against diphtheria, pertussis, and tetanus (DPT) vaccine manufacturers.¹⁹⁶ The absence of an express congressional declaration as to whether federal regulation preempts state law concerning the labeling and design of the DPT vaccination has led to a split in the decisional law.¹⁹⁷ Many courts have held that FDA approval of the DPT vaccine does not preempt more stringent state standards. These courts reason that the product's design may not necessarily be the safest, technologically achievable design, because the FDA is only able to approve those designs that are submitted by the manufacturers. Therefore, the reasoning continues, states are able to impose higher standards upon these manufacturers, in order to promote product and public safety.¹⁹⁸

While the FDCA contains no provision that would expressly preempt state food and drug requirements in general, there are several areas where the FDA has interposed product specific or

195. *Mazur v. Merck & Co., Inc.*, 742 F. Supp. 239, 247 (E.D. Pa. 1990) (citations omitted) (suit against manufacturer of measles, mumps and rubella vaccine).

196. See Ausness, *supra* note 186, at 219.

197. Compare *Wack v. Lederle Labs.*, 666 F. Supp. 123 (N.D. Ohio 1987) (disallowing defendant's claim of implied "field" preemption based on FDA's extensive regulation of the subject matter); *Patten v. Lederle Labs.*, 676 F. Supp. 233 (D. Utah 1987); *MacGillivray v. Lederle Labs.*, 667 F. Supp. 743 (D.N.M. 1987) (state tort remedies allowed) with *Hurley v. Lederle Laboratories (Hurley I)*, 651 F. Supp. 993 (E.D. Tex. 1986) (DPT design actions preempted by the comprehensive nature of FDCA's testing requirements); *Morris v. Parke, Davis & Co.*, 667 F. Supp. 1332 (C.D. Cal. 1987). But see *Hurley v. Lederle Labs. (Hurley II)*, 863 F.2d 1173 (5th Cir. 1988) (although plaintiff's failure to warn claims preempted by the FDCA, other state tort remedies permitted as Congressional intent to protect industry or product not sufficient to strip plaintiffs of claims against any manufacturer that has achieved regulatory compliance).

198. See *id.*

subject matter specific rules which are not identical to state standards, or which would be vulnerable to a conflict with a later promulgated state standard. In some of these settings, the agency's regulatory initiatives have been held to impliedly preempt inconsistent state claims or regulations.¹⁹⁹ The Supreme Court has explained that even conceding that most statutes and accompanying regulations administered by the FDA do not expressly preempt state statutory or decisional law, such FDA statutes may be found to impliedly preempt state law where application of state law would frustrate effectuation of "the full purpose and objective" of the FDA's broad ranging safety-related mandates.²⁰⁰ As is characteristic of agencies charged with implementing federal health and safety statutes, the FDA has interpreted both its governing statute and its own regulations as carrying a broad preemptive mantle. For example, in 1982, the FDA issued a Final Rule on Tamper-Resistant Packaging Requirements for Certain Over-the-Counter Human Drug and Cosmetic Products²⁰¹ due to a tragic incidence of product tampering of over the counter (OTC) drugs.²⁰² According to the final FDC rule, all OTC drug products that are subject to retail sale must be packaged in specific tamper-resistant packages (TRPs).²⁰³ The FDA stated that as the manufacturing and distribution of these products is national in scope, only national regulations are adequate to safeguard the interest of "the entire population."²⁰⁴ Its rule provided further that all local or state

199. See Geiger and Rosen, *Rationalizing Product Liability for Prescription Drugs: Implied Preemption, Federal Common Law, and Other Paths to Uniform Pharmaceutical Safety Standards*, 45 DEPAUL L. REV. 395, 421 (1996) ("[S]tate tort law should be preempted because it may well discourage the development or marketing of beneficial drugs. The possibility of deterring development is contrary to the FDC Act's fundamental goal of making such drugs available.") (citations omitted).

200. *Medtronic*, 518 U.S. at 496.

201. 21 C.F.R. § 211.132 (current through September 29th, 2000)(cited in 46 FOOD DRUG COSM. L.J. 629, 639 (1991).

202. See *Lewis v. Beeler*, 949 F.2d 325 (10th Cir. 1991); *Elsroth v. Johnson & Johnson*, 700 F. Supp. 151 (S.D.N.Y. 1988); *McNeilab, Inc. v. North River Ins. Co.*, 645 F. Supp. 525 (N.J. 1986).

203. See 21 C.F.R. § 211.132(a). There were certain exceptions to this rule, including dermatological, dentifrice, and insulin products that did not have to be packaged in compliance with the ruling. See 46 FOOD DRUG COSM. L.J. 629, 639.

