

THE NORMALIZATION OF PRODUCT PREEMPTION DOCTRINE

Jean Macchiaroli Eggen*

INTRODUCTION

Scholars have long observed that the United States Supreme Court's preemption doctrine has been fraught with uncertainty, leading to unpredictable results in the lower courts.¹ One area of the law in which the doctrine of preemption has been especially difficult to interpret has been tort law, and particularly product liability law.² State product liability law operates in fields that are entwined with federal regulation. Cigarettes, medical devices, pesticides, and motor vehicles are examples of the many products that traditionally have been subjects of both federal regulation and state common law actions. Federal statutes and regulations often incorporate measures to assure product safety,³ but the statutes rarely include provisions to compensate for personal injuries or other damages associated with the regulated products.⁴ Rather, federal law and state common law exist in a

* Professor of Law, Widener University School of Law. The author wishes to thank Laura Ray for her comments on an earlier draft of this Article. The author also wishes to express appreciation to her colleagues Martin Kotler and Geoffrey Moulton for their useful and insightful comments when this Article was presented at a faculty development event.

1. See, e.g., DAVID G. OWEN, PRODUCTS LIABILITY LAW § 14.4, at 896 (2005) (“[Preemption doctrine] continues to wallow in a state of utter chaos”); Richard C. Ausness, *Preemption of State Tort Law by Federal Safety Statutes: Supreme Court Preemption Jurisprudence Since Cipollone*, 92 KY. L.J. 913, 916 (2003) (“[T]he Court’s preemption jurisprudence appears to be bereft of any coherent theory or methodology.”); Viet D. Dinh, *Reassessing the Law of Preemption*, 88 GEO. L.J. 2085, 2085 (2000) (“Notwithstanding its repeated claims to the contrary, the Supreme Court’s numerous preemption cases follow no predictable jurisprudential or analytical pattern.”); Betsy J. Grey, *Make Congress Speak Clearly: Federal Preemption of State Tort Remedies*, 77 B.U. L. REV. 559, 588 (1997) (“The changing climate within the Supreme Court as to federal preemption of state tort claims has left lower court decisions in disarray.”); Marin R. Scordato, *Federal Preemption of State Tort Claims*, 35 U.C. DAVIS L. REV. 1, 8 (2001) (“Most commentators who write about preemption agree on at least one thing: Modern preemption jurisprudence is a muddle.” (quoting Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 232-33 (2000))).

2. This Article uses the term “product preemption doctrine” to refer to the preemption processes and rules as developed by the United States Supreme Court in a series of preemption cases involving product liability actions brought under state law. These processes and rules are uniquely geared to the health and safety issues involved in product liability actions. Nothing in this term, or in this Article, is intended to suggest that the rules of the product preemption cases form or do not form a continuum with other preemption cases decided by the Court. Rather, this body of preemption caselaw addresses a discrete set of problems. For this reason, it is best treated as a whole.

3. See, e.g., Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified at 21 U.S.C. §§ 360c-360k (2000)) [hereinafter MDA]; Toxic Substances Control Act, 15 U.S.C. §§ 2601-2692 (2000 & Supp. II 2002).

4. A rare exception is the Black Lung Benefits Act, 30 U.S.C. §§ 901-944 (2000 & Supp. II 2002), which establishes an administrative mechanism for providing compensation to miners suffering from, or

sometimes uncomfortable balance in our federalist society.⁵ This discomfort is enhanced by the lack of clear direction from Congress in its statutory enactments and from federal agencies in their administrative regulations. Since the 1990s, product sellers have argued with increasing frequency that plaintiffs' product liability actions under state common law are preempted by the existence of federal regulation governing the alleged injurious product.⁶ In most of these cases, the proponent of the preemption defense has asked the court to preclude the plaintiffs' claims without explicit direction from Congress.⁷

When the United States Supreme Court issued its seminal product preemption decision in *Cipollone v. Liggett Group, Inc.*⁸ in 1992, the Court signaled certain important guidelines for courts examining the applicability of preemption to product liability claims generally.⁹ Other product cases led to Supreme Court decisions on preemption during the 1990s and 2000s, but the clarity that courts and commentators had anticipated from *Cipollone* eluded them. The Supreme Court's 2005 decision in *Bates v. Dow Agrosciences LLC*¹⁰ was a new and important turn of events. With *Bates*, the Court made a firm, substantive statement about the doctrine of product preemption. It made clear that certain normative rules and policy judgments are firmly a part of product preemption doctrine. *Bates* not only reflects these norms; the Court also affirmatively states their force.¹¹ In ruling contrary to the majority of the federal courts of appeals that had considered the same preemption question,¹² the Supreme Court has made a powerful policy

deceased as a result of, pneumoconiosis. *Id.* § 922. The act explicitly supplants state common law for the injuries covered. In contrast, the National Childhood Vaccine Injury Act of 1986, Pub. L. 99-660, 100 Stat. 3756 (codified as amended at 42 U.S.C. § 300aa-1 to -34 (2000)), while providing a similar administrative remedy for persons claiming injury from vaccine exposures, expressly declines to supplant the common law. Rather, the Vaccine Act offers claimants a choice between accepting the compensation available under the administrative system or rejecting the administrative remedy and pursuing the claims under state tort law. *Id.* § 300aa-21(a). For a detailed examination of government compensation systems and the considerations that are necessary to provide just compensation while serving government efficiency goals, see John G. Culhane, *Tort, Compensation, and Two Kinds of Justice*, 55 RUTGERS L. REV. 1027 (2003).

5. See Jack W. Campbell IV, *Regulatory Preemption in the Garcia/Chevron Era*, 59 U. PITT. L. REV. 805, 808 (1998) ("Current [preemption] doctrine enables Congress to evade political accountability for sensitive federalism questions."); Mary J. Davis, *Unmasking the Presumption in Favor of Preemption*, 53 S.C. L. REV. 967, 969 (2002) ("[P]reemption is about power and politics because it involves the fundamental balance of Congress's power in relation to the states."). See generally Caleb Nelson, *Preemption*, 86 VA. L. REV. 225 (2000) (discussing preemption in the context of Supremacy Clause jurisprudence).

6. See *Bates v. Dow Agrosciences LLC*, 125 S. Ct. 1788, 1796-97 (2005); Richard C. Ausness, *Federal Preemption of State Products Liability Doctrines*, 44 S.C. L. REV. 187, 203 (1993); Lars Noah, *Reconceptualizing Federal Preemption of Tort Claims as the Government Standards Defense*, 37 WM. & MARY L. REV. 903, 904 (1996).

7. See, e.g., *Bates*, 125 S. Ct. at 1793.

8. 505 U.S. 504 (1992).

9. See Jean Macchiaroli Eggen, *Sense or Sensibility?: Toxic Product Liability Under State Law After Cipollone and Medtronic*, 2 WIDENER L. SYMP. J. 1, 11-15 (1997) (discussing the preemption principles embodied in the *Cipollone* decision).

10. *Bates*, 125 S. Ct. 1788.

11. See *id.* at 1798-99, 1801-02; *infra* notes 222-26 and accompanying text.

12. *Bates*, 125 S. Ct. at 1794 (noting that the ruling of the court below, the Fifth Circuit, to preempt

statement in favor of consumer protection and recognized the value and efficacy of state tort law to achieve deterrence and product safety—at least in most situations. Accordingly, product preemption doctrine has begun to coalesce into a predictable, if not fixed, set of rules.

In *Cipollone*, the Court interpreted the express preemption provisions contained in the two federal cigarette labeling acts,¹³ concluding that some, but not all, of the plaintiffs' product liability claims were preempted by the acts.¹⁴ The Court's decision was intensely statute-specific. Indeed, the distinction between the language of the preemption provision in the earlier cigarette labeling act and the provision in the second act was key to the Court's interpretation of the preemptive scope of the acts.¹⁵ When the Court followed with *Medtronic, Inc. v. Lohr*¹⁶ in 1996, the Court's attention to the details of the statute in question—in that case, the Medical Device Amendments¹⁷ (MDA) to the Food, Drug, and Cosmetic Act—was the interpretive key to the decision.¹⁸ The result in *Medtronic* was that none of the plaintiffs' claims was preempted because of the unique statutory and regulatory scheme of the MDA.¹⁹ These two cases, focusing so intensely on the respective language and meaning of the statutes, left the lingering impression that preemption was idiosyncratic to the purpose and provisions of the specific statute. Thus, the utility of those two cases in contexts other than cigarettes or medical devices appeared to be limited.²⁰ The Court did little to dispel those concerns in the product preemption cases following *Medtronic*. In *Bates*, however, in analyzing preemption under the Federal Insecticide, Fungicide, and Rodenticide Act²¹ (FIFRA), the Court returned to the principles of *Cipollone* and *Medtronic* to reach its conclusion that many of the plaintiffs' product claims survived preemption.²² In so doing, the Court stressed the value of the two earlier decisions as embodying certain norms that define preemption generally and product preemption doctrine in particular.²³

Much of the scholarship on preemption over the past two decades has focused on demonstrating the apparent arbitrariness of the Supreme Court's analysis. In particular, some scholars have argued that the Court says one thing, but does another in its approach to determining whether state laws or

all of the plaintiff's claims was consistent with the majority of the federal courts of appeals).

13. See Federal Cigarette Labeling and Advertising Act of 1965, Pub. L. No. 89-92, 79 Stat. 282 (codified as amended at 15 U.S.C. §§ 1331-1340 (2000)); Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87 (codified as amended at 15 U.S.C. §§ 1340 (2000)).

14. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 530-31 (1992) (plurality opinion).

15. *Id.* at 520-23.

16. 518 U.S. 470 (1996).

17. MDA, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended at 21 U.S.C. §§ 360-360k (2000 & Supp. II. 2002)).

18. See *Medtronic*, 518 U.S. at 486-90.

19. See *id.* at 493-501.

20. See Eggen, *supra* note 9, at 11-15.

21. 7 U.S.C. §§ 136-136y (2000 & Supp. II 2002).

22. See *Bates v. Dow Agrosciences LLC*, 125 S. Ct. 1788, 1798 (2005).

23. See *id.* at 1798-1801.

state law claims have been preempted.²⁴ This Article will demonstrate that, at least in the area of product preemption, the Court has in fact embraced certain standards and principles, which have become clear in the *Bates* decision. While the Court is surely far from finished with its consideration of product preemption, this normative approach provides guidance for district courts confronted with preemption motions by manufacturers of products subject to federal safety regulation.

This Article begins in Part I with a brief presentation of generally accepted preemption principles and their application in the series of modern product preemption decisions issued by the United States Supreme Court in the years prior to *Bates*. Part II then discusses the *Bates* decision, emphasizing its consistency with *Cipollone* and *Medtronic*. Part III identifies and discusses the norms and policies embodied in product preemption doctrine and demonstrates that the Supreme Court has embraced the value of normalizing preemption doctrine in the area of product liability. This Article argues that the product preemption cases, read in light of *Bates*, show a Supreme Court committed to maintaining the traditional role of state common law—particularly tort actions in health and safety matters—except in very narrow circumstances. The Article concludes that the balance struck by the Supreme Court in *Bates* has gone a long way toward clearing up the confusion engendered by the Court's earlier product preemption decisions and providing some measure of predictability to courts faced with product preemption decisions.

I. THE PRODUCT PREEMPTION CONUNDRUM PRIOR TO *BATES*

A. *The Doctrinal Context*

The preemption doctrine is derived from the Supremacy Clause of the United States Constitution,²⁵ a fact that the Supreme Court has noted over the years.²⁶ The Court has also recognized the existence of a presumption against preemption.²⁷ The deceptively simple statement in the Constitution

24. See Ausness, *supra* note 1, at 940; Davis, *supra* note 5, at 1013; Grey, *supra* note 1, at 563; Karen A. Jordan, *The Shifting Preemption Paradigm: Conceptual and Interpretive Issues*, 51 VAND. L. REV. 1149, 1158-60 (1998); Susan Raeker-Jordan, *A Study in Judicial Sleight of Hand: Did Geier v. American Honda Motor Co. Eradicate the Presumption Against Preemption?*, 17 BYU J. PUB. L. 1, 2-3 (2002).

25. U.S. CONST. art. VI, cl. 2.

26. See, e.g., *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 663 (1993); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992); *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981). Some scholars have noted that the preemption doctrine is, in fact, separate from the concept of supremacy. For example, one commentator proposed that the power of Congress to preempt state law derives from the Necessary and Proper Clause, rather than the Supremacy Clause. See Stephen A. Gardbaum, *The Nature of Preemption*, 79 CORNELL L. REV. 767, 770 (1994); see also Campbell, *supra* note 5, at 813-14 (agreeing with Gardbaum, *supra*). In the product preemption cases, the Supreme Court consistently refers to the Supremacy Clause as the source of the preemption doctrine. See, e.g., *Cipollone*, 505 U.S. at 516 (citing *McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 316, 427 (1819)); *Maryland*, 451 U.S. at 746.

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

that federal law is the “Law of the Land” belies the complexity of implementing that edict, and the doctrine of preemption is one means that has evolved to balance federal and state interests when Congress has not been explicit.²⁸ Moreover, the Supreme Court has held that a federal regulation duly promulgated by a federal agency operating under its delegated authority may preempt state law under appropriate circumstances.²⁹ Preemption can be either express or implied,³⁰ but the line between the two has not always been clear. A court presented with a preemption question conducts an express preemption analysis when the federal statute contains a preemption provision.³¹ The task of the court is to interpret the statutory language to discern the intent of Congress and, thus, the scope of preemption.³² This language, at best, may be ambiguous, and its precise scope open to different interpretations. Where the statute’s language is unclear, the court must examine legislative history and other relevant matters to determine congressional intent.³³ A question in many product preemption cases has been the extent to which Congress intended to preempt state common law tort claims by operation of the preemption provision in a particular statute.³⁴

A court conducting an implied preemption analysis may do so through two distinct approaches. Implied preemption analysis requires the court to look beyond the express language of the statutory scheme to the fundamental purposes and goals of the statute and its relationship to the state law involved in the case. In determining whether the federal statutory scheme was intended to “occup[y] the field” of the subject in question, the court will determine whether the statute is so comprehensive that it can fairly be said that Congress intended that there be no room for the states to regulate or to

28. See, e.g., *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 146-47 (1963) (seeking “an unambiguous congressional mandate” of an intent to displace state law).

29. See *Fid. Fed. Sav. & Loan Ass’n v. De la Cuesta*, 458 U.S. 141, 162 (1982). This Article does not engage in the debate about the respective roles of federal statutes and regulations within the preemption doctrine. For a discussion of some issues involving the role of federal administrative agencies in relation to state law, see Nina A. Mendelson, *Chevron and Preemption*, 102 MICH. L. REV. 737 (2004).

30. The Court has stated: “Congress’ intent may be ‘explicitly stated in the statute’s language or implicitly contained in its structure and purpose.’” *Cipollone*, 505 U.S. at 516 (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)).

31. See *Rice*, 331 U.S. at 233-34.

32. *Cipollone*, 505 U.S. at 517.

33. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 486 (1996). The Court stated in *Medtronic* that “Congress’ intent, of course, primarily is discerned from the language of the pre-emption statute and the ‘statutory framework’ surrounding it.” *Id.* (citing *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 111-12 (1992) (Kennedy, J., concurring in judgment and concurring in part)). This may cause a court to look beyond the statute to other matters to determine a “reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law.” *Id.*

34. See, e.g., *Bates v. Dow Agrosciences LLC*, 125 S. Ct. 1788, 1793, 1797 n.15 (2005) (alleging failure to warn, defective design and manufacture, negligent testing, breach of express warranty, fraud, and violation of Texas consumer protection statute); *Cipollone*, 505 U.S. at 508 (alleging failure to warn, breach of express warranties, and fraud). Many statutes also contain saving clauses, which preserve some or all remedies under state law. See, e.g., National Traffic and Motor Vehicle Safety Act of 1966, 15 U.S.C. § 1397(k) (repealed 1994) (applied in both *Geier* and *Myrick*). These clauses also tend to be broad and vague. For a discussion of saving clauses, see *infra* notes 371-87 and accompanying text.

impose common law duties.³⁵ A second approach examines whether the state rule actually conflicts with the obligations under the federal statute in one of two ways:³⁶ Either compliance with both the state rule and the federal obligation would be impossible,³⁷ or the state rule would operate as an obstacle to the accomplishment of the federal statutory goals.³⁸

In the product liability context, preemption questions have arisen frequently with regard to whether a federal statute preempts common law tort claims under state law. Beginning with *Cipollone v. Liggett Group, Inc.*³⁹ in 1992 and culminating in the 2005 decision in *Bates v. Dow Agrosciences LLC*,⁴⁰ the United States Supreme Court has issued a string of decisions in product liability cases addressing various aspects and permutations of preemption, defining the contemporary doctrine of product preemption. Commentators have remarked that these decisions have seemed arbitrary and contradictory, particularly as to the vitality and scope of the presumption against preemption.⁴¹ The lower courts have had difficulty applying the Supreme Court's preemption rules and generally have been poor predictors of the direction the Court would take on new preemption issues.⁴² Nevertheless, as an image seen through a lens eventually comes into focus, the Court's product preemption doctrine has worked its way incrementally into a recognizable image.

B. *The Development of the Product Preemption Doctrine Prior to Bates*

The seeds of the contemporary product preemption doctrine may be found in *Silkwood v. Kerr-McGee*,⁴³ a tort action that did not involve product liability. The plaintiff's decedent claimed radiation injury while working

35. *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 256 (1984). The Court has explained, "The scheme of federal regulation may be so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it." *Rice*, 331 U.S. at 230.

36. *Pac. Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n*, 461 U.S. 190, 204 (1983).

37. *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963) (stating that preemption may apply where there is a "physical impossibility" to comply with both the state and federal rules).

38. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941) (stating that a state rule would be preempted where it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress").

39. 505 U.S. 504.

40. 125 S. Ct. 1788.

41. See Davis, *supra* note 5, at 1013; Grey, *supra* note 1, at 563; Raeker-Jordan, *supra* note 24, at 2-3; Alexander K. Haas, Note, *Chipping Away at State Tort Remedies Through Pre-Emption Jurisprudence: Geier v. American Honda Motor Co.*, 89 CAL. L. REV. 1927, 1943 (2001); cf. Scordato, *supra* note 1, at 30-31 ("[T]he maintenance of a presumption against preemption puts the courts into a position in which they are forced to treat essentially similar cases in very different manners.").

42. See, e.g., *Bates*, 125 S. Ct. at 1794 (noting that the majority of the federal courts of appeals and the highest courts of several states have applied preemption to claims similar to the ones raised in this case). In *Bates*, the U.S. Supreme Court rejected the strong majority position of the courts below. See *id.* at 1804; cf. Grey, *supra* note 1, at 582 ("The Supreme Court made clear in *Freightliner Corp. v. Myrick* that the lower courts had overreacted to *Cipollone*." (footnote omitted)); Noah, *supra* note 6, at 925 ("As feared by a number of the Justices in [*Cipollone*], the lower courts have struggled to apply the plurality's judgment in other contexts.").

43. 464 U.S. 238 (1984).

at defendant's nuclear power plant. Her father, as administrator of her estate, obtained a judgment for negligence and \$10 million in punitive damages,⁴⁴ but the Tenth Circuit reversed the judgment, partially on preemption grounds.⁴⁵ The Tenth Circuit held that federal statutes, including the Atomic Energy Act of 1954,⁴⁶ preempted the plaintiff's state law claim for punitive damages.⁴⁷ Its decision was issued less than a year after a Supreme Court ruling that the Atomic Energy Act "occupied the entire field of nuclear safety concerns, except the limited powers expressly ceded to the States."⁴⁸ In *Silkwood*, the Supreme Court reversed, explaining that while Congress intended to preempt state regulation of safety in the nuclear power industry, there was nothing to indicate that Congress also intended tort remedies to be barred.⁴⁹ The Court stated:

Indeed, there is no indication that Congress even seriously considered precluding the use of such remedies either when it enacted the Atomic Energy Act in 1954 or when it amended it in 1959. This silence takes on added significance in light of Congress' failure to provide any federal remedy for persons injured by such conduct. It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.

More importantly, the only congressional discussion concerning the relationship between the Atomic Energy Act and state tort remedies indicates that Congress assumed that such remedies would be available.⁵⁰

Thus, as a matter of both statutory interpretation and public policy, the *Silkwood* Court rejected the application of preemption to bar the plaintiff's punitive damages claim.⁵¹

44. *Id.* at 245.

45. *Silkwood v. Kerr-McGee Corp.*, 667 F.2d 908, 923 (10th Cir. 1981), *rev'd*, 464 U.S. 238 (1984). The case involved a substantial workers' compensation question: whether the exclusivity of the state workers' compensation statute barred the plaintiff from bringing the decedent's claim for personal injuries in court. *Id.* at 913. The Tenth Circuit held that the personal injury claims were matters within the exclusive jurisdiction of the workers' compensation tribunal. *See id.* at 916-20. The punitive damages claim, however, did not fall within workers' compensation. *Id.* at 923. As to that claim, the court held that preemption applied. *Id.*

46. Pub. L. No. 94-197, sec. 6, § 170(e), 89 Stat. 1111, 1113 (1988).

47. *See Silkwood*, 667 F.2d at 923.

48. *Pac. Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n*, 461 U.S. 190, 212 (1983).

49. *Silkwood*, 464 U.S. at 256.

50. *Id.* at 251 (citation omitted). In fact, the Court observed that it was concern over the financial impact of such lawsuits on private enterprises participating in the nuclear industry that induced Congress to enact the Price-Anderson Act in 1957. *Id.* The Price-Anderson Act contained provisions for government indemnification of nuclear facility operators and a limitation on their liability. *Id.* Thus, the Court concluded, Congress presumed the continued viability of tort actions. *Id.* at 252.

51. *See id.* at 257-58.

Silkwood is significant in the product liability context because it places the Supreme Court on record fairly early as interpreting a federal statute—and one that represents a significant federal interest—so as to allow private tort actions under state law. The Court did so even when it had previously ruled that state regulation was impliedly preempted on grounds of field preemption. Significantly, the Court presumed that Congress intended to leave common law tort remedies available to persons who may be injured. The legacy of *Silkwood* is apparent in the most recent Supreme Court pronouncement on preemption.

The Court began to turn its attention to product preemption in earnest in 1992. In *Cipollone v. Liggett Group, Inc.*,⁵² the Supreme Court focused intensely on the statutory language of the express preemption provisions in two federal cigarette labeling statutes.⁵³ The *Cipollone* decision, which involved an assortment of product liability claims brought by a smoker,⁵⁴ came across as a Solomonic compromise on preemption. The split in the Court over preemption was magnified by the fact that seven justices joined in the part of the Court's opinion stating the basic principles of preemption, but only four justices agreed on the construction of the 1969 cigarette act's preemption provision and the impact of that construction on the plaintiff's individual claims.⁵⁵ The plurality opinion was written by Justice Stevens, and the separate opinions of Justice Blackmun and Justice Scalia demonstrated a strong division in the Court. This division was over both fundamental principles and the application of the doctrine in the *Cipollone* case.⁵⁶ Yet, as *Bates* has demonstrated, *Cipollone* has now become the gold standard for express preemption analysis generally.

In *Cipollone*, the Court engaged in a detailed examination of the scope of the preemption provisions contained in the two cigarette labeling acts of 1965 and 1969.⁵⁷ The Court explained that because the Acts contained pre-

52. 505 U.S. 504 (1992) (plurality opinion).

53. See *id.*; Federal Cigarette Labeling and Advertising Act of 1965, Pub. L. No. 89-92, 79 Stat. 282 (codified as amended at 15 U.S.C. §§ 1331-1340 (2000)); Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87 (codified as amended at 15 U.S.C. § 1340 (2000)).

54. The Supreme Court ruled on the following claims, alleged in the complaint, on review of the preemption motion: failure to warn, breach of express warranty, fraudulent misrepresentation, and conspiracy to defraud. See *Cipollone*, 505 U.S. at 512.

55. See *id.* at 507.

56. See *infra* notes 244-58 and accompanying text.

57. The preemption provision in the 1965 Act stated that “[n]o statement relating to smoking and health shall be required in the advertising [or labeling] of . . . cigarettes . . . which are labeled in conformity with the provisions of this Act.” Federal Cigarette Labeling and Advertising Act of 1965, Pub. L. No. 89-92, § 5(b), 79 Stat. 282 (codified as amended at 15 U.S.C. § 1334 (2000)). The act prescribed specific mandatory labeling language to warn of the hazards of cigarettes. The act required that the label be displayed on all packages of cigarettes sold in the United States and that it state: “Caution: Cigarette Smoking May Be Hazardous to Your Health.” *Id.* § 4. In contrast, the preemption provision of the 1969 Act stated: “No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.” Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, § 5(b), 84 Stat. 87 (1970) (codified as amended at 15 U.S.C. §§ 1331-1341 (2000)). The change in the language of the preemption provision accompanied a change in the prescribed warning label to require a statement that cigarette smoking “is dangerous.” *Id.* § 4. The 1969 Act also banned electronic

emption provisions, the preemption analysis would be confined to express preemption—determining whether in drafting the provisions, Congress intended to preempt the plaintiff’s personal injury claims based upon smoking.⁵⁸ In conducting its analysis, the Court focused closely on the change in language from a prohibition of any “statement relating to smoking and health”⁵⁹ in the 1965 Act to any “requirement or prohibition based on smoking and health”⁶⁰ in the 1969 Act.⁶¹ Determining that “requirement” had a broader connotation than “statement,” the Court inferred a congressional intent to expand the scope of the preemption provision in the 1969 Act to encompass at least some state common law actions.⁶² The Court then proceeded to compare the claims asserted in the plaintiff’s complaint—examining the substance of the claims, not merely the language characterizing those claims—and held that the claims relating to the failure to adequately warn regarding the hazards of cigarettes were preempted.⁶³ In contrast, the claims for negligent testing, breach of express warranty, and fraudulent misrepresentation for failure to disclose hazards were not preempted.⁶⁴

The next year, the Court decided another tort—though non-product—preemption case, involving negligence claims arising from a fatal accident at a railroad crossing. In *CSX Transportation, Inc. v. Easterwood*,⁶⁵ the

advertising of cigarettes. *Id.* § 6.

58. The Court stated:

When Congress has considered the issue of pre-emption 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,” “there is no need to infer congressional intent to pre-empt state laws from the substantive provisions” of the legislation.

Cipollone, 505 U.S. at 517 (quoting *Malone v. White Motor Corp.*, 435 U.S. 497, 505 (1978); *Cal. Fed. Sav. & Loan Ass’n v. Guerra*, 479 U.S. 272, 282 (1987)). The Court was addressing the Third Circuit’s opinion, in which the court held that express preemption was unavailable because of the ambiguity of the preemption provisions in the cigarette labeling acts. *See Cipollone v. Liggett Group, Inc.*, 789 F.2d 181 (3d Cir. 1986), *rev’d*, 505 U.S. 504 (1992). Instead, the Third Circuit had applied principles of implied preemption and suggested that most, if not all, of the plaintiffs’ claims were preempted. *Id.* at 188; *accord Pennington v. Vistron Corp.*, 876 F.2d 414 (5th Cir. 1989); *Roysdon v. R.J. Reynolds Tobacco Co.*, 849 F.2d 230 (6th Cir. 1988). Some courts held, however, that the cigarette labeling acts did not preempt tort claims brought under state law. *See Forster v. R.J. Reynolds Tobacco Co.*, 437 N.W.2d 655 (Minn. 1989); *Dewey v. R.J. Reynolds Tobacco Co.*, 577 A.2d 1239 (N.J. 1990).

59. *Cipollone*, 505 U.S. at 514 (quoting Federal Cigarette Labeling and Advertising Act of 1965, § 5(a)).

60. *Id.* at 515 (quoting Federal Cigarette Labeling and Advertising Act of 1965, § 5(b)).

61. *See id.* at 514-15.

62. *Id.* at 522.

63. *See id.* at 524-29.

64. *Id.* at 524-27. In closely examining the allegations of the complaint, the Court observed that at least a portion of the failure-to-warn claim was based upon negligent testing, rather than the labeling or packaging of the cigarettes. *Id.* at 524-25. The negligent testing claim was not preempted because it did not fit within the scope of the preemption provision (labeling and packaging) contained in the 1969 Act. *Id.* Similarly, the Court examined the fraud claims and held that to the extent that the plaintiff was claiming fraudulent misrepresentation or conspiracy to defraud in neutralizing the mandated warnings through advertising, the fraud claims were preempted. *Id.* at 527-28. To the extent that the claims alleged breach of a general duty not to deceive, however, they withstood the preemption challenge. *Id.* at 528-29.

65. 507 U.S. 658 (1993).

Court considered whether the Federal Railroad Safety Act of 1970 (FRSA)⁶⁶ and regulations promulgated pursuant to the Highway Safety Act of 1973⁶⁷ preempted the respondent's claims based on an inadequate warning device at the crossing and the operation of the train at an excessive rate of speed. The FRSA preemption and saving provision were part of a statutory and regulatory scheme that struck a complex balance between federal and state regulation with the goal of uniformity in railroad safety matters.⁶⁸ Ultimately, after analyzing the extent of regulation by the Secretary of Transportation on the respective issues,⁶⁹ the Supreme Court agreed with the Tenth Circuit that the claim based upon excessive speed was preempted but the claim based upon an inadequate warning was not preempted.⁷⁰ In so ruling, the Court again recognized the important role of the common law. The Court stated that even where there was a specific federal scheme such as that in FRSA and related statutes and regulations, "the scheme of negligence liability could just as easily complement these regulations by encouraging railroads—the entities arguably most familiar with crossing conditions—to provide current and complete information to the state agency responsible."⁷¹ Thus, the Court acknowledged the deterrent value of state tort law, even in areas of the law in which federal regulation is in place.