204. 47 Fed.Reg. 50442-01, 50448 (1982), discussed in Mark B. Gelbert, *State Statutes Affecting the Labeling of OTC Drugs: Constitutionality Based on Com-*

packaging requirements that were not identical to the new federal regulation were specifically preempted by the new regulation.²⁰⁵

The FDA supplied three justifications for preemption in this area. First, if localities were permitted to have specific local requirements, the supply of specific OTC drugs might be diminished if those drugs did not comply with the local packaging requirements. Second, the federal requirements could be essentially negated if a large state could force a drug manufacturer to use that state's standards throughout the country. Third, the product cost for each drug would substantially increase if the drug manufacturers were forced to adopt the different packaging requirements for different states.²⁰⁶

The FDA maintains that its requirement of a pregnancy warning on a broad range of OTC drug products has been held to impliedly preempt all associated state regulations.²⁰⁷ In 1982, the FDA issued the rule that required "[a]ll over-the-counter drugs that are intended for systematic absorption, unless specifically exempted" to contain the warning: "As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product."²⁰⁸ While some states, such as California, had adopted similar legislation, the FDA felt that "[p]roliferation of such state requirements may weaken FDA's efforts to develop comprehensive national labeling and other requirements for OTC drugs"²⁰⁹ If each state had different warnings, the FDA suggested, such state by state warning requirements would "prevent the full purpose and objectives of the agency in issuing the regulation and that under the doctrine of implied preemption, these State requirements are preempted by the regulation as a matter of law."²¹⁰

merce Clause and Federal Preemption Theories, 46 FOOD DRUG COSM. L.J. 629, 640 (1991).

205. 47 Fed. Reg. at 50447.

206. See Gelbert, *supra* note 204, at 640.

207. 21 C.F.R. §§ 201.63(a), (330.2) (current through September 29th, 2000), *cited in* Gelbert, *supra* note 204, at 640.

208. 47 Fed.Reg. 54,750-01 (1982).

209. 47 Fed.Reg. 39,470-01, 39471 (1982).

210. 47 Fed.Reg. 54,750-01, 54,756 (1982).

In *Jones v. Rath Packing Co.*,²¹¹ the Supreme Court held that inconsistent state food labeling regulations were impliedly preempted by the Fair Packaging and Labeling Act ("FPLA") and regulations thereunder. At issue in *Rath Packing* was a California statute that regulated the labeling of the net weight of food commodities.²¹² The record below was sufficient to show that the average net weight for a proportion of this seller's bacon and flour was less than the net weight stated on the packages, resulting in subsequent removal of those commodities from the shelves insofar as they were in violation of the California statute.²¹³ The food packing company claimed that the state statute was preempted by federal laws which regulated labeling and the net weight requirements,²¹⁴ drafted by Congress with the intent of informing consumers of accurate information about a package's quantity and contents.²¹⁵ The Court found that the FDCA did not preempt the state requirements because the FDCA did not "contain a preemption clause with regard to its food misbranding requirements[.]"²¹⁶ The Court explained that the issue of express preemption arises when the "state requirements are less stringent than or require information different from federal law,"²¹⁷ and further found that the California law was not expressly preempted by any provision of the FPLA as the California law was more stringent than the federal requirements and did not require any information that was different from the federal law.²¹⁸ Even absent express preemption, however, the Court concluded that the federal FPLA regimen impliedly preempted the state law inasmuch as effectuation of the state law would "prevent the accomplishment and execution of the full purposes and objective of Congress in passing the FPLA."²¹⁹

211. 430 U.S. 519 (1977), *reh'g denied*, 431 U.S. 925 (1977).

212. *See id.* at 522.

213. *See id.*

214. *See id.* at 523-24.

215. *See* 15 U.S.C.A. § 1451 (West 1997).

216. 430 U.S. at 538.

217. *Id.*

218. *See id.* at 540.

219. *Id.* at 543.

E. Medical Devices

i. Medical Device Act Amendments of 1976 generally

The Food and Drug Administration is empowered by the 1976 Medical Device Amendments ("MDA")²²⁰ to the FDCA²²¹ to classify and regulate medical devices. Medical devices have been divided into three categories: Class I devices are subject to "general controls" insofar as they represent only a low level of risk to public health and safety.²²² Class II devices are governed by an order of federal regulation known as "special controls,"²²³ a higher level of superintendence because "general controls by themselves are insufficient to provide reasonable assurances of the safety and effectiveness of [such] devices."²²⁴ Lastly, Class III devices are subject to the most rigorous MDA controls as they represent "a potential unreasonable risk of illness or injury."²²⁵

As to devices denominated as Class III, the MDA provides: "Before a new Class III device may be introduced to the market, the manufacturer must provide the MDA with 'reasonable assurance' that the device is both safe and effective."²²⁶ The process of providing the FDA with "reasonable assurance" is known as "premarket approval" or "PMA."²²⁷ The process by which a new class III device may gain premarket approval was described by the Supreme Court in *Medtronic, Inc. v. Lohr*²²⁸ as involving submission of detailed safety and efficacy information about the device followed by equally meticulous FDA review.²²⁹ Upon receipt of PMA, marketing of the device may begin. Sub-

220. See 21 U.S.C. § 360c(b)-(f) (West 1999); 21 U.S.C. § 371(a) (1999).

221. See 21 U.S.C. § 360k(a) (West 1999).

222. 21 U.S.C. § 360c(a)(1)(A) (West 1999), *discussed in* *Oja v. Howmedica, Inc.*, 111 F.3d 782, 786 (10th Cir. 1997).