Cipollone invited a bright-line distinction between express preemption and implied preemption. In its wake, one of the assumptions Court observers made was that courts must conduct only an express preemption analysis when the statute in question contains a preemption provision.⁷² In *Freightliner Corp. v. Myrick*,⁷³ however, the Court apparently countermanded *Cipollone* by considering both express preemption and implied preemption. The plaintiffs in *Myrick* claimed injuries arising from two separate automobile accidents.⁷⁴ They brought individual actions against the manufacturers of the tractor-trailers involved in their accidents, claiming that the vehicles were negligently designed because they were not equipped with anti-lock

66. Pub. L. No. 91-458, 84 Stat. 971 (codified as amended at 49 U.S.C. §§ 20101-20153 (2000)).

67. Pub. L. No. 93-87, 87 Stat. 282 (codified as amended at 23 U.S.C. § 152 (2000)).

68. See *CSX Transp.*, 507 U.S. at 662 n.2 (quoting 45 U.S.C. § 434 (1988) (repealed 1994)). The provision stated in part: "The Congress declares that laws, rules, regulations, orders, and standards relating to railroad safety shall be nationally uniform to the extent practicable." *Id.*

69. Cf. *Norfolk S. Ry. Co. v. Shanklin*, 529 U.S. 344 (2000). In *Shanklin*, the Court once again analyzed the impact of the preemption and saving provision of the Federal Railroad Safety Act of 1973, 49 U.S.C. § 20106 (2000 & Supp. II 2002), on claims alleging inadequate warnings at a railroad crossing. *Shanklin*, 529 U.S. at 350. This time, the Court held that the plaintiff's warning claim was preempted because the NHTSA had issued standards for grade crossings that included specifications for warning devices. *Id.* at 348-49. Thus, *Shanklin* was consistent with *CSX*, while reaching a different result on the facts of the case.

70. *CSX Transp.*, 507 U.S. at 661.

71. *Id.* at 668.

72. See, e.g., Ausness, *supra* note 1, at 939; Eggen, *supra* note 9, at 12; Jordan, *supra* note 24, at 1157-58; M. Stuart Madden, *Federal Preemption of Inconsistent State Safety Obligations*, 21 PACE L. REV. 103, 112 (2000).

73. 514 U.S. 280 (1995).

74. *Id.* at 282.

braking systems (ABS).⁷⁵ The National Traffic and Motor Vehicle Safety Act of 1966 (NTMVSA) contained both a preemption provision and a saving clause.⁷⁶ The saving clause provided that “[c]ompliance with any Federal motor vehicle safety standard issued under this subchapter does not exempt any person from any liability under common law.”⁷⁷ Rather than employing the saving clause to solve the preemption question, the Court, instead, used the preemption provision, which essentially barred states from establishing or continuing in effect a motor vehicle safety standard “[w]henever a Federal motor vehicle safety standard established under this subchapter is in effect”⁷⁸ with respect to the same safety matter.⁷⁹

At the time of the action, no federal standard was in effect regarding locking of brakes on tractor-trailers.⁸⁰ The Court thus held that no federal standard existed to invoke the express preemption provision.⁸¹ The manufacturers attempted to argue that the absence of regulation *constituted* regulation in this instance, by demonstrating that NHTSA intended that tractor-trailers not be equipped with ABS.⁸² The Court disagreed, stating that “there is no evidence that NHTSA decided that trucks and trailers should be free from all state regulation of stopping distances and vehicle stability.”⁸³ Thus, the claims were not expressly preempted.

Cipollone had strongly suggested that express preemption would end the inquiry under those circumstances. But instead, the Court in *Myrick* went on to conduct an implied preemption analysis.⁸⁴ Addressing *Cipollone*, and engaging in some *ex post* reanalysis, the Court stated:

The fact that an express definition of the pre-emptive reach of a statute “implies”—*i.e.*, supports a reasonable inference—that Con-

75. *Id.* at 282-83.

76. *Id.* at 284.

77. 15 U.S.C. § 1397(k) (1988) (repealed 1994).

78. *Id.* § 1392(d) (repealed 1994).

79. *Id.* The entire preemption provisions read as follows:

Whenever a Federal motor vehicle safety standard established under this subchapter is in effect, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, with respect to any motor vehicle or item of motor vehicle equipment any safety standard applicable to the same aspect of performance of such vehicle or item of equipment which is not identical to the Federal standard. Nothing in this section shall be construed as preventing any State from enforcing any safety standard which is identical to a Federal safety standard.

Id.

80. The Court discussed Standard 121, 49 C.F.R. § 571.121 (1972), promulgated by the Administrator of the National Highway Safety Traffic Administration (NHTSA), which imposed certain braking requirements on vehicles with air brakes, including tractor-trailers. *Myrick*, 514 U.S. at 284 n.2. The Standard did not explicitly require ABS, but the effect of imposing the safety requirements was to mandate ABS. *Id.* at 284-85. In response to lawsuits, NHTSA amended the Standard so that the stopping distance and lock-up requirements did not apply to tractor-trailers. *Id.* at 285. Contemplating that at some point in the future the requirements would be reinstated, NHTSA left the original Standard 121 in the Code of Federal Regulations to facilitate reinstatement. *Id.* at 284-86.

81. *Myrick*, 514 U.S. at 286.

82. *Id.*

83. *Id.*

84. *Id.* at 280.

gress did not intend to pre-empt other matters does not mean that the express clause entirely forecloses any possibility of implied preemption. Indeed, . . . in *Cipollone*, we engaged in a conflict preemption analysis of the Federal Cigarette Labeling and Advertising Act and found “no general, inherent conflict between federal preemption of state warning requirements and the continued vitality of state common-law damages actions.” Our subsequent decisions have not read *Cipollone* to obviate the need for analysis of an individual statute’s pre-emptive effects.⁸⁵

The Court then rather perfunctorily concluded that the plaintiffs’ claims neither made compliance with both federal and state law impossible nor frustrated the purpose of the federal statutory scheme.⁸⁶ It would take several years before the full impact of the Court’s statements regarding the interplay of express and implied preemption would become apparent in *Geier v. American Honda Motor Company*,⁸⁷ *Buckman Co. v. Plaintiffs’ Legal Committee*,⁸⁸ and *Sprietsma v. Mercury Marine*.⁸⁹

In *Medtronic, Inc. v. Lohr*,⁹⁰ the Court again explored the parameters of express preemption. *Medtronic* involved the impact of the preemption provision contained in the 1976 Medical Device Amendments⁹¹ to the FDCA on common law claims related to a product that had been granted marketing approval by the FDA pursuant to the MDA’s § 510(k) “substantial equivalency” designation.⁹² The pacemaker lead in question was a Class III medical device⁹³ subject to marketing approval by the FDA. Manufacturers are generally required to submit Class III devices to the premarket approval process (PMA), unless they can demonstrate that their devices constitute the “substantial equivalent” of a device already on the market at the time of the enactment of the MDA.⁹⁴ *Medtronic* sought and obtained marketing ap-

85. *Id.* at 288-89 (quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 518 (1992)) (citations omitted).

86. *Id.* at 289-90.

87. 529 U.S. 861 (2000).

88. 531 U.S. 341 (2001).

89. 537 U.S. 51 (2002).

90. 518 U.S. 470 (1996).

91. 21 U.S.C. §§ 360-369k (2000 & Supp. II 2002).

92. *Medtronic*, 518 U.S. at 480.

93. The MDA divide all medical devices into three categories, which are related to the possible threat of injury to patients from the products. *See id.* at 476-80. Class I devices pose a low threat of harm to the public and include devices like crutches and tongue depressors. § 360c(a)(1)(A). Class II devices demonstrate some possibility of injury, *id.* § 360c(a)(1)(B), and include such items as tampons and oxygen masks. These devices are subject to general and special controls, including, but not limited to, manufacturing standards and post-market surveillance rules. *See, e.g., id.* §§ 360d, 360h, 360j, 360k, 360l. Class III devices, which pose the greatest likelihood of injury, are subject to the pre-market approval process (PMA), *id.* § 360e, because Congress deemed the general and special controls to be insufficient. *Id.* § 360c(a)(1)(C).

94. § 360c(i). Another exemption from the PMA process is the exemption for investigational devices, which have separate requirements. *Id.* § 360g.

proval for the device pursuant to the § 510(k) “substantial equivalency” provision.⁹⁵

The Supreme Court addressed the scope of the MDA’s preemption provision in relation to § 510(k) “substantially equivalent” medical devices. The MDA’s preemption provision states that “no State . . . may establish or continue in effect . . . any requirement . . . which is different from, or in addition to, any requirement applicable”⁹⁶ to the device under the act and “which relates to the safety or effectiveness of the device.”⁹⁷ In interpreting the language of the provision, the Court also looked to an FDA regulation explaining the preemption provision.⁹⁸ The FDA’s regulation stated that preemption should be allowed only where a device-specific MDA requirement existed that conflicted with the specific state tort law requirement in question.⁹⁹

For a variety of reasons, the Court, in another plurality opinion, held that none of the product claims presented by the plaintiffs was preempted by the MDA. Some of the claims survived the preemption challenge because the § 510(k) process was merely an expedited process to determine equivalency—not a determination of the safety or effectiveness of the device.¹⁰⁰ Accordingly, the state tort law claims alleging defective design of the device were not “different from, or in addition to”¹⁰¹ any requirement contemplated by the preemption provision because the § 510(k) process did not establish any requirement with respect to the safety or effectiveness of the device.¹⁰² A second set of claims, characterized by the Court as noncompliance claims, alleged in essence that the manufacturer breached a common law duty because it did not meet the standards set forth in the MDA for the device. The law on which these claims were based, the Court said, could not be considered “different from, or in addition to”¹⁰³ the requirements of the act because the plaintiffs claimed that the manufacturer did not meet the identical standards as those established under the MDA.¹⁰⁴ The third and final set of claims included allegations based upon the manufacturing and labeling of the device. These claims were not preempted because, on the basis of the FDA regulation interpreting the preemption provision, the MDA

95. *Medtronic*, 518 U.S. at 480.

96. *Id.* at 481 (quoting § 360k(a)(1)).

97. *Id.* (quoting § 360k(a)(2)).

98. *See* 21 C.F.R. § 808.1(d) (2005).

99. *Id.*

100. Most Class III medical devices on the market have been granted marketing approval through the § 510(k) “substantially equivalent” process. *Medtronic*, 518 U.S. at 477. Citing Congressional hearings, the Court noted that “in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours.” *Id.* at 479 (citing *Hearings before the Subcomm. on Health and the Env’t of the H. Comm. on Energy & Comm.*, 100th Cong. 384 (1987)).

101. § 360k(a)(1).

102. *Medtronic*, 518 U.S. at 493-94.

103. § 360k(a)(1).

104. *Medtronic*, 518 U.S. at 495.

provisions relating to manufacturing and labeling were not device-specific requirements, but rather general controls.¹⁰⁵

The Supreme Court decided *Medtronic* solely as a matter of express preemption. For its next MDA preemption case, *Buckman Co. v. Plaintiffs' Legal Committee*,¹⁰⁶ decided in 2001, the Court took an entirely different approach. Though not chronologically the Court's next product preemption case, *Buckman* provides an interesting and instructive contrast to *Medtronic* because the Court employed an implied preemption analysis. *Buckman* involved multiple applications for a § 510(k) "substantially equivalent" designation for a bone screw for use in spinal surgery.¹⁰⁷ After two applications failed for lack of equivalency—and the FDA expressed concern for the safety of the device in spinal surgery—AcroMed, the manufacturer, and its consultant, Buckman Company, filed separate applications for two component parts of the device and sought § 510(k) approval for each part for insertion in the long bones of the arms and legs.¹⁰⁸ The FDA approved the applications.¹⁰⁹ The manufacturer expected that once the device was on the market, physicians would use it in spinal surgery as a reasonable off-label use of the device.¹¹⁰ Physicians did, in fact, use the device for spinal surgery. The plaintiffs, claiming injury from insertion of the device in the pedicles of their spines, alleged that AcroMed and Buckman attempted to defraud the FDA into approving their device by providing materially misleading information regarding the device, including allowing the FDA to believe that it would only be used in the long bones of the arms and legs.¹¹¹

The Supreme Court held that the plaintiffs' fraud-on-the-FDA claims were impliedly preempted by the FDCA. Chief Justice Rehnquist, writing for the Court, held that conflict preemption barred the claims because the FDCA established a federal scheme for addressing fraudulent practices perpetrated against the FDA.¹¹² The unique federal nature of the FDA's process for policing fraud in drug and medical device matters outweighed the interests of the individual states in establishing their own procedures for enforcement.¹¹³ The need to maintain "a somewhat delicate balance of statutory objectives"¹¹⁴ in the FDCA, as amended by the MDA, drove the Court

105. *Id.* at 497-502.

106. 531 U.S. 341 (2001).

107. *In re Orthopedic Bone Screw Prod. Liab. Litig.*, 159 F.3d 817, 820 (3d Cir. 1998), *rev'd sub nom.* *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001).

108. *Id.*

109. *Id.*

110. *See* 21 U.S.C. § 396 (2000 & Supp. II 2002) (acknowledging the authority of health care providers to prescribe off-label uses for medical devices).

111. *Buckman*, 531 U.S. at 347.

112. *See* 21 U.S.C. § 372 (2000) (granting the FDA the power to investigate fraudulent practices); 18 U.S.C. § 1001 (2000) (authorizing criminal sanctions); 21 U.S.C. § 333(a) (2000) (authorizing criminal sanctions); *id.* § 332 (authorizing injunctive relief); *id.* § 333(g)(1)(A) (2000 & Supp. II 2002) (authorizing civil penalties); *id.* § 334(a)(2)(D) (2000) (authorizing seizure of the medical device); 21 C.F.R. §§ 5.35 & 10.30 (2005) (power of FDA to investigate fraudulent practices).

113. *See Buckman*, 531 U.S. at 347-48.

114. *Id.* at 348.

toward this conclusion.¹¹⁵ The Court focused on the comprehensive federal nature of the scheme for policing fraud under the FDCA and noted that federal law initiated and governed the relationship between the manufacturer and the FDA.¹¹⁶ Accordingly, the Court stated, the presumption against preemption would not apply in this case because of the unique federal interest.¹¹⁷

Among other things, Chief Justice Rehnquist recognized the federal interest in allowing reasonable off-label uses of medical devices and leaving that determination to health care providers.¹¹⁸ Congress had expressly stated in the FDCA that “[n]othing in this Act shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care . . . relationship.”¹¹⁹ The Court was concerned that state lawsuits would have a chilling effect on the latitude of health care providers to care for their patients, as well as on the ability of the FDA to do its job effectively.¹²⁰ An additional concern was that allowing state law actions would provide applicants with “an incentive to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA’s evaluation of an application.”¹²¹

Further, in a curious twist, the Court did not conduct an express preemption analysis before moving on to the implied preemption analysis. Indeed, the Court relegated the only mention of express preemption to a footnote in which the subject was summarily dispatched.¹²² Additionally, the Court did not engage in any distinctions between fraud claims that parallel the fraud provisions in the statute and fraud claims that impose higher or different standards.¹²³

A year earlier, the Court had taken the opportunity to discuss and apply implied preemption in *Geier v. American Honda Motor Company*.¹²⁴ *Geier*

115. *See id.*

116. *Id.* at 347-48.

117. *Id.* at 347; *see* *United States v. Locke*, 529 U.S. 89, 108 (2000) (refusing to apply presumption against preemption because of unique federal interest in maritime commerce); *see also infra* notes 240-293 and accompanying text (discussing vitality of presumption against preemption, even though the Court has occasionally declined to apply the presumption).

118. The Court referred to off-label uses as “an accepted and necessary corollary of the FDA’s mission to regulate in this area without directly interfering with the practice of medicine.” *Buckman*, 531 U.S. at 350.

119. 21 U.S.C. § 396 (2000 & Supp. II 2002).

120. *Buckman*, 531 U.S. at 350.

121. *Id.* at 351.

122. *Id.* at 348 n.2. In reference to its conclusion that implied preemption barred the claims, the Court said only: “In light of this conclusion, we express no view on whether these claims are subject to express pre-emption under 21 U.S.C. § 360k.” *Id.*

123. Justice Stevens, in his concurrence in *Buckman*, envisioned a role for state fraud actions under certain circumstances. *See Buckman*, 531 U.S. at 354-55 (Stevens, J., concurring). For a discussion of *Buckman* and its projected impact, see Jean Macchiaroli Eggen, *Shedding Light on the Preemption Doctrine in Product Liability Actions: Defining the Scope of Buckman and Sprietsma*, 6 DEL. L. REV. 143, 162-68 (2003).

124. 529 U.S. 861 (2000).

was largely responsible for creating most of the confusion over the application of the preemption doctrine generally. Apparently eschewing some of the foundational principles of the preemption doctrine, including the presumption against preemption, the Court held that state tort claims were impliedly preempted by a federal statute that contained a preemption provision.¹²⁵ *Geier* has received much scholarly criticism directed at the Court's failure to elucidate the principles on which it based its decision.¹²⁶

The claims involved in *Geier* arose from a motor vehicle accident in a car with no airbag or other passive-restraint system. The plaintiffs brought suit claiming that the car was negligently and defectively designed with no driver's-side airbag. The applicable federal standard, Federal Motor Vehicle Safety Standard 208,¹²⁷ did not require the manufacturer to equip the plaintiff's vehicle with particular passive restraints, but rather established a gradual phase-in of passive-restraint requirements.¹²⁸ Thus, the plaintiffs' action, effectively claiming that under state tort law the manufacturer should have installed an airbag in the vehicle involved in the accident, was in conflict with the federal standard.¹²⁹

The federal statute authorizing the regulation in question contained an express preemption provision, as well as a saving clause. Reading both provisions together, the Court concluded that there was "no convincing indication that Congress wanted to pre-empt, not only state statutes and regulations, but also common-law tort actions."¹³⁰ Having determined that express preemption did not apply, the Court moved on to consider implied preemption. The Court acknowledged the apparent contradiction by saying, on the one hand, that the combination of the preemption provision and the saving clause did not preempt common law tort actions but, on the other hand, that implied preemption could do so.¹³¹ Principles of implied preemption may still apply, in the Court's opinion, where there is an actual conflict between a jury-imposed standard and a standard contained in the federal statute.¹³²

In *Geier*, a jury verdict in the plaintiffs' tort action holding the manufacturer liable for failing to equip the car with an airbag would have conflicted with the non-mandatory federal standard. Accordingly, allowing the

125. *Id.* at 886.

126. *See, e.g.*, Stacey Allen Carroll, Note, *Federal Preemption of State Products Liability Claims: Adding Clarity and Respect for State Sovereignty to the Analysis of Federal Preemption Defenses*, 36 GA. L. REV. 797, 819-28 (2002); Haas, *supra* note 41, at 1943-47; Raeker-Jordan, *supra* note 24, at 2.

127. The Standard was promulgated pursuant to the National Traffic and Motor Vehicle Safety Act of 1966, Pub. L. No. 89-563, 80 Stat. 718 (codified as amended at 49 U.S.C. §§ 30101-30169 (2000)).

128. The Department of Transportation (DOT) had rejected an absolute requirement for airbags in favor of granting manufacturers a choice in the types of passive restraints they installed in their vehicles. Moreover, the standard was designed to phase in the passive-restraint requirement over a period of several years. *See Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 878-79 (2000). The standard provided an incentive to manufacturers to install airbags, but it did not require them to do so. *Id.* at 879-80.

129. *Id.* at 881.

130. *Id.* at 868.

131. *See id.* at 869.

132. *Id.* at 871. The Court stated that conflict preemption could arise by virtue of either an inability to comply with both standards or the frustration of federal objectives by the state law. *Id.* at 873-74.

plaintiffs' claims "would have presented an obstacle to the variety and mix of devices that the federal regulation sought. . . . It thereby also would have stood as an obstacle to the gradual passive restraint phase-in that the federal regulation deliberately imposed."¹³³ Thus, the Court was able to point to a very direct conflict between the federal standard (no absolute duty to install an airbag) and the plaintiffs' claims if successful (absolute duty to install an airbag).¹³⁴

Taken together, *Geier* and *Buckman* sent mixed signals regarding the distinction—if there was one—between express preemption and implied preemption. These decisions offered no clear delineation between cases in which the preemption analysis ended with express preemption (*Cipollone*, for example) and those in which the court should consider both express preemption and implied preemption (such as *Geier*). Speculation was rife that the Court was engaging in a "free wheeling judicial inquiry"¹³⁵ involving implied preemption analysis in an effort to limit the force and effectiveness of product liability remedies.¹³⁶

In *Sprietsma v. Mercury Marine*,¹³⁷ the Supreme Court again addressed the question whether implied preemption may bar state law tort claims when the federal statute in question includes both a preemption provision and a saving clause. The plaintiff's decedent suffered fatal injuries in a boating accident after falling overboard and being struck by the propeller.¹³⁸ The plaintiff claimed that the boat should have been equipped with a propeller guard.¹³⁹ The Federal Boat Safety Act of 1971 (FBSA)¹⁴⁰ authorized the

133. *Id.* at 881.

134. Justice Breyer wrote for the Court, demonstrating consistency with his concurring opinion in *Medtronic*. In the earlier case, he stated that he believed that in appropriate circumstances, some medical-device product liability claims could be preempted by the MDA's preemption provision. Essentially, Justice Breyer said that where the statute or regulations contain a device-specific requirement, and state tort law would have the effect of imposing a stricter standard, then preemption would bar the tort claims. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 504-05 (1996) (plurality opinion) (Breyer, J., concurring in part). That level of specificity—in the federal statute or regulation and in the applicable state tort law—would presumably be required for the claims to be preempted. In addition, Justice Breyer was not averse to using basic principles of implied preemption in *Medtronic*. His analysis was quite brief, however, because he quickly concluded that under the circumstances of the Lohrs' case, implied preemption did not bar the claims. *Id.* at 507-08. Justice Breyer's opinion in *Geier* followed through on his argument that specificity in the regulation, and a countervailing specificity in tort law, could trigger preemption. He also followed through on his belief that implied preemption analysis may still play a role when a court has determined that the plaintiffs' common law claims are not expressly preempted. Justice Stevens, the author of several of the Court's product preemption decisions, dissented in *Geier*. *See Geier*, 529 U.S. at 886-913 (Stevens, J., dissenting).

135. *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 111 (1992) (Kennedy, J., concurring in judgment & concurring in part).

136. *See, e.g.*, Haas, *supra* note 41, at 1928; Raeker-Jordan, *supra* note 24, at 43; *see also* Grey, *supra* note 1, at 623-24 (published prior to *Geier*, but noting the potential for preemption to effect non-legislative tort reform); Robert B. Leflar & Robert S. Adler, *The Preemption Pentad: Federal Preemption of Products Liability Claims After Medtronic*, 64 TENN. L. REV. 691, 692 n.4 (1997) (published prior to *Geier*, but reflecting the same concerns); *cf.* Madden, *supra* note 72, at 158 ("The inevitable consequence of the Supreme Court's failure to harmonize *Cipollone* and *Geier* will be a bumper crop of conflicting decisions . . .").

137. 537 U.S. 51 (2002).

138. *Id.* at 54.

139. *Id.* at 51.

Secretary of Transportation to promulgate boat safety regulations,¹⁴¹ and the Secretary delegated that authority to the Commandant of the United States Coast Guard.¹⁴² Ultimately, the Coast Guard declined to require propeller guards on boat motors.¹⁴³

Justice Stevens, writing for a unanimous Court, first held that express preemption did not bar the plaintiff's claims.¹⁴⁴ The preemption provision in the FBSA stated that any state or local "law or regulation" was preempted,¹⁴⁵ and the Court held that Congress intended by that language to preempt only state positive law enactments.¹⁴⁶ The Court also held that the presence of the broad saving clause¹⁴⁷ in the statute indicated that Congress intended that at least some common law claims not be preempted.¹⁴⁸ Quoting from its decision in *Geier*, the Court stated that the presence of the saving clause "assumes that there are some significant number of common-law liability cases to save."¹⁴⁹ Further, the Court opined that Congress did not intend to expressly preempt common law actions because "common-law claims, which—unlike most administrative and legislative regulations—necessarily perform an important remedial role in compensating accident victims."¹⁵⁰

The Court was firm, however, in restating *Geier*'s point that the presence of an express preemption provision in the applicable statute does not prevent implied preemption from barring at least some common law claims.¹⁵¹ But *Geier* was distinguishable from *Sprietsma*, in the Court's opinion. The most significant point of distinction was that, in *Geier*, an affirmative policy decision was reflected in the Motor Vehicle Safety Standard at issue, determining that motor vehicle manufacturers not be required to install a particular passive restraint in all cars.¹⁵² In contrast, in *Sprietsma*, the Coast Guard's decision did not have the force of an affirmative policy decision intended to supplant state policy making on the issue. Nor was there any indication that the Coast Guard's silence was to be read as an affirmative statement that boats were not to be equipped with propeller guards.¹⁵³ Rather, the Coast Guard's decision not to impose a propeller

140. 46 U.S.C. § 4301-11 (2000 & Supp. II 2002).

141. *Id.* § 4302.

142. *Sprietsma*, 537 U.S. at 57.

143. *Id.* at 62.

144. *Id.* at 63-64.

145. § 4306.

146. *Sprietsma*, 537 U.S. at 63.

147. § 4311(g) ("Compliance with this chapter or standards, regulations, or orders prescribed under this chapter does not relieve a person from liability at common law or under State law.").

148. *Sprietsma*, 537 U.S. at 63.

149. *Id.* (quoting *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 868 (2000)).

150. *Id.* at 64.

151. *Id.* at 65.

152. *Id.* at 67-68.

153. *Id.* at 67 ("The Coast Guard did not . . . [decide] that, as a matter of policy, the States and their political subdivisions should not impose some version of propeller guard regulation, and it most definitely did not reject propeller guards as unsafe.").

guard requirement for motorboats was “fully consistent with an intent to preserve state regulatory authority pending the adoption of specific federal standards.”¹⁵⁴ The history of the Coast Guard’s decision not to require propeller guards was replete with evidence supporting this interpretation of the Coast Guard’s position.¹⁵⁵

This theme formed the basis of the Court’s decision that there was no actual conflict between the common law and the FBSA provisions. Because the Coast Guard never expressed the opinion that there should be no requirement of propeller guards—or of any other safeguards not otherwise required under the federal regulations—state law could operate in this area.¹⁵⁶ Thus, the Court stated: “[N]othing in [the Coast Guard’s] official explanation would be inconsistent with a tort verdict premised on a jury’s finding that some type of propeller guard should have been installed on this particular kind of boat equipped with respondent’s particular type of motor.”¹⁵⁷

The Court did not stop at conflict preemption but went on to determine whether field preemption barred the plaintiff’s claims.¹⁵⁸ The Court observed that the FBSA did not mandate that the Coast Guard promulgate a comprehensive regulatory scheme that would encompass all aspects of recreational boat design and safety.¹⁵⁹ The Court suggested that the FBSA might be construed to occupy the field to the limited extent of preempting state statutes and regulations on the same matter.¹⁶⁰ Beyond that, not even the policy goals of promoting uniformity in the design and manufacture of motorboats would justify preemption of common law claims.¹⁶¹ This firm resistance to the application of implied preemption under the circumstances presented in *Sprietsma* demonstrated the unanimous Court’s intention to rein in the use of implied preemption, particularly where the statute in question contained a preemption provision and saving clause. *Sprietsma* did not, however, offer any comprehensive explication of the doctrine of preemption in product liability cases.

154. *Id.* at 65.

155. *See id.* at 65-68.

156. *Id.* at 67.

157. *Id.*

158. *See id.* at 68-70.

159. *Id.* at 69. The Court contrasted *Ray v. Atlantic Richfield Co.*, 435 U.S. 151 (1978), in which the Court had applied field preemption. In examining a federal statute directed at the safety of oil tankers in navigable waters, the Court held field preemption barred state regulation because of the comprehensive and mandatory nature of the regulatory scheme established by the statute. *See id.* at 165; *see also* *United States v. Locke*, 529 U.S. 89, 111 (2000) (involving the same statute and reaching a similar result as *Ray*).

160. *Sprietsma*, 537 U.S. at 69.

161. *See id.* at 70 (“Absent a contrary decision by the Coast Guard, the concern with uniformity does not justify the displacement of state common-law remedies that compensate accident victims and their families and that serve the Act’s more prominent objective . . . of promoting boating safety.”).

II. *BATES* AND THE MOVE TOWARD NORMALIZATION

The United States Supreme Court's most recent pronouncement on the product preemption doctrine came in the context of Federal Insecticide, Fungicide, and Rodenticide Act. Courts had disagreed for years over whether the preemption provision in FIFRA preempted state common law actions for damages associated with pesticides regulated under the Act. But the federal courts of appeals that had considered this issue, attempting to apply the rule of *Cipollone v. Liggett Group, Inc.*, held that the plaintiffs' claims were expressly preempted by FIFRA.¹⁶² In *Bates*, the Supreme Court emphatically went against the trend in the federal appellate courts and held that many of the petitioners' product liability claims were not expressly preempted.¹⁶³ Surprisingly, given the *Geier-Buckman-Sprietsma* group of cases, the Court did not go on to consider implied preemption principles.¹⁶⁴ On one level, this could be considered not only curious, but also erratic. Upon close analysis, however, *Bates* brought together more than a decade of product preemption decisions and affirmed certain standards and norms that the Court has come to value in the product preemption doctrine.

FIFRA requires registration of pesticides with the Environmental Protection Agency (EPA) prior to marketing.¹⁶⁵ Since it was amended in 1972, FIFRA has regulated several matters related to pesticides, including labeling, registration, use, and sale.¹⁶⁶ Environmental and health concerns underlie the standard for pesticide registration,¹⁶⁷ but the regulations promulgated pursuant to FIFRA do not mandate any specific label language.¹⁶⁸ Rather, manufacturers may design labels for their products and draft the label language, and then submit them to EPA for approval.¹⁶⁹ Originally, EPA granted registration to a pesticide upon a determination of efficacy.¹⁷⁰ Fur-

162. See *Lowe v. Sporicidin Int'l*, 47 F.3d 124, 127-30 (4th Cir. 1995); *Taylor AG Indus. v. Pure-Gro*, 54 F.3d 555, 561 (9th Cir. 1995); *MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1024-25 (5th Cir. 1994); *King v. E.I. DuPont De Nemours & Co.*, 996 F.2d 1346, 1347 (1st Cir. 1993); *Shaw v. Dow Brands, Inc.*, 994 F.2d 364, 371 (7th Cir. 1993); *Ark-Platte & Gulf P'ship v. Van Waters & Rogers, Inc.*, 981 F.2d 1177, 1179 (10th Cir. 1993); *Papas v. Upjohn Co.*, 985 F.2d 516, 517 (11th Cir. 1993). *But cf.* *Worm v. Am. Cyanamid Co.*, 5 F.3d 744, 747, 749 (4th Cir. 1993) (holding that while claims based upon labeling were preempted by the FIFRA provision, including claims for express and implied warranties, claims for negligent testing and formulation of the product were not preempted). A typical example of the cases concluding that FIFRA preempted state common law tort claims was *Lowe*, in which the Fourth Circuit held preempted claims for failure to warn; for negligent design, manufacturing, distribution and sale; and for breach of the warranty of merchantability. *Lowe*, 47 F.3d at 127-30.