223. 21 U.S.C. § 360c(a)(1)(B) (West 1999); 21 C.F.R. § 860.3(c)(2) (2000).

224. 21 U.S.C. § 360c(a)(1)(B) (West 1999). See *Oja v. Howmedica, Inc.*, 111 F.3d 782, 786 (10th Cir. 1997).

225. *Id.*

226. 21 U.S.C. § 360e(d)(2) (West 1999). See *Steele v. Collagen Corp.*, 63 Cal. Rptr. 2d 879 (Cal. Ct. App. 1997), stating, "With respect to medical devices that represent the highest risk to human life, the federal government imposes standards specific to each of those devices, and Congress has declared that the federal standard is preemptive." *Id.* at 880.

227. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996).

228. 518 U.S. 470 (1996).

229. See *id.* at 477.

sequent changes in the product trigger a requirement that the manufacturer submit a PMA supplemental application.²³⁰ Moreover, the regulations require annual post-approval reports detailing changes in the device, clinical investigational results, or pertinent scientific literature.²³¹

Two exceptions exist as to the general requirement that Class III medical devices obtain premarket approval. First, the MDA includes a “grandfathering” provision that permits devices that were on the market prior to the 1976 passage of the MDA to remain on the market until the FDA undertakes and completes the required PMA.²³² Second, as the Supreme Court would later summarize, and “to prevent manufacturers of grandfathered devices from monopolizing the market while new devices clear the MDA hurdle, and to insure that improvements to existing devices can be rapidly introduced into the market,” the MDA “also permits devices that are ‘substantially equivalent’ to preexisting devices to avoid the PMA process.”²³³

ii. *Medical Device Act Amendments of 1976 preemption provision*

The MDA’s preemption provision states:

[N]o 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 device²³⁴

The FDA has interpreted this preemption provision in these terms:

State or local requirements are preempted only when the [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the Act, thereby making any existing divergent state or local require-

230. See 21 C.F.R. § 814.39 (current through September 29th, 2000).

231. See 21 C.F.R. § 814.84 (current through September 29th, 2000).

232. See 21 U.S.C. § 360e(b)(1)(A) (West 1999); 21 C.F.R. § 814.1 (c)(1) (current through September 29th, 2000).

233. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996) (citation omitted).

234. 21 U.S.C. § 360k (West 1999).

ments applicable to the device different from or in addition to, the specific [FDA] requirements.²³⁵

iii. *Medtronic, Inc. v. Lohr and the decisional law thereafter*

*Medtronic, Inc. v. Lohr*²³⁶ was a products liability claim against the manufacturer of a failed pacemaker. On the issue of potential preemption, the manufacturer argued that plaintiff's claims were preempted by the FDA's "general 'good manufacturing practices' regulations, which establish general requirements for most steps in every device's manufacture, and by the FDA labeling regulations, which require devices to bear various warnings."²³⁷ The Court was unanimous in finding that these general FDA strictures did not constitute specific FDA requirements applicable to a particular device.²³⁸ Rather, the court concluded that as to MDA § 510(k) devices, state products liability claims would not be preempted, as the § 501(k) process "does not constitute FDA approval of the safety or effectiveness of the device, but was merely the preservation of the pre-1976 status quo, which included potential liability under state law."²³⁹

The *Medtronic* Court adopted a two-pronged inquiry to determine if a state regulation was preempted by regulations or policies issued by the FDA. First, the federal requirement had to be "applicable to the device" in question,²⁴⁰ i.e., the federal requirement would have preemptive effect only if it was "specific" to a "particular device."²⁴¹ Second, the state requirement had to be "different from, or in addition to" the federal requirement,²⁴² and thus "[s]tate regulations of 'general applicability'

235. 21 C.F.R. § 801.1(d) (current through September 29th, 2000).

236. 518 U.S. 470 (1996).

237. *Id.* at 483-84 (citations omitted).

238. *Id.* at 498-99.

239. *Martin v. American Medical Systems, Inc.*, 116 F.3d 102, 104 (4th Cir. 1997) (interpreting *Medtronic*).

240. *Medtronic*, 518 U.S. at 472 (quoting 21 U.S.C. § 360k (West 1999)).

241. *Id.* at 472 (quoting 21 C.F.R. § 801.1(d) (current through September 29th, 2000)).

242. *Id.* (quoting 21 U.S.C. § 360k (West 1999)).

are not preempted except where they have 'the effect of establishing a substantive requirement of a specific device.'"²⁴³

Speaking finally of the relationship between the PMA process and the limited MDA 510(k) procedure, the Supreme Court stated:

Thus, even though the FDA may well examine § 510(k) applications for Class III devices (as it examines the entire medical device industry) with a concern for the safety and effectiveness of the device, . . . it did not 'require' Medtronic's pacemaker to take any particular form for any particular reason; the agency simply allowed the pacemaker, as a device substantially equivalent to one that existed before 1976, to be marketed without running the gauntlet of the PMA process. . . . There is no suggestion in either the statutory scheme or the legislative history that the § 510(k) exemption process was intended to do anything other than maintain the status quo with respect to the marketing of existing medical devices and their substantial equivalents. That status quo included the possibility that the manufacturer of the device would have to defend itself against state-law claims of negligent design.²⁴⁴

In *Medtronic*, the Court appeared to build on its analysis in *Cipollone*, focusing on express and not implied preemption analysis. It concluded that the FDA regulations did not expressly preempt damages actions based on the design of the pacemaker in question because the language of the express preemption provision, which preempted state "requirement[s] . . . different from or in addition to" any federal requirement related to safety or effectiveness, was not intended to include common law damages actions based on design defects in instances where there was no device-specific federal requirement with which such a claim actually conflicted.

Of the various *Medtronic* opinions, that of Justice Stevens garnered the plurality. Redolent of the express preemption analysis articulated in *Cipollone*, the plurality wrote:

243. *Id.* (quoting 21 C.F.R. § 808.1(d)(1) (current through September 29th, 2000)). See also discussion in *Oja v. Howmedica, Inc.*, 111 F.3d 782, 787-788 (10th Cir. 1997).

244. *Id.* at 493. See also *Reeves v. Acromed Corp.*, 103 F.3d 442 (5th Cir. 1997). See generally Robert J. Katerberg, *Patching the "Crazy Quilt" of Cipollone: A Divided Court Rethinks Federal Preemption of Products Liability in Medtronic, Inc. v. Lohr*, 75 N.C. L. REV. 1440 (1997).

[W]e have long presumed that Congress does not cavalierly preempt state law causes of action. . . . [W]e “start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.” . . . [W]e used a “presumption against the preemption of state police power regulations” to support a narrow interpretation of such an express command in *Cipollone*. That approach is consistent with both federalism concerns and the historic primacy of state regulation of matters of health and safety.²⁴⁵

A majority of the justices would have included common law damages actions within the scope of the preemption provision but, again, differed on whether that particular preemption provision was to be interpreted narrowly or broadly. The plurality found no preemption by interpreting the scope of the statute and regulations narrowly, using the legislative history and the FDA’s own interpretation as support. None of the justices applied an implied preemption analysis.²⁴⁶ The concurring opinion of Justice Breyer confirmed the importance of Congressional intent in determining the statute’s preemptive scope and complained of the “highly ambiguous” nature of the preemption provision in issue, requiring that courts look elsewhere for help as to “just which federal requirements preempt just which state requirements, as well as just how they might do so.”²⁴⁷ Justice Breyer’s frustration over Congress’s inability to clearly identify and plainly state the purpose and the scope of this and other preemption provisions, together with his explicit dissatisfaction with the task of interpreting ambiguous language, foreshadowed the Court’s return, in *Grier v. American Honda Motor Company*, to a focus on the implied preemption doctrine.²⁴⁸

245. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (citations omitted).

246. *Id.* But see Justice Stevens’s plurality opinion, which ended with the following cryptic notation: “Until such a case [announcing a device specific requirement which might require preemption] arises, we see no need to determine whether the statute explicitly preempts such a claim. Even then, the issue may not need to be resolved if the claim would also be preempted under conflict preemption analysis, see *Freightliner Corp. v. Myrick*, 514 U.S. 280 (1995).” *Id.* at 503 (italics omitted).

247. *Id.* at 505.

248. ___ U.S. ___, 120 S. Ct. 1919, 1927 (2000).

In *Martin v. American Medical Systems, Inc.*²⁴⁹ the Court of Appeals for the Fourth Circuit held that the MDA did not preempt common law tort and implied warranty claims brought, under Virginia law, by a penile implant recipient alleging that he suffered an injurious infection due to a lack of the device's sterility.²⁵⁰ Explaining its decision, the federal appeals court stated: "Because the 1976 amendments so abruptly changed the status quo, Congress was compelled to take the existing market into account. Any device on the market at the time was permitted to stay on the market until and unless the FDA, after conducting a review like that for new devices, ordered otherwise."²⁵¹ Simple identification or classification regulations have been held not to preempt state regulation. As such, federal regulations do not "relate to the safety or effectiveness of the device."²⁵²

Another departure from the PMA process is for investigational devices. The MDA exempts investigational devices from the PMA process "to encourage, to the extent consistent with the protection of public health and safety and with ethical stan-

249. 116 F.3d 102 (4th Cir. 1997).

250. *Id.* at 105.