163. See *Bates v. Dow Agrosciences LLC*, 125 S. Ct. 1788, 1797-1804 (2005). The product liability claims were counterclaims asserted by peanut farmers in a declaratory judgment action brought by Dow.

164. See *id.* at 1807 (Thomas, J., concurring in judgment in part & dissenting in part).

165. 7 U.S.C. § 136a(a) (2000).

166. *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991-92 (1984).

167. See *id.* at 991.

168. See 40 C.F.R. § 156.10 (2005).

169. *Id.* § 156.10; see, e.g., *id.* § 156.66.

170. 7 U.S.C. § 136a(c)-(d) (2000). The manufacturer is required to submit its information and proposed label to EPA for registration, which EPA must then do after determining that the product will not cause harm to humans or the environment. *Id.* § 136a(c)(5). The act makes it illegal to sell a pesticide that has been registered but is "misbranded." To be misbranded, the label must contain information

ther amendments to FIFRA in 1978 gave EPA the authority to waive certain requirements relating to efficacy.¹⁷¹ Shortly thereafter, EPA ceased evaluating proposed pesticide labels for efficacy.¹⁷²

FIFRA contains a preemption provision, which states in pertinent part:

(a) In general

A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.

(b) Uniformity

Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.¹⁷³

“Such State,” for the purpose of subsection (b), refers directly to a state regulating in the manner described in subsection (a).¹⁷⁴ The legislative history of the provision was unclear as to whether “requirements” imposed by a state were intended to encompass state common law tort actions.¹⁷⁵

In *Bates*, the United States Supreme Court held that while the term “requirements” could, under appropriate circumstances, encompass state common law actions, most of the petitioners’ claims were not preempted.¹⁷⁶ *Bates* arose from crop damage suffered by farmers who used Dow’s pesticide Strongarm.¹⁷⁷ The farmers believed that the stunted growth of their peanut crop was caused by the failure of Dow to warn of the dangers of using Strongarm in areas with soil pH levels of 7.0 or higher.¹⁷⁸ After receiving notice of the farmers’ intent to sue, Dow initiated a declaratory judgment action in federal district court seeking a ruling that the farmers’ claims were preempted by FIFRA.¹⁷⁹ The farmers counterclaimed with product liability claims, under both strict liability and negligence, and with

regarding the pesticide’s efficacy that is “false or misleading in any particular,” or the warnings on the label must be inadequate. *Id.* § 136(q)(1)(A); § 156.10(a)(5).

171. *Id.* § 136a(c)(5)(D).

172. *Bates v. Dow Agrosciences LLC*, 125 S. Ct. 1788, 1796 (2005).

173. 7 U.S.C. § 136v.

174. *Bates*, 125 S. Ct. at 1797-98.

175. *See id.* at 1794-98.

176. *See id.* at 1798-99.

177. *Id.* at 1792.

178. *Id.* at 1793.

179. *Id.* The notice of intent to sue was initiated pursuant to the Texas Deceptive Trade Practices-Consumer Protection Act, TEX. BUS. & COM. CODE ANN. §§ 17.01-17.885 (Vernon 2002 & Supp. 2005).

claims based upon fraud, breach of warranty, and violation of the Texas Deceptive Trade Practices-Consumer Protection Act (DTPA).¹⁸⁰ The district court granted summary judgment for Dow, holding that all of the farmers' claims were expressly preempted by FIFRA,¹⁸¹ and the Fifth Circuit affirmed on appeal.¹⁸²

In yet another opinion authored by Justice Stevens,¹⁸³ the Court held that most claims under state product liability laws are not preempted by FIFRA. In a dramatic return to *Cipollone* and *Medtronic*, the Court focused on the express preemption issues presented by the preemption provision contained in the Act. Specifically referencing *Cipollone* and ruling consistently with the string of earlier product preemption decisions, the Court agreed with the Fifth Circuit that the term "requirements" is broad enough to encompass duties created under the common law of the state in addition to state positive-law enactments.¹⁸⁴ However, the Court sharply disagreed with the Fifth Circuit on the scope of preemption.¹⁸⁵ Several scope issues arose in the context of FIFRA. First, to what extent is a requirement one "for labeling or packaging,"¹⁸⁶ as required by the preemption provision? Second, at what point will a requirement be deemed to be "in addition to or different from"¹⁸⁷ the requirements imposed under FIFRA? In particular, the Court was concerned with whether obligations imposed on manufacturers by common law verdicts fell within the language of the preemption provision.¹⁸⁸ Finally, the Court addressed the specific claims alleged by the petitioners to determine how they fit into the preemption scheme envisioned by Congress in FIFRA.¹⁸⁹ These issues were interwoven in the Court's discussion.

The Court first stated that the Fifth Circuit was simply "wrong when it assumed that any event, such as a jury verdict, that might 'induce' a pesticide manufacturer to change its label should be viewed as a requirement."¹⁹⁰ Rather, the Court emphasized that this determination should be made by examining the specific scope of the preemption provision, beyond Congress's mere choice to use the term "requirement."¹⁹¹ In defining what is

180. *Bates*, 125 S. Ct. at 1793.

181. *Dow Agrosciences LLC v. Bates*, 205 F. Supp. 2d 623, 624 (N.D. Tex. 2002), *aff'd*, 322 F.3d 323 (5th Cir. 2003), *vacated*, 125 S. Ct. 1788 (2005).

182. *Dow Agrosciences LLC v. Bates*, 322 F.3d 323, 325 (5th Cir. 2003), *vacated*, 125 S. Ct. 1788 (2005).

183. The *Bates* case was decided in the Supreme Court by a vote of seven to two. See *Bates*, 125 S. Ct. at 1788. In contrast, both the *Cipollone* decision and the *Medtronic* decision—also authored by Justice Stevens—were plurality opinions. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 474 (1996); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 507 (1992).

184. *Bates*, 125 S. Ct. at 1798 (citing *Cipollone*, 505 U.S. at 521).

185. *Id.*

186. *Id.* (quoting 7 U.S.C. § 136v(b) (2000)).

187. *Id.* (quoting § 136v(b)).

188. *Id.* at 1803.

189. *Id.* at 1803-04.

190. *Id.* at 1798.

191. *Id.* The Court also advised that blindly following *Cipollone* as to the meaning of "requirement" was incorrect. The Court stated that "some [earlier] courts too quickly concluded that failure-to-warn

meant by a requirement for “labeling or packaging,” the Court was equally adamant. Common law duties of care, such as those imposed for design, testing, and manufacture under the law of negligence do not constitute such requirements.¹⁹² The primary reason for this determination was that such common law standards do not mandate specific labeling or packaging, but impose a general standard of conduct.¹⁹³ On this basis, the Court concluded that the petitioners’ claims for defective design and manufacture and for negligent testing were not preempted.¹⁹⁴ Similarly, the express warranty claim was not preempted on the same basis. The Court explained that the appearance of an express warranty on the label does not make it a requirement for labeling or packaging, as the common law did not require the manufacturer to make the warranty nor did it require the warranty to be placed on the label.¹⁹⁵

In contrast, the claims based upon fraud and failure to warn fell within the meaning of requirements for labeling or packaging. Unlike the duties of care that underlay many of the petitioners’ claims, the common law standards on which the fraud and failure-to-warn claims were based “set a standard for a product’s labeling that the Strongarm label is alleged to have violated by containing false statements and inadequate warnings.”¹⁹⁶ Although it unfortunately did not offer further discussion, the Court clearly was contemplating *Cipollone* and establishing some consistency between that case and *Bates*.

In asserting that all of the petitioners’ claims were preempted by FIFRA, the respondent Dow had successfully argued to the court below that because liability under state common law would have the effect of “inducing” the manufacturer to change the label on its product, state law imposed a requirement for labeling or packaging.¹⁹⁷ The Supreme Court firmly rejected this interpretation, stating that such an “inducement” or “effects-based” test was irrelevant because it did not fit the ordinary meaning of the term “requirement.” The Court stated: “A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an

claims were pre-empted under FIFRA, as they were in *Cipollone*, without paying attention to the rather obvious textual differences between the two pre-emption clauses.” *Id.* at 1800; *see also* Eggen, *supra* note 9, at 12 (“The second lesson of *Cipollone* is that general language in a preemption provision must be interpreted within the unique context of that particular statute.”).

192. The Court stated: “Rules that require manufacturers to design reasonably safe products, to use due care in conducting appropriate testing of their products, to market products free of manufacturing defects, and to honor their express warranties or other contractual commitments plainly do not qualify as requirements for ‘labeling or packaging.’” *Id.* at 1798.

193. *See id.*

194. *Id.*

195. *Id.* at 1798-99 (citing *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 525-26 (1992)). The Court’s analysis of the express warranty claim was identical to the Court’s analysis in *Cipollone*, where the Court stated that “a common-law remedy for a contractual commitment voluntarily undertaken should not be regarded as a ‘requirement . . . imposed under State law’ within the meaning of [the preemption provision].” *Cipollone*, 505 U.S. at 526 (ellipsis in original).

196. *Bates*, 125 S. Ct. at 1799-1800.

197. *Id.* at 1799.

optional decision is not a requirement.”¹⁹⁸ Thus, a jury verdict on a design, manufacture, or testing claim may invite speculation as to whether the manufacturer will alter its label in response, so as to avoid liability in the future, but ordinarily does not mandate any particular action.¹⁹⁹ The Court noted that a decision on the part of the manufacturer to take any action as a result of a liability under state law is a complex one, including a cost-benefit analysis that considers factors peculiar to that manufacturer’s business.²⁰⁰ The Court contrasted a jury verdict on a fraud or failure-to-warn claim, reasoning that it would “set a standard for a product’s labeling” or packaging.²⁰¹

The Court emphasized that even though the fraud and failure-to-warn claims could be preempted, further analysis was needed to determine whether their requirements were “in addition to or different from”²⁰² those imposed under FIFRA.²⁰³ On this point, the Court turned to “the authority of *Medtronic*.”²⁰⁴ As in *Medtronic*, the Court held that where the claims are based upon state standards parallel to standards in FIFRA, whether statutory, regulatory, or common law, preemption would not apply.²⁰⁵ The Court stated that “a state-law labeling requirement is not pre-empted . . . if it is equivalent to, and fully consistent with, FIFRA’s misbranding provisions.”²⁰⁶ Moreover, the FIFRA requirements did not need to be expressly referenced in the state law for the state standards to be considered “parallel requirements.”²⁰⁷

The Court did not move on to address implied preemption, nor did it explain why it was not addressing that subject. The answer, however, was intrinsic to the decision. Early in the Court’s opinion, Justice Stevens pointed to a 1991 Court decision relating to a different aspect of FIFRA preemption, in which the Court had held that FIFRA was not “sufficiently

198. *Id.*

199. *Id.* The Court also noted that use of the “inducement” test to determine whether a requirement is for labeling or packaging would conflict with the plain meaning of subsection (a) of § 136v, in which Congress expressly recognized that states may regulate the sale or use of a pesticide registered under the act to the extent that FIFRA does not prohibit it. *Id.*

200. *Id.*

201. *Id.* at 1799-1800.

202. *Id.* at 1800 (emphasis omitted).

203. *Id.*

204. *Id.* at 1801. The respondent argued that preemption was necessary to provide uniformity and that allowing common law actions would create “a crazy-quilt of anti-misbranding requirements” that conflict with the requirements under FIFRA. *Id.* The Court rejected this argument, stating that “the clear text of § 136v(b) and the authority of *Medtronic* cannot be so easily avoided.” *Id.*

205. *Id.* at 1800. All nine justices had agreed in *Medtronic* that the noncompliance claims—or claims under state law based upon violation of federal requirements—were not preempted. Justice Stevens, in the plurality opinion, stated: “Nothing in [the preemption provision] denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements.” *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996). Justice O’Connor, in her concurring and dissenting opinion, stated: “Where a state cause of action seeks to enforce an FDCA requirement, that claim does not impose a requirement that is ‘different from, or in addition to,’ requirements under federal law.” *Medtronic*, 518 U.S. at 513 (O’Connor, J., concurring in part & dissenting in part).

206. *Bates*, 125 S. Ct. at 1800.

207. *Id.*

comprehensive” to invoke the operation of field preemption.²⁰⁸ Moreover, FIFRA was designed to allow states and local governments to regulate pesticides, a concept that is built into both the letter and spirit of the Act.²⁰⁹

With respect to conflict preemption, it may seem strange that the Court did not directly address why conflict preemption principles did not fit into its analysis, in light of the attention the Court gave to that subject in *Geier*, *Buckman*, and *Sprietsma*. The silence of the majority on implied preemption suggests that at least seven members of the Court agreed that moving to an implied preemption analysis is not automatic when an analysis of express preemption fully resolves the question. Indeed, this narrow position seems to have been espoused by all nine justices. Justice Thomas, joined by Justice Scalia, wrote a partial dissent in *Bates* that set forth his understanding of why the Court was correct in not considering implied preemption. He stated: “Because we need only determine the ordinary meaning of § 136v(b), the majority rightly declines to address respondent’s argument that petitioners’ claims are subject to other types of pre-emption.”²¹⁰ In Justice Thomas’s opinion, however, FIFRA’s express preemption provision was sufficiently clear to bar more of the petitioners’ claims than the majority allowed.²¹¹

In an unusual moment of Court unity, Justice Thomas acknowledged that the Court’s decision in *Bates* “comports with this Court’s increasing reluctance to expand federal statutes beyond their terms through doctrines of implied pre-emption.”²¹² He rejected the notion that preemption analysis is “[a] freewheeling judicial inquiry into whether a state statute is in tension with federal objectives.”²¹³ His words suggest that the Court’s earlier decisions in *Geier*, *Buckman*, and *Sprietsma* drew a functional line between situations in which implied preemption may operate and those in which it clearly would not.²¹⁴ It is noteworthy in this regard that *Sprietsma*, rejecting implied preemption in the context of the FBSA, was a unanimous decision.

On another level, the thrust of the majority’s opinion in *Bates* was that many common law claims could not be considered “requirements” for labeling and packaging that could impose conflicting obligations on pesticide manufacturers. Part of the support for this conclusion was that the FIFRA statutory scheme—and the language of the preemption provision—

208. See *Wis. Public Intervenor v. Mortier*, 501 U.S. 597, 607 (1991).

209. *Bates*, 125 S. Ct. at 1797 (citing *Mortier*, 501 U.S. at 613).

210. *Id.* at 1806 (Thomas, J., concurring in judgment in part & dissenting in part).