251. 116 F.3d at 103 (citing 21 U.S.C. § 360e (b) (1) (A) (West 1999)); *see also* *Sylvester v. Mentor Corp.*, 663 So.2d 176 (3d Cir. 1995), in which the state appellate court followed *Medtronic* and held that the MDA § 360k did not apply to those medical devices which had been allowed to enter the stream of commerce subjected to only the premarket notification process by being "substantially equivalent" to a product already on the market. *Id.* at 178. *See also* *Dutton v. AcroMed Corp.*, 691 N.E.2d 738 (Ohio Ct. App. 1997), which held that devices allowed to enter the market via the "substantial equivalence" standard were not subject to the blanket preemption under the MDA. *Id.* at 740. The appellate court also held that Plaintiff's claim of fraudulent misrepresentation was not preempted because the MDA preempts claims raised as to the device's safety and effectiveness, not fraudulent misrepresentation. *Id.* at 742. *But see* *English v. Mentor Corp.*, 67 F.3d 477 (3d Cir. 1995), holding that the fact that the inflatable penile implants had been introduced to the market via the "substantial equivalence" test preempted state law claims against the manufacturers. *Id.* at 482. The court reasoned that the MDA preempted the state law claims because the "substantial equivalence" test or standard was related to the product's safety and effectiveness, barring the implementation of state standards of the same. The Supreme Court vacated the judgment and remanded for reconsideration in light of *Medtronic*. *Id.* at 482-83.

252. *Kealoha v. E.I. Du Pont De Nemours & Co.*, 82 F.3d 894, 898-99 (9th Cir. 1996) (action brought by recipient of temporomandibular jaw (TMJ) implants against supplier of raw polytetrafluoroethylene (PTFE) used in the manufacture of the implants). *Accord* *Anguiano v. DuPont*, 44 F.3d 806, 809-10 (9th Cir. 1995); *LaMontagne v. DuPont*, 41 F.3d 846, 853 (2d Cir. 1994).

dards, the discovery and development of useful devices intended for human use.”²⁵³ Unlike the “substantial equivalent” § 510(k) process, however, which can be completed in an average of only 20 hours,²⁵⁴ investigational device status only is granted after a comprehensive and particularized procedure in which the applicant must set forth a report of all prior investigations, as well as a “description of the methods, facilities, and controls used for the manufacture, processing, packing storage, and, where appropriate, installation of the device, in sufficient detail so that a person generally familiar with good manufacturing practices can make a knowledgeable judgment about the quality control used in the manufacture of the device.”²⁵⁵ It is in the context of these exacting standards and others²⁵⁶ that FDA approval of investigational devices has been held to preempt state law products liability claims. Thus, in *Martin v. Teletronics Pacing Systems, Inc.*,²⁵⁷ a case involving an implantable cardioverter-defibrillator-demand pacemaker, one of only 50 such devices, the Sixth Circuit Court of Appeals held that “where the FDA has specifically approved the design of the device for investigational purposes,” to permit a state law design defect claim “would thwart [the federal] goals of safety and innovation[,]” and, accordingly, investigational device approval would be held to preempt the common law claim.²⁵⁸

In other settings, such as claims relating to super absorbant tampons, there have been numerous cases concerning tampons and toxic shock syndrome which have held that general FDA requirements of warning statements do, in actuality, constitute particularized FDA regulations that are specific to a particular device.²⁵⁹ As tampons have been classified as Class III medical devices, the FDA requires that certain information and warnings be affixed to the product and that the average

253. 21 U.S.C. § 360j(g)(1) (West 1999).

254. *Medtronic*, 518 U.S. at 479.

255. 21 C.F.R. § 812.20(b)(3) (current through September 29th, 2000).

256. See 21 C.F.R. § 812.25 (current through September 29th, 2000) (descriptions of methodology, protocols, controls, written procedures, etc.).

257. 105 F.3d 1090 (6th Cir. 1997).

258. *Id.* at 1099.

259. See e.g., *National Bank of Commerce of El Dorado v. Kimberly-Clark Corporation*, 38 F.3d 988 (1994).

individual be able to understand that information.²⁶⁰ For example, the district court in *Krause v. Kimberly-Clark Corp.*²⁶¹ held that the state law claims as to the sufficiency of warnings or labels were preempted, but that claims of negligence or claims of breach of an implied warranty were not.²⁶² In *Papike v. Tambrands, Inc.*²⁶³ the Ninth Circuit Court of Appeals reached the same conclusion, holding that “[t]he tampon labeling regulation is device—and disease—specific and preemption is warranted in this case.”²⁶⁴ In making its decision, the court noted the highly individualized tampon labeling requirements set forth in FDA regulations.²⁶⁵

Upholding the principle that FDA regulations preempt state regulations concerning inadequate warning claims with regard to tampons, there is authority to the effect that “FDA labeling requirements, which establish a uniform standard, were intended to strike a balance between product safety and protecting interstate commerce from the undue burdens imposed by non-uniform standards.”²⁶⁶ Because of the detailed warning requirements concerning toxic shock syndrome, many plaintiffs fight an uphill battle when litigating a negligence or breach of implied warranty claim. The court in *Krause* noted that the “plaintiff may have a difficult time establishing and proving her negligence and breach of warranty claims.”²⁶⁷ The plaintiff in *Haddix v. Playtex Family Products, Corp.*²⁶⁸ was unable to maintain her burden of proving that the tampon was unreasonably dangerous because of the warnings concerning toxic shock syndrome that were affixed to the product’s package, as mandated by federal law.²⁶⁹

260. See Ausness, *supra* note 186, at 227-28 (citing 21 CFR § 884.5460(b)) (current through September 29th, 2000)).

261. 749 F. Supp. 164 (W.D. Mich. 1990).