211. See *id.* at 1805-06.

212. *Id.* at 1807.

213. *Id.* (quoting *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 111 (1992) (Kennedy, J., concurring in judgment & concurring in part)).

214. The preemption doctrine cannot be completely separated from the Supreme Court’s federalism jurisprudence. Some commentators on product preemption have directly addressed the federalism implications. See, e.g., Nim Razook, *The Perils of Pragmatic Preemption: A Caution About Using Efficiency Norms in Federal Preemption Decisions*, 15 J.L. & POL. 37 (1999). Others have addressed it in a broader context. See, e.g., Campbell, *supra* note 5. For a more general discussion of the Court’s federalism, see Kathleen M. Sullivan, *The Balance of Power Between the Federal Government and the States*, in *NEW FEDERALIST PAPERS: ESSAYS IN DEFENSE OF THE CONSTITUTION* (Alan Brinkley et al. eds., 1997).

accommodated state regulation of registered pesticides.²¹⁵ In other words, the preemption provision expressly took into account the conflict issue. While Congress's meaning could have been clearer, all nine justices were convinced that the matter was one that fell squarely within an express preemption analysis. On a larger scale, *Bates* emphasized by contrast that the concept of conflict preemption employed in *Geier* was actually very narrow and specific to the statute in that case.

Justice Stevens supported the *Bates* decision with a substantial policy discussion comprising three broad points. First, he noted that tort litigation against pesticide manufacturers was "a common feature of the legal landscape"²¹⁶ by the time FIFRA was first amended in 1972.²¹⁷ Accordingly, he presumed that Congress would have explicitly referenced common law tort actions in the preemption provision if it intended FIFRA to broadly preempt them.²¹⁸ Second, Justice Stevens emphasized that FIFRA's scheme contemplated a partnership between the federal government and the states in the area of pesticide regulation and did not manifest an overriding federal interest.²¹⁹ Third, he praised the common law, tort litigation in particular, for the deterrent effect lawsuits have on manufacturer conduct related to the safety of pesticides.²²⁰ Moreover, he stated: "We have been pointed to no evidence that such tort suits led to a 'crazy-quilt' of FIFRA standards or otherwise created any real hardship for manufacturers or for EPA."²²¹ When multiple lawsuits arise from a particular product, jury verdicts often conflict. Justice Stevens seemed to say that this is a fact of legal life with which manufacturers—and Congress—are well acquainted, and nothing in the Court's decision in *Bates* created any greater obstacles for manufacturers. Thus, lest there had been any doubt, the Court affirmed the value of tort litigation in the legal system.

III. THE NORMALIZATION OF PRODUCT PREEMPTION

Bates closed the circle of decisions that began with *Cipollone*. It addressed the preemptive scope of an express preemption provision contained in a major product safety statute. And the Court's approach was remarkably

215. See 7 U.S.C. § 136v (2000).

216. *Bates*, 125 S. Ct. at 1796.

217. See *id.* at 1801.

218. *Id.*

219. "[T]he statute authorizes a relatively decentralized scheme that preserves a broad role for state regulation. . . . A literal reading of § 136v(b) is fully consistent with the concurrent authority of the Federal and State Governments in this sphere." *Id.* at 1802 (citations omitted).

220. Among other things, the Court emphasized the important role of toxic tort litigation, such as pesticide litigation, in encouraging research to minimize the hazards of chemicals and other toxic substances. *Id.* (citing *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1541-42 (D.C. Cir. 1984)). This is particularly important when the plaintiff is a "first-case" litigant, meaning that he or she is among the first persons to bring a tort action based upon exposure to a particular substance. See Jean Macchiaroli Eggen, *Toxic Torts, Causation, and Scientific Evidence After Daubert*, 55 U. PITT. L. REV. 889, 946-51 (1994) (discussing novel scientific evidence, "first-case" plaintiffs, and the *Ferebee* case).

221. *Bates*, 125 S. Ct. at 1803.

similar to its approach in *Cipollone*—an express preemption analysis with virtually no reference to implied preemption. What are we to make of this in light of the intervening cases relying on implied preemption? In *Bates*, the Court has shown that in the product preemption context, certain norms and rules underlie the preemption analysis. The decisions in the late 1990s and early 2000s flummoxed many commentators and caused them to accuse the Court of abandoning the presumption against preemption.²²² I suggest, however, that that is not the case. Rather, the Court has embraced the presumption against preemption within certain normative analytical standards. Although the Court seemed to expand product preemption by stretching into the area of implied preemption, the Court's most recent decisions contract that part of the doctrine and place limitations on its utility in product cases.

The overriding theme in product liability caselaw is health and safety. Virtually every statute relevant to product liability cases is directed at improving the safety of the products or activities within its jurisdiction with the goal of ensuring the health of the consuming public. Health and safety problems underlying tort litigation and governmental regulation differ from problems arising in the commercial sphere. The close relationship between health and safety and science and technology means that often the courts and governmental agencies are dealing with novel questions not capable of ready answers, requiring a protracted time period to reach workable and effective solutions.²²³ This fact necessarily raises challenges for both courts and regulating agencies in an area that traditionally has been consigned to the states for the setting of appropriate standards. When the doctrine of preemption is raised in the health and safety context, courts have difficulty sorting out the respective roles of the federal government and the states.²²⁴ This problem is exacerbated by Congress's typical lack of clarity regarding the relationship between state law and the health and safety statutes it has enacted.²²⁵ Certain policies come into play in this unique confluence of public and private law. These policies include the need for uniform standards, the need to encourage new technologies, and the need to make remedies available for personal injuries or property and economic damage associated with the products.

Preemption, whether express or implied, requires a balancing of these interests and policies. The Supreme Court has not clearly articulated the way in which that balancing process factors into the preemption analysis in the area of product liability. *Bates* reflects a normalization of the analysis in product preemption, however, and represents a major step toward under-

222. See articles cited *supra* note 41.

223. Mary Loring Lyndon, *Tort Law, Preemption and Risk Management*, 2 WIDENER L. SYMP. J. 69, 71-72 (1997) (“[C]ombining and coordinating tort law and regulation to address [health, safety and environmental] problems achieves a better result than can be achieved by choosing one or the other as the exclusive legal mechanism for monitoring risky technologies.”).

224. See Noah, *supra* note 6, at 938-59 (discussing the various approaches to preemption deriving from *Cipollone*).

225. See Grey, *supra* note 1, at 565.

standing the way the Court integrates these policies into its preemption doctrine. By that I mean that the Court has espoused a set of normative rules in *Bates* which, read in conjunction with the Court's other product preemption decisions since *Cipollone*, provides a guide to the Court's analytical process. Far from being the arbitrary process commentators have often suggested, there is a method to the Court's approach. That method, however, may not be true to the traditional distinctions between express and implied preemption, but rather, has become a discrete doctrine. The process of normalization, made clear in *Bates*, is discussed below.

A. Prominence of Consumer Protection

The products involved in the Supreme Court's product preemption decisions have been subject to regulation under a broad spectrum of federal statutes and regulatory regimes. The modern decisions have spanned more than a dozen years, culminating in *Bates*'s strong public policy statements on consumer protection. Noting in *Bates* that, as early as the time of the enactment of FIFRA in 1947, Congress was well aware of the existence of tort litigation against pesticide manufacturers,²²⁶ Justice Stevens applied the presumption against preemption to uphold the availability of most remedies for injured consumers. This policy of making available remedies for injured consumers has pervaded the Court's product preemption decisions and is a powerful underlying current that supports both the viability of the presumption against preemption and a very restricted role for implied preemption in product cases.

Although in *Cipollone* the Court did not directly address the purposes of the tort system,²²⁷ the next year, in *CSX*, the Court mentioned the deterrent value of tort law. Rejecting the defendant's argument that Congress intended to preempt all common law tort claims, the Court stated: "[T]he scheme of negligence liability could just as easily complement these regulations by encouraging railroads . . . to provide current and complete information to the state agency responsible for determining priorities for improvement projects"²²⁸ Even in *Geier*, the Court acknowledged the value of saving clauses, at least in some contexts, in preserving tort actions with deterrent value: "[The saving provision] preserves those actions that seek to establish greater safety than the minimum safety achieved by a federal regu-

226. *Bates*, 125 S. Ct. at 1796. Preemption was not really an issue for much of that time, however. "Indeed, for at least a decade after [the 1970s] amendments, arguments that such tort suits were preempted by § 136v(b) either were not advanced or were unsuccessful." *Id.*

227. Justice Blackmun, in his partial dissent in *Cipollone*, did address the role of the tort system. He stated: "[T]here is absolutely no suggestion in the legislative history that Congress intended to leave plaintiffs who were injured as a result of cigarette manufacturers' unlawful conduct without any alternative remedies; yet that is the regrettable effect of the ruling today that many state common-law damages claims are pre-empted." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 541 (1992) (Blackmun, J., concurring in part & dissenting in part).

228. *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 668 (1993).

lation intended to provide a floor.”²²⁹ The Court’s statement in *Geier* was made in conjunction with a statement that a broad saving clause did not necessarily exempt all common law claims from the preemption provision.²³⁰

The Court has also acknowledged the reluctance of Congress to deny common law remedies to injured persons. In *Medtronic*, countering the manufacturer’s argument that the MDA preemption provision was broad enough to preempt all common law tort claims, Justice Stevens stated: “If Congress intended [across-the-board preemption], its failure even to hint at it is spectacularly odd, particularly since Members of both Houses were acutely aware of ongoing product liability litigation.”²³¹ In *Sprietsma*, Justice Stevens, noting that one of the purposes of the FBSA was to effect uniformity in boat safety regulations applicable to manufacturers, firmly stated that when Congress and the regulating body have not taken a clear position, “the concern with uniformity does not justify the displacement of state common-law remedies that compensate accident victims and their families and that serve the Act’s more prominent objective, emphasized by its title, of promoting boating safety.”²³² He expressed the same view in *Bates*, stating that “[i]f Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly.”²³³ He pointed to the amendments made to FIFRA that permitted EPA to waive evaluation of the efficacy of pesticides and stated that in that context, Congress no doubt would not have intended the preemption provision “to give pesticide manufacturers virtual immunity from certain forms of tort liability.”²³⁴ The Court also took the position that, under FIFRA, allowing most common law tort claims would ultimately advance enforcement of the statute by contributing to the development of standards imposed upon pesticide manufacturers.²³⁵

In *Buckman*, the important role of state tort law in product cases was overshadowed by the overriding federal interests reflected in the federal enforcement scheme. Chief Justice Rehnquist was concerned that allowing the state fraud claims would interfere with the federal interest of allowing a federal agency to police its own process, particularly where the duties underlying the common law remedies directly involved the relationship of the manufacturer to the federal agency.²³⁶ Furthermore, he was concerned that allowing state law remedies would create a disincentive to medical device manufacturers. Stating that medical device applicants could encounter “unpredictable civil liability”²³⁷ if claimants were allowed to pursue state

229. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 870 (2000).

230. *Id.*

231. *Medtronic, Inc. v. Lohr*, 518 U.S. 420, 491 (1996).

232. *Sprietsma v. Mercury Marine*, 537 U.S. 51, 70 (2002).

233. *Bates v. Dow Agrosiences LLC*, 125 S. Ct. 1788, 1801 (2005).

234. *Id.* at 1802.

235. *Id.*

236. *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 349 (2001).

predictable civil liability”²³⁷ if claimants were allowed to pursue state fraud actions, he warned that such actions could have an undesirable deterrent effect in discouraging companies from seeking approval for therapeutic devices.²³⁸ This would be particularly true if any of the state fraud rules were more stringent than the FDA enforcement standard.²³⁹ The approach in *Buckman* is not inconsistent with the other cases. The distinguishing factor in *Buckman* was the presence of a strong federal interest and the threat of a manufacturer disincentive that would have inhibited effectuation of the statute’s purpose of efficient approval of medical devices for marketing.

These cases demonstrate that the Court values the remedial and deterrent roles of tort law and considers them when rendering a product preemption decision. Even in *Buckman*, when the Court held that the federal interests outweighed the value of tort actions under state law, the Court recognized that the issue was important enough to merit direct consideration. After *Bates*, there can be no doubt that state tort law, a traditional function of the police powers of the states, must be reconciled with the preemption result achieved.

B. *Vitality of the Presumption Against Preemption*

The Supreme Court has stated that the underlying basis of the Supremacy Clause is “the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that [is] the clear and manifest purpose of Congress.”²⁴⁰ That principle has taken on the designation, if not always the full legal force, of a “presumption” against preemption.²⁴¹ Accordingly, it would appear that the primary focus of the preemption doctrine is to determine whether it was the purpose of Congress to replace state law with federal law, and, if so, to what extent.²⁴²

In *Cipollone*, Justice Stevens stated this basic rule and proceeded to follow it by conducting a narrow analysis of the cigarette labeling preemption provisions, holding that only the claims clearly based upon a failure to adequately warn were preempted by the 1969 Act.²⁴³ The middle ground achieved by the Court in Justice Stevens’s plurality opinion served, by way of contrast, to illuminate the disagreement among the justices over the scope of the preemption provision in the 1969 Act and over preemption doctrine generally. That disagreement, however, never shook the foundation of the

237. *Id.* at 350.

238. *Id.*

239. *Id.* at 351.

240. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

241. *See, e.g., Bates v. Dow Agrosciences LLC*, 125 S. Ct. 1788, 1801 (2005) (“The long history of tort litigation against manufacturers of poisonous substances adds force to the basic presumption against pre-emption.”).

242. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (plurality opinion); *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978).

243. *See Cipollone*, 505 U.S. at 524-25.

presumption against preemption,²⁴⁴ a principle upon which a majority of the justices agreed. What the justices in *Cipollone* disagreed about was the *scope* of the presumption against preemption, and this disagreement has been reflected in subsequent decisions as well.

Justice Blackmun, in his separate opinion in *Cipollone*, gave the presumption a broad application. He began by chastising the plurality, stating, “The Court today would craft a compromise position concerning the extent to which federal law pre-empts persons injured by cigarette manufacturers’ unlawful conduct from bringing state common-law damages claims against those manufacturers.”²⁴⁵ He then proceeded to argue that the 1969 Act preempted none of the plaintiffs’ claims.²⁴⁶ Justice Blackmun’s opinion, joined by Justices Kennedy and Souter, examined the language of both preemption provisions²⁴⁷ and the legislative history of the provisions²⁴⁸ and argued that Congress did not intend to deprive consumers of their remedies under tort law.²⁴⁹

In contrast, Justice Scalia, joined by Justice Thomas, expressed the opinion that the presumption against preemption had no place in an express preemption analysis and argued that all of the plaintiffs’ common law tort claims should be expressly preempted, including those that arose prior to

244. Justice Stevens stated: “[W]e must construe these provisions in light of the presumption against the pre-emption of state police power regulations. This presumption reinforces the appropriateness of a narrow reading of [the preemption provision].” *Id.* at 518.

245. *Id.* at 531 (Blackmun, J., concurring in part & dissenting in part).

246. *Id.* at 535-44.