262. See *id.* at 169.

263. 107 F.3d 737 (9th Cir. 1997).

264. *Id.* at 742.

265. *Id.* at 739-40.

266. Ausness, *supra* note 186, at 228 (citing *Lindquist v. Tambrands, Inc.*, 721 F. Supp. 1058, 1063 (D. Minn. 1989)).

267. *Krause*, 749 F. Supp. at 169.

268. 138 F.3d 681 (7th Cir. 1998).

269. *Id.* at 686.

F. *Miscellaneous Product and Subject Classifications*

Congress has included preemption-like language in numerous statutes in addition to those highlighted in the previous sections. Some of these legislative initiatives are fairly old, while others are quite modern. As has been seen, the law of federal preemption "to a large extent defies useful generalization[.]"²⁷⁰ Rather, "[t]he cases are very specific to the regulated subject [matter]."²⁷¹

i. *Federal Boat Safety Act*

The Federal Boat Safety Act ("FBSA")²⁷² is intended to promote boating safety through various means that include, inter alia, requiring manufacturers of certain boating equipment to comply with safety standards promulgated by the Secretary of Transportation.²⁷³ The Coast Guard is the federal agency to which this regulatory function is delegated.²⁷⁴ In 1988 the Coast Guard "directed" the National Boating Safety Advisory Council to evaluate whether or not the Coast Guard should promulgate a regulatory standard requiring propeller guards. The Council recommended that no such regulatory action be taken.²⁷⁵ The Coast Guard adopted the Council's recommenda-

270. *Gurrieri v. William Zinsser & Co.*, 728 A.2d 832, 836 (N.J. Super. Ct. App. Div. 1999) (citing WILLIAM A. DRIER ET AL., *NEW JERSEY PRODUCTS LIABILITY & TOXIC TORTS LAW* § 6.3 -.5 (1999)).

271. *Id.*

272. 46 U.S.C.A. § 4301 et seq (West 2000).

273. *See* 46 U.S.C.A. § 4302(a)(1) (West 2000).

274. *See* 46 U.S.C.A. § 4303(a) (West 2000); *see* *Carstensen v. Brunswick Corp.*, 49 F.3d 430, 431 (8th Cir. 1995), *cert. denied*, 546 U.S. 866 (1995).

275. *See* National Boating Safety Advisory Council, Report of the Propeller Guard Subcommittee 14 (1989), stating:

The regulatory process is very structured and stringent regarding justification. Available propeller guard accident data do not support imposition of a regulation requiring propeller guards on motorboats. Regulatory action is also limited by the many questions about whether a universally acceptable propeller guard is available or technically feasible in all modes of boat operation. Additionally, the question of retrofitting millions of boats would certainly be a major economic consideration. The Coast Guard will continue to collect and analyze data for changes and trends. . . . The Coast Guard will also review and retain any information made available regarding development and testing of new propeller guard devices or other information on the state of the art.

tion, and in official correspondence recognized and detailed its ongoing supervision of this subject matter.²⁷⁶

The issue of whether the Coast Guard's decision not to implement a standard requiring propeller guards on recreational boats preempted state law personal injury claims arising from a claimed causal connection between the absence of such guards and injuries suffered was litigated in *Ryan v. Brunswick Corp.*²⁷⁷ The suit was brought by the wife of a swimmer who was killed following an accident in which he came into contact with a revolving propeller on a recreational watercraft.²⁷⁸ The FBSA preemption provision reads:

[A] state . . . may not establish, continue in effect, or enforce a law or regulation establishing a recreational vessel or associated equipment performance standard or imposing a requirement for associated equipment . . . that is not identical to a regulation prescribed under [this title].²⁷⁹

The Michigan Supreme Court, evaluating the FBSA language "law or regulation" with the preemptive language "requirement or prohibition" in the statute interpreted in *Cipollone v. Liggett Group*,²⁸⁰ found the difference between the two phrases to be "insignificant."²⁸¹ Finding that the federal regulatory decision that propeller guards should not be required preempted state tort law claims based upon the absence of such devices, the *Ryan* court noted that it was "join[ing] numerous other courts that have held that '[c]ommon law causes of action may constitute state regulation and [impermissibly] impose a requirement on manufacturers to have propeller guards through an award of damages'"²⁸²

276. Letter from Rear Admiral Robert T. Nelson, Chief, Office of Navigation, Safety and Waterway Service, to A. Newell Garden, Chair., National Boating Safety Advisory Council.