247. *Id.* at 535. Justice Blackmun took issue with the plurality’s interpretation of the 1969 Act language “[n]o requirement or prohibition . . . imposed under State law,” *id.* at 534 (quoting 15 U.S.C. § 1334(b) (1988)), stating that “those words are in reality far from unambiguous and cannot be said clearly to evidence a congressional mandate to pre-empt state common-law damages actions.” *Id.* at 535. Justice Blackmun also emphasized that the purpose and function of the common law is significantly different from that of positive law enactments and should not be lightly dismissed. *Id.* at 536. This point surfaced in an important way in the *Bates* decision. See *Bates v. Dow Agrosciences LLC*, 125 S. Ct. 1788, 1801-02 (2005).

248. Justice Blackmun disagreed with the plurality’s dismissal of Congress’s own statement that the preemption provision in the 1969 Act was a “clarification” of preemption as set forth in the 1965 Act. See *Cipollone*, 505 U.S. at 539 (Blackmun, J., concurring in part & dissenting in part). He viewed “clarification” as just that—explaining the word “statement” in the 1965 preemption provision. Justice Blackmun stated:

By replacing the word “statement” with the slightly broader term, “requirement,” and adding the word “prohibition” to ensure that a State could not do through negative mandate . . . that which it already was forbidden to do through positive mandate . . . , Congress sought to “clarif[y]” the existing precautions against confusing and nonuniform state laws and regulations.

Id. at 539-40 (alteration in original).

249. *Id.* at 541 (Blackmun, J., concurring in part & dissenting in part). Justice Blackmun stated:

[T]here is absolutely no suggestion in the legislative history that Congress intended to leave plaintiffs who were injured as a result of cigarette manufacturers’ unlawful conduct without any alternative remedies; yet that is the regrettable effect of the ruling today that many state common-law damages claims are pre-empted. The Court in the past has hesitated to find pre-emption where federal law provides no comparable remedy.

Id. On this point, he cited the Court’s preemption opinion in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984). In conducting an implied preemption analysis, the Court in *Silkwood* stated that it was “difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.” *Id.* at 251.

the effective date of the 1969 Act.²⁵⁰ In general, Justice Scalia would have applied a broad test to determine whether the cigarette labeling acts' preemption provisions precluded a particular state law claim. He labeled that test a "'proximate application' methodology" and described it as follows: "I would ask . . . whether, whatever the source of the duty, it imposes an obligation in this case because of the effect of smoking upon health."²⁵¹ This simple, yet exceedingly broad, test would have precluded any claims by the plaintiffs related to smoking and health—in essence, the entire substance of the lawsuit.

Justice Scalia sharply criticized the plurality's reliance on the presumption against preemption and its narrow application of preemption principles.²⁵² Referring to the presumption with the weaker—albeit more accurate—term "assumption," he stated:

[T]hat assumption dissolves once there is conclusive evidence of intent to pre-empt in the express words of the statute itself, and the only remaining question is what the *scope* of that pre-emption is meant to be. . . . [O]ur responsibility is to apply to the text ordinary principles of statutory construction.²⁵³

A broad preemption provision in the statute, in his opinion, should not be given a narrow meaning because of the presumption against preemption.²⁵⁴ Accordingly, having agreed with the plurality that the "requirement or prohibition"²⁵⁵ could include common law claims, he argued that all of the plaintiff's claims should be preempted under the language of the provision.²⁵⁶

Justice Scalia stopped short of stating that the presumption against preemption should be eliminated altogether, but his opinion left little, if any, room for the presumption in preemption jurisprudence. In short order, he swept away the presumption for both express and implied preemption.²⁵⁷ To a lesser degree, his words were echoed by Justice Thomas in his concurring and dissenting opinion in *Bates*. Joined by Justice Scalia in that opinion, Justice Thomas stated: "[T]he majority states that the presumption against pre-emption requires choosing the interpretation of § 136v(b) that disfavors

250. With regard to applicability of the 1965 preemption provision, Justice Scalia stated, "To require a warning about cigarette health risks is to require a 'statement relating to smoking and health.'" *Cipollone*, 505 U.S. at 549 (Scalia, J., concurring in judgment in part & dissenting in part).

251. *Id.* at 554.

252. One prediction made by Justice Scalia was that the questions that remained open after the Court's *Cipollone* decision "will fill the lawbooks for years to come." *Id.* at 556. Indeed, they have not just filled the law books, but they have also served as the basis for further preemption opinions of the Supreme Court.

253. *Id.* at 545.

254. *Id.* at 548.

255. *See id.* at 555.

256. *See id.*

257. *Id.* at 545 (stating in absolute terms that state law is to be displaced by federal law where expressly stated or impliedly necessitated).

pre-emption. That presumption does not apply, however, when Congress has included within a statute an express pre-emption provision.”²⁵⁸

In *Cipollone*, seven justices concurred on the basic approach toward preemption, including the Court’s reliance on the presumption against pre-emption.²⁵⁹ In *Medtronic*, those same preemption principles were espoused substantially by five justices,²⁶⁰ with the other four joining in an opinion by Justice O’Connor that focused exclusively on the interpretation of the language in the MDA preemption provision and not on the foundations of the preemption doctrine. In 2000, *Geier* seemed to signal a different approach. *Geier* was the source of confusion because, among many other oddities, the majority did not directly refer to the presumption against preemption, thus causing speculation about its continued vitality.

The language in the *Geier* opinion that instigated the debate over whether the presumption against preemption was dead was far from clear. Analyzing the preemption provision and saving clause in the National Traffic and Motor Vehicle Safety Act, Justice Breyer, writing for the majority,²⁶¹ stated that he did not believe that “the pre-emption provision, the saving provision, or both together, create some kind of ‘special burden’ beyond that inherent in ordinary pre-emption principles—which ‘special burden’ would specially disfavor pre-emption here.”²⁶² Perhaps through lack of clarity, or perhaps because the Court then went on to hold the plaintiffs’ claims impliedly preempted after having held them not expressly preempted by the preemption provision, this passage lent itself to the interpretation that the Court disfavored the presumption against preemption altogether.

Some illumination of the Court’s meaning in *Geier* may be gleaned from Justice Breyer’s concurring opinion in *Medtronic*. In *Medtronic*, Justice Breyer agreed with a substantial portion of Justice Stevens’s plurality opinion and concurred in the judgment.²⁶³ It is therefore instructive to examine Justice Breyer’s opinion in that case for some sign of his meaning in *Geier*. Notably, Justice Breyer agreed with the *Medtronic* plurality in the portion of the opinion that reaffirmed the viability of the presumption against preemption: “First, because the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action.”²⁶⁴ Further, Justice Stevens ex-

258. *Bates v. Dow Agrosciences LLC*, 125 S. Ct. 1788, 1806 (2005) (Thomas, J., concurring in part & dissenting in part) (citation omitted).

259. Those justices were Chief Justice Rehnquist and Justices Stevens, White, Blackmun, O’Connor, Kennedy, and Souter, who joined Parts I, II, III, and IV of the Court’s opinion. *Cipollone*, 505 U.S. at 507.

260. The justices joining in the portions of the plurality opinion that discussed the presumption against preemption were Justices Stevens, Kennedy, Souter, Ginsburg, and Breyer. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 473, 508 (1996).

261. Justice Breyer was joined by the Chief Justice and Justices O’Connor, Scalia, and Kennedy. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 863 (2000).

262. *Id.* at 870.

263. *Medtronic*, 518 U.S. at 503-08 (Breyer, J., concurring in judgment & concurring in part).

264. *Id.* at 485.

pressed the view that the presumption applies to all matters relating to the scope of Congress's intent to preempt, thus pervading the entire analysis.²⁶⁵ Presumably, Justice Breyer agreed with this point.

If Justice Breyer had intended to discount or reject the presumption against preemption in the context of the MDA, he had ample opportunity to do so in his opinion in *Medtronic*. He stated that he believed, under appropriate circumstances not present in the *Medtronic* case, that the MDA could preempt certain state tort actions, either expressly or impliedly.²⁶⁶ To emphasize his point that the Court should have moved on to an implied preemption analysis—because, in his opinion, the MDA preemption provision was ambiguous—he conducted his own very brief conflict and field preemption analyses and determined that the result in the case would not change.²⁶⁷ Nothing in his opinion suggested that he believes that the presumption against preemption dissolves when a court moves from express preemption to implied preemption—or under any other circumstances, for that matter.

Justice Breyer's statements in *Geier* should be read with his *Medtronic* opinion in mind. Much of the *Geier* opinion takes the position that the application of the principles of express preemption does not bar the application of implied preemption.²⁶⁸ It is illogical to conclude that the Court intended to reject the presumption against preemption altogether without discussion. What is more likely is that the circumstances in *Geier* raised a specific situation in which the presumption gave way to other considerations. In *Geier*, it is appropriate to read Justice Breyer's opinion very narrowly as applicable solely to the unique characteristics of that case, nothing more. In fact, the portion of the opinion in which Justice Breyer rejected any kind of "special burden" is one that heavily emphasized the uniquely federal nature of the safety standards embodied in the federal regulations.²⁶⁹ Regardless of how narrowly Justice Breyer's words may have been intended, at least prior to *Sprietsma* and *Bates*, the Court, by its actions if not by its words, gave the impression that it may have eroded, or even eliminated, the presumption against preemption.

Following on the heels of *Geier*, Chief Justice Rehnquist, writing for the Court in *Buckman*, used language that seemed to support the erosion of the presumption against preemption. Nevertheless, Chief Justice Rehnquist's words can be read consistently with maintaining a strong presumption against preemption in most situations. Relying heavily on the statement of

265. *Id.*

266. *Id.* at 503-08.

267. *Id.* at 508 (Breyer, J., concurring in judgment & concurring in part). Justice Breyer stated: "I can find no actual conflict between any federal requirement and any of the liability-creating premises of the plaintiffs' state-law tort suit; nor . . . can I find any indication that either Congress or the FDA intended the relevant FDA regulations to occupy entirely any relevant field."

268. See *infra* note 291 and accompanying text.

269. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 870-71 (2000).

the presumption in *Rice v. Santa Fe Elevator Corporation*,²⁷⁰ he stated: “Policing fraud against federal agencies is hardly ‘a field which the States have traditionally occupied’ such as to warrant a presumption against finding federal pre-emption of a state-law cause of action.”²⁷¹ Rather, the Court characterized this matter as one that is “inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law.”²⁷² Thus, when the statutory provision in question is not in an area traditionally within the realm of state regulation and is “inherently federal”—as when it is a matter of policing fraud allegedly perpetrated against a federal agency, and the federal agency’s powers are expressly designated in the federal statute—the plaintiff’s common law tort claims will not be granted a presumption against preemption.²⁷³ Stated more broadly, the Court’s rejection of the presumption against preemption seems to be severely limited to situations in which (1) express preemption does not bar the claims, (2) the state law is either in an area not traditionally governed by

270. 331 U.S. 218, 230 (1947).

271. *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 347 (2001) (citation omitted).

272. *Id.*

273. The *Buckman* Court used a “*cf.*” signal in referencing *Boyle v. United Technologies Corp.*, 487 U.S. 500, 504-05 (1988). *Buckman*, 531 U.S. at 347. Although *Boyle* did not involve preemption by a federal statute, the Court held that federal common law displaced state common law on the subject of the federal government contractor defense. The test for applying federal common law is distinct from the preemption doctrine, and Chief Justice Rehnquist’s citation of *Boyle* suggests that his concept of preemption—and his notion of when the presumption against preemption may be ignored—is closely tied to this separate, but related doctrine. Obviously, the federal common law analysis does not directly involve an existing federal statute, although the Court invoked the Federal Tort Claims Act, 28 U.S.C. § 1346 (2000 & Supp. II 2002) and its exceptions—28 U.S.C. § 2680 (2000 & Supp. II 2002)—on matters of federal policy. Thus, the intent of Congress is not implicated in the analysis, at least not directly. Whether federal common law should displace state law on a particular subject focuses intensely on whether there exists an overriding federal interest. In *Boyle*, the Court distinguished preemption and characterized its approach as follows:

In most fields of activity, to be sure, this Court has refused to find federal pre-emption of state law in the absence of either a clear statutory prescription or a direct conflict between federal and state law. But we have held that a few areas, involving “uniquely federal interests,” are so committed by the Constitution and laws of the United States to federal control that state law is pre-empted and replaced, where necessary, by federal law of a content prescribed (absent explicit statutory directive) by the courts—so-called “federal common law.”

Boyle, 487 U.S. at 504 (citations omitted). Those “uniquely federal interests” were present in *Boyle* and included “the civil liability of federal officials for actions taken in the course of their duty.” *Id.* at 505. While the underlying action in the *Boyle* case was brought against a military contractor, rather than the United States, the Court stated that “there is obviously implicated the same interest in getting the Government’s work done.” *Id.* The Court saw the invocation of the defense as implicating the same policies as the underlying relationship between the Government and the contractor. *Id.* at 506-07. The decision went on to discuss in detail the federal policies underlying the defense and the federal interests that required a uniform federal common law. *Id.* at 509-10. Viewing Chief Justice Rehnquist’s statements in *Buckman* in light of his reference to *Boyle*, a logical interpretation is that *Buckman* actually states a limitation on the situations in which the presumption against preemption does not apply. Chief Justice Rehnquist seemed to suggest in *Buckman* that abandonment of the presumption against preemption would be appropriate only if the federal interest embodied by the statute is so great that, if the federal statute did not exist, the test would be met for federal common law on that subject. See *Buckman*, 531 U.S. at 347-53. Thus, only situations lacking a traditional state interest and bearing an exceptionally strong federal interest would overcome the presumption against preemption. Cf. Dinh, *supra* note 1, at 2099 (discussing *Boyle* in relation to preemption and stating that “all of the multifarious ways through which state law can be displaced are closely related to each other analytically and functionally”).

the states or where the federal government has actively and pervasively undertaken regulation, and (3) there is an exceptionally high federal interest, as evidenced by the provisions of the federal statute.

This interpretation gains support from *United States v. Locke*,²⁷⁴ a non-tort preemption case decided the year before *Buckman* and the same year as *Geier*. *Locke* involved the issue of whether state regulations governing oil tankers were preempted by various federal statutes.²⁷⁵ Justice Kennedy, writing for a unanimous Court, returned to the precedent of *Rice v. Santa Fe Elevator Corp.*²⁷⁶ in seeking to explain the role of the presumption against preemption. Justice Kennedy stated:

As *Rice* indicates, an “assumption” of nonpre-emption is not triggered when the State regulates in an area where there has been a history of significant federal presence. . . . In . . . the case before us, Congress has legislated in the field from the earliest days of the Republic, creating an extensive federal statutory and regulatory scheme.²⁷⁷

Thus, *Locke* was consistent with interpreting *Geier*'s rejection of the presumption against preemption as a narrow exception to the general rule recognizing the presumption.

Similarly, in *Buckman*, the exceptionally high federal interest was inherent in the power granted to the FDA to police fraud in the medical device application process. But it was not raised by other kinds of claims,²⁷⁸ as

274. 529 U.S. 89 (2000).

275. *Id.* at 94.

276. 331 U.S. 218, 230 (1947).

277. *Locke*, 529 U.S. at 108 (citations omitted).