277. 557 N.W.2d 541 (Mich. 1997).

278. *See id.* at 543-44.

279. 46 U.S.C. § 4306.

280. 505 U.S. 504 (1992).

281. *Ryan*, 557 N.W.2d at 547-48.

282. *Id.* at 548-49, (quoting *Lewis v. Brunswick Corp.*, 922 F. Supp. 613, 615 (S.D. Ga. 1996)); *see also id.* at 549, n.24 (collecting authority).

Reaching the opposite conclusion, the Missouri Court of Appeals in *Ard v. Jensen*²⁸³ was persuaded that the FBSA savings clause was properly considered *in pari materia* with legislative history indicating a legislative purpose that state statutes and common law continue to provide a floor for appropriate safety measures, or, in the court's words, "the common law [should] be the minimum standard to be built upon by the Secretary's regulations."²⁸⁴ In finding no preemption of an injured skier's suit, the Missouri appellate court found particularly telling the language of the accompanying Senate Report that "[t]he purpose of the [savings clause] is to assure that in a product liability suit mere compliance by a manufacturer with the minimum standards promulgated under the Act will not be a complete defense to liability."²⁸⁵

ii. *Consumer Product Safety Act*

In *Moe v. MTD Products, Inc.*²⁸⁶ the Court of Appeals for the Eighth Circuit ruled that the Consumer Product Safety Act (CPSA)²⁸⁷ preempted a state common law damages claim.²⁸⁸ The court examined the preemptive effect of the CPSA's lawn mower safety standard,²⁸⁹ which requires (1) that each power lawn mower have a blade control system that stops the blade rotation within three seconds after the operator's hands leave the handle; and (2) that each mower contain a label warning "DANGER, KEEP HANDS and FEET AWAY" and showing a blade cutting into the forefinger of a hand. Plaintiff injured his hand when reaching into his mower's side chute to remove some grass, and his hand came into contact with the blade, which had unexpectedly begun to turn.

283. 996 S.W.2d 594 (Mo. Ct. App. 1999) (A suit was brought against the boat operator and its manufacturer when a waterskier suffered injuries when the boat backed over him as he prepared to ski.).

284. *Id.* at 599.

285. *Id.* at 594 (citing S. REP. NO. 92-248 (1971), reprinted in 1971 U.S.C.C.A.N. 1333, 1352, stating "This section is a Committee Amendment and is intended to clarify that compliance with the Act or standards, regulations, or orders promulgated thereunder does not relieve any person from liability at common law or under State law." *Id.*)

286. 73 F.3d 179 (8th Cir. 1995).

287. See 15 U.S.C. § 2051 et seq. (West 1997).

288. See *id.* at 181. See *Moe*, 73 F.3d at 181.

289. See 16 CFR § 1205.5(a) (current through September 29th, 2000).

The CPSA preemption clause provides:

Whenever a consumer product safety standard under this chapter is in effect and applies to a risk of injury associated with a consumer product, no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision of a safety standard or regulation which prescribes any requirements as to the performance, composition, design, finish, construction, packaging, or labeling of such product which are designed to deal with the same risk of injury associated with such consumer product, unless such requirements are identical with the requirements of the Federal standard.²⁹⁰

The Act's "savings clause" reads: "Compliance with consumer product safety rules or other rules or orders under this Act shall not relieve any person from liability at common law or under state statutory law to any other person."²⁹¹ The Court of Appeals for the Eighth Circuit held that plaintiff's warning claim was preempted, but that the design claim was not.²⁹²

iii. *Federal Hazardous Substances Act*

The majority of courts considering the matter have concluded that compliance with Federal Hazardous Substances Act ("FHSA")²⁹³ labeling regulations preempt state common law claims premised upon a party's argument that the manufacturer should have provided better hazard warnings.²⁹⁴ The legislative history of the FHSA announced that its purpose was to "provide nationally uniform requirements for adequate cautionary labeling on packages of hazardous substances which are

290. 15 U.S.C. § 2075(a) (West 1997).

291. 15 U.S.C. § 2074(a) (West 1997).

292. *See Moe*, 73 F.3d at 183.

293. *See* 15 U.S.C. § 1261 et. seq (West 1997).

294. *See* *Salazar v. Whink Products, Co.*, 881 P.2d 431 (Colo. Ct. App. 1994); *see also* *Busch v. Graphic Color Corp.*, 662 N.E.2d 397, 407-08 (Ill. 1996) (failure to warn claim only available in instances of noncompliance with federal labeling requirements; to extent plaintiff urges that manufacturer should have a different label, claim preempted by FHSA); *Kirstein v. W.M. Barr & Co.*, 983 F. Supp. 753, 760-61 (N.D. Ill. 1997) (to same effect regarding warnings claim pertaining to adhesive remover); *Comeaux v. National Tea Co.*, 81 F.3d 42 (5th Cir. 1996) (to same effect, lighter fluid) (authority collected at *Gurrieri v. William Zinsser & Co., Prod. Liab. Rep. (CCH) ¶ 15,516* (N.J.Super.Ct. 1999) (paint primer).

sold in interstate commerce and are intended or suitable for household use.”²⁹⁵ The Act’s preemption clause reads:

[I]f a hazardous substance or its packaging is subject to a cautionary labeling requirement . . . [under this title] designed to protect against a risk of illness or injury associated with the subject, no State or political subdivision of a State may establish or continue in effect a cautionary labeling requirement applicable to such substance or packaging and designed to protect against the same risk of illness or injury unless such cautionary labeling requirement is identical to the labeling requirement [imposed pursuant to this title].²⁹⁶

*Gurrieri v. William Zinsser & Co.*²⁹⁷ was a personal injury suit arising from the injurious inhalation of and contact exposure to a stain remover.²⁹⁸ The plaintiff claimed that the label on the defendant’s product, which contained about 2% methyl alcohol, should have had more vigorous language or hazard signage, such as a skull and crossbones, that would be mandated had the product contained more than 4% methyl alcohol.²⁹⁹ The court found that the product’s label complied with the warning label standard set pursuant to the FHSA,³⁰⁰ and, affirming judgment for the defendant, wrote:

[T]o the extent that the plaintiff proposes additional, different, or more clearly-stated warnings, [these claims are preempted by the FHSA].³⁰¹ . . . In the present case, both [the statute and the regulations] address the labeling of hazardous or dangerous substances. . . . A finding that specific local warnings pursuant to state law must apply to products containing less than 4% of methyl alcohol would create system of possibly fifty or more different labeling requirements throughout the country, contrary to Congress’ obvious intent in passing the FHSA to ‘provide nation-

295. H.R. REP. NO. 86-1861(1960), reprinted in 1960 U.S.C.C.A.N 2833.

296. 15 U.S.C.A § 1261(b)(1)(A) (West 1997).

297. 728 A.2d 832 (N.J. Super. Ct. App. Div. 1999).

298. See *id.* at 833.

299. See *id.* at 841.

300. See 15 U.S.C. § 1261(p) (West 1997); but see, 16 C.F.R. § 1500.14(b)(4) (current through September 29th, 2000) (imposing different labeling requirement for household products containing 4% or more ethyl alcohol).

301. *Gurrieri*, 728 A.2d at 841 (citing *Salazar v. Whink Products Co.*, 881 P.2d 431 (Colo. Ct. App. 1994)).

ally uniform requirements for adequate cautionary labeling.³⁰²
We reject this result.³⁰³

In *State ex rel. Jones Chemicals, Inc. v. Seier*,³⁰⁴ a Missouri appeals court found similarly that the FHSA statutory language pertaining to product labeling preempted a plaintiff's products liability claim under state law and that the labeling of a container of muriatic (hydrochloric) acid contained inadequate notice of the product's risks.³⁰⁵ In reaching this conclusion, the Missouri court found that the FHSA reflected congressional intent to establish uniform nationwide standards for labeling of hazardous substances, and to avoid the "impracticality of having states produce potentially fifty different labels for a particular hazardous substance."³⁰⁶

IV. CONCLUSION

*Cipollone v. Liggett Group, Inc.*³⁰⁷ ended the long reign of judicial deference to state common law liability and regulatory obligations, and intimated that the existence of an express preemption provision might, standing alone, suffice to permit a finding of federal preemption. In so doing, the Court stifled the effect of equivalently specific savings clauses that purported to preserve state products liability or regulatory actions from federal suffocation.

In *Geier v. American Honda Motor Co.*,³⁰⁸ the Court refined its *Cipollone* analysis, and in so doing gave breathing room to extant and future savings clauses in federal safety-related statutes. The *Geier* court expanded little in suggesting a means for lower courts to proceed with confidence in reconciling express preemption provisions with similarly explicit savings clauses. The result of the Court's recalcitrance will surely be played out in the decisions of lower courts which are now left to decide if savings and preemption clauses may be interpreted in a comple-

302. *Id.* at 841 (quoting H.R.REP. NO. 86-1861 at 1 (1960), *reprinted in* 1960 U.S.C.C.A.N. 2833.)

303. *Id.* at 841.

304. 871 S.W.2d 611 (Mo.App. 1994).

305. *See id.* at 614.

306. *Id.* at 612-13, quoting *Moss v. Parks Corp.*, 985 F.2d 736 (4th Cir. 1993).

307. 505 U.S. 504 (1992).

308. ___ U.S. ___, 120 S. Ct. 1913 (2000).

mentary way. The inevitable consequence of the Supreme Court's failure to harmonize *Cipollone* and *Geier* will be a bumper crop of conflicting decisions brought about by the inability of courts to determine in a consistent way whether the polar magnetic field of express preemption clauses, or that of savings clauses, is the stronger.