278. One issue in MDA preemption not yet resolved by the United States Supreme Court is whether the MDA's preemption provision expressly preempts claims based upon devices that gained marketing approval via the MDA's full premarket approval (PMA) process. The distinction between the § 510(k) process and the PMA process is that the former is a determination of equivalency, based upon minimal hours of application review, whereas the latter is a more comprehensive and protracted process. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 479 (1996). The FDA's engagement in the PMA process is significantly greater than its participation in § 510(k) review, but the regulations that govern the PMA process are not much more specific. *Medtronic* directly governs these claims, but courts have split on whether the PMA process imposes “requirements” within the meaning of the MDA's preemption provision. For example, in *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000), the Sixth Circuit held that the plaintiffs' claims arising from a device that underwent the PMA process were preempted. Following *Medtronic*'s lead, the court looked to whether the FDA had established specific requirements that applied to the device at issue. *Id.* at 225. The court reasoned that the give-and-take of the PMA process, in which the FDA comments on the manufacturer's submissions and the manufacturer makes alterations based on the FDA's input, constituted a specific determination of the safety and effectiveness of the device. *Id.* at 226-27. Moreover, the specifications for the device that were submitted to and approved by the FDA constituted specific requirements. *Id.* at 228 & n.5. In contrast, in *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999), the Eleventh Circuit, on similar facts, held that the plaintiff's claims survived preemption. Also applying *Medtronic*, the court held that, even though the PMA process was rigorous, “neither the FDA's actual review of a device and its supporting information nor the agency's eventual approval of the device imposes any ascertainable requirement upon the device.” *Id.* at 1375. The court also noted that the FDA has provided no information about “its substantive benchmark” in approving a device, concluding that “approval represents only a finding that the manufacturer's proposal to market a device has reasonably assured the FDA of the device's safety and effectiveness.” *Id.* In an earlier article,

illustrated by *Medtronic*, which were correctly resolved under express preemption analysis and clearly subject to the presumption against preemption.²⁷⁹ Intimately connected to the fraud claim in *Buckman*, the Court reasoned, was the federal policy regarding off-label uses of medical devices. Congress had expressly stated in the FDCA that “[n]othing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care . . . relationship.”²⁸⁰ In *Buckman*, the Court was concerned that the underlying fraud-on-the-FDA suit would have a chilling effect on the latitude of health care providers to care for their patients, as well as on the ability of the FDA to do its job effectively.²⁸¹ An additional concern was that allowing state law actions would provide applicants with “an incentive to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA’s evaluation of an application.”²⁸² The fact that the federal statute promotes off-label uses as a matter of federal policy underscores the fact that the FDA policing powers are rooted in specific, strong federal policies. Accordingly, the Court emphasized that the uniquely federal nature of the regulatory and enforcement scheme established in the FDCA was controlling in the face of potentially conflicting state schemes.²⁸³

It was within this context of a unique and inherently federal interest that the *Buckman* Court made the following statement:

Here, petitioner’s dealings with the FDA were prompted by the MDA, and the very subject matter of petitioner’s statements were dictated by that statute’s provisions. Accordingly—and in contrast to situations implicating “federalism concerns and the historic primacy of state regulation of matters of health and safety,” *Medtronic*, 518 U.S. at 485, 116 S. Ct. 2240—no presumption against pre-emption obtains in this case.²⁸⁴

I argued that *Cipollone* and *Medtronic* led to the conclusion that claims arising from PMA devices should not be preempted. See Eggen, *supra* note 9, at 38-42. But see Gregory J. Scandaglia & Therese L. Tully, *Express Preemption and Premarket Approval Under the Medical Device Amendments*, 59 FOOD & DRUG L.J. 245 (2004) (arguing in favor of preemption of claims arising from PMA devices). As in *Medtronic*, it would not be proper to go beyond the express preemption analysis because no inherently federal interest is involved. Rather, the PMA device claims have the same level of federal interest as the § 510(k) claims.

279. See *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 352 (2001). The Court distinguished the claims presented in *Medtronic* and stated: “[I]t is clear that the *Medtronic* claims arose from the manufacturer’s alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements.” *Id.*

280. 21 U.S.C. § 396 (2000).

281. *Buckman*, 531 U.S. at 350.

282. *Id.* at 351.

283. *Id.* at 352.

284. *Id.* at 347-48.

The Court implied that because of the intense federal nature of the interest at stake in the matters giving rise to the plaintiffs' fraud claims, where the manufacturer and its consultant allegedly perpetrated a fraud on the FDA in the application process for approval of the device from which the plaintiffs claimed injury, the presumption against preemption would not apply.²⁸⁵ The question left open was whether the presumption would ever apply in an implied preemption analysis.

It was not until the Court revisited the implied preemption doctrine in *Sprietsma* that the narrowness of the decision in *Buckman* became fully apparent in the product preemption context. *Sprietsma* strongly suggested not only that the presumption against preemption was generally intact, but also that the circumstances under which it would not be applied were extremely narrow.²⁸⁶ Some strong federal policies—such as an interest in federal uniformity absent a specific federal regulatory scheme—were deemed insufficient to preempt state tort claims in the absence of clear indicia of an intent to displace state law.²⁸⁷ In *Sprietsma*, none of the requirements of *Geier* that would lead to ignoring the presumption against preemption was met.²⁸⁸ Accordingly, the presumption against preemption had to be applied. Thus, the Court held that the plaintiff's claims were not preempted.²⁸⁹ For implied preemption to bar plaintiffs' state common law claims under such circumstances, it must be irrefutable that both Congress and the regulating agency contemplated no common law actions. This will rarely be the case, as *Sprietsma* demonstrated.

The *Bates* Court returned to the presumption against preemption in the context of express preemption.²⁹⁰ The Court, once again in the voice of Justice Stevens—though this time as a majority of seven to two—gave the most explicit statement yet of the presumption against preemption in a product preemption case:

Even if Dow had offered us a plausible alternative reading of [the FIFRA preemption provision]—indeed, even if its alternative were just as plausible as our reading of that text—we would nevertheless have a duty to accept the reading that disfavors pre-emption. . . . In areas of traditional state regulation, we assume that a federal statute has not supplanted state law unless Congress has made such an intention “clear and manifest.”²⁹¹

285. *See id.*

286. *Sprietsma v. Mercury Marine*, 537 U.S. 51, 65-69 (2002).

287. *Id.* at 70.

288. *See id.* at 65-68 (The Court expressly contrasted *Geier* throughout this discussion.)

289. *Id.* at 70.

290. *Bates v. Dow Agrosciences LLC*, 125 S. Ct. 1788, 1801 (2005).

291. *Id.* at 1801 (quoting *N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995)).

The Court's interpretation was that Congress demonstrated no clear intent to supplant state common law with FIFRA. At several junctures in the opinion, the Court emphasized that the FIFRA scheme was in fact one of decentralization, allowing the states a great deal of latitude in establishing and enforcing standards.²⁹² Thus, the presumption against preemption had to be applied because the plaintiffs' product liability claims were a matter traditionally left to state law,²⁹³ and the statute did not evidence an intent to federalize that area of the law.

The Court is quite clear in *Bates* that the only circumstances under which the presumption against preemption would be ignored were circumstances that applied in very few cases. *Geier* and *Buckman* demonstrated two of those situations. In *Geier*, the statute and regulations set forth a detailed, incremental federal process for introducing passive restraints in motor vehicles. In *Buckman*, the federal process was in place for policing fraud committed against the federal agency in the application for market approval of medical devices. In a significant distinction from *Medtronic*, then, *Buckman* demonstrated by contrast that claims based upon matters traditionally within the powers of the states—product liability claims—should be accorded the presumption against preemption. In *Sprietsma* and *Bates*, the Court fully demonstrated its commitment to the presumption against preemption except in the narrowest of circumstances.

C. Reconciling Express and Implied Preemption

The Supreme Court has repeatedly stated that the presence of a preemption provision in the relevant federal statute, while triggering express preemption analysis, does not necessarily mean that implied preemption would

292. Before conducting the express preemption analysis, the Court noted—without referencing implied preemption—that FIFRA was not “sufficiently comprehensive” to have been intended to occupy the field and bar the states from acting. *Id.* at 1797. That point regarding FIFRA had been previously established in another Supreme Court decision. See *Wisc. Public Intervenor v. Mortier*, 501 U.S. 597, 607 (1991). Later in the *Bates* opinion, the Court was more explicit about the role that the states may play in determining uses and restrictions of pesticides registered by EPA. *Bates*, 125 S. Ct. at 1802.

293. Since *Bates* was decided, it was used as what amounted to controlling authority by one district court analyzing preemption in the context of the Federal Hazardous Substances Act, 15 U.S.C. §§ 1261-1278 (2000). The FHSA preemption provision states: “[N]o State . . . may establish or continue in effect a cautionary labeling requirement applicable to such substance or packaging . . . unless such cautionary labeling requirement is identical to the labeling requirement under [the Act].” *Id.* § 1261 historical note (b)(1)(A). In *Gouglar v. Sirius Prods., Inc.*, 370 F. Supp. 2d 1185, 1193 (S.D. Ala. 2005), the court, noting that few cases exist construing the preemption provision in the FHSA, closely followed *Bates* in holding that the plaintiff's defective design claims were not preempted, but the warning claims were preempted. *Id.* at 1196-99. The court found *Bates* to be strong authority even though it involved a different statute, stating that “given *Bates*' obvious significance to the legal issues presented, the Court will consider and apply that decision here.” *Id.* at 1195 n.10; see also *Eggen*, *supra* note 9, at 64-66 (discussing FHSA preemption in the wake of *Medtronic* and predicting that “it is probable that any new development in FIFRA preemption analysis will be reflected in the FHSA cases as well”). Interestingly, the court referred to “two critical presumptions” in product preemption jurisprudence—the presumption against preemption and the need to narrowly construe a preemption provision in determining whether, and to what extent, Congress intended that the federal statute displace state law. *Id.* at 1192.

not apply.²⁹⁴ The corollary to that rule has now been clarified by *Bates*—implied preemption does not necessarily apply if express preemption analysis fully solves the preemption question. This set of rules seems to confound the express preemption/implied preemption dichotomy so frequently referenced in the literature. The rules are vague enough that they create substantial difficulties for courts in practical application.

A brief review of the approaches taken by the Court in key cases demonstrates the problems. In *Cipollone*, the Court applied an express preemption analysis to determine that some, but not all, of the plaintiff's product liability claims were preempted.²⁹⁵ The Court stated: "When Congress has considered the issue of pre-emption 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,'"²⁹⁶ the provision governs on the preemption question.²⁹⁷ Further, "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted. . . . Therefore, we need only identify the domain expressly pre-empted by [the pre-emption provisions]."²⁹⁸ The Court left the distinct impression that because the statutes contained preemption provisions, only express preemption analysis was appropriate.²⁹⁹ Indeed, the Court rejected the implied preemp-

294. *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001) ("[N]either an express pre-emption provision nor a saving clause 'bar[s] the ordinary working of conflict pre-emption principles.'" (quoting *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869 (2000) (alteration in original))); *Geier*, 529 U.S. at 869 ("[T]he pre-emption provision, by itself, does not foreclose (through negative implication) 'any possibility of implied [conflict] pre-emption.'" (quoting *Freightliner Corp. v. Myrick*, 514 U.S. 280, 288 (1995) (alteration in original))); *Sprietsma v. Mercury Marine*, 537 U.S. 51, 65 (2002) ("Congress' inclusion of an express pre-emption clause 'does not bar the ordinary working of conflict pre-emption principles . . .'" (quoting *Geier*, 529 U.S. at 869)); *Myrick*, 514 U.S. at 288 ("The fact that an express definition of the pre-emptive reach of a statute 'implies' . . . 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.").

295. See *supra* notes 52-64 and accompanying text.

296. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992) (plurality opinion) (quoting *Malone v. White Motor Corp.*, 435 U.S. 497, 505 (1978)).

297. The same conclusion could be drawn from another 1992 preemption decision. In *Gade v. National Solid Wastes Management Ass'n*, 505 U.S. 88 (1992), the Court's introductory recitation of preemption-doctrine basics stated: "Absent explicit pre-emptive language, we have recognized at least two types of implied pre-emption . . ." *Id.* at 98. In *Gade*, the Court held the state's occupational safety and health regulations preempted by the federal Occupational Safety and Health Act on a theory of conflict preemption. The act contained no express preemption provision, though the petitioners argued that certain language in the act was sufficient to preempt the state regulation in question. *Id.* at 99-100. The plurality chose to take the implied preemption route, however. See *id.* at 108-09.

298. *Cipollone*, 505 U.S. at 517.

299. The Court stated: "In our opinion, the pre-emptive scope of the 1965 Act and the 1969 Act is governed entirely by the express language in [the Acts]." *Id.* This apparently was the impression of both Justice Scalia and Justice Blackmun, the authors of the partial dissents in *Cipollone*. In fact, Justice Scalia identified it as one of the "new rules" he thought the Court announced regarding preemption: "Once there is an express pre-emption provision, in other words, all doctrines of implied pre-emption are eliminated." *Cipollone*, 505 U.S. at 547 (Scalia, J., concurring in judgment in part & dissenting in part). Justice Scalia went on to disagree with this position with regard to conflict preemption, while stating that it may be correct insofar as field preemption is involved. *Id.* Justice Blackmun, in his separate opinion, agreed with the plurality on this point: "We resort to principles of implied pre-emption—that is, inquiring whether Congress has occupied a particular field with the intent to supplant state law or whether

tion analysis employed by the Third Circuit below.³⁰⁰ When the Court decided *Myrick* on implied preemption grounds in 1995, Justice Thomas, writing for the Court, latched onto a little-noticed statement in *Cipollone*, in which Justice Stevens had stated that “there is no general, inherent conflict between federal pre-emption of state warning requirements and the continued vitality of state common-law damages actions.”³⁰¹ Justice Thomas then went on to conduct an implied preemption analysis in *Myrick*.³⁰² But the clear impression left by *Cipollone* was that the Court had only analyzed express preemption.

In *Geier*, the National Traffic and Motor Vehicle Safety Act of 1966 contained both a preemption provision and a saving clause. The Supreme Court began with an express preemption analysis of the preemption provision³⁰³ and the saving clause.³⁰⁴ Reading both provisions together, the Court concluded that there was “no convincing indication that Congress wanted to pre-empt, not only state statutes and regulations, but also common-law tort actions.”³⁰⁵ The Court then moved on to consider implied preemption and decided the case on conflict preemption grounds.³⁰⁶ Jury verdicts in the plaintiffs’ tort actions holding the manufacturer liable for failing to equip the car with an airbag would conflict with the non-mandatory federal standard. Accordingly, allowing the plaintiffs’ claims “would have presented an obstacle to the variety and mix of devices that the federal regulation sought. . . . It thereby also would have stood as an obstacle to the gradual passive restraint phase-in that the federal regulation deliberately imposed.”³⁰⁷ Determining first that the federal statutory and regulatory scheme reflected a strong federal plan and high federal interest, the Court determined that a conflict existed with the state claims.³⁰⁸ The gist of the Court’s analysis was that the standard was specific in both what it required and what it did not require, backed up by extensive regulatory history and ample clarification

state law actually conflicts with federal law—only when Congress has been silent with respect to pre-emption.” *Id.* at 532 (citation omitted) (Blackmun, J., concurring in part & dissenting in part). Thus, it was no wonder that courts and commentators believed that *Cipollone* stood for implied preemption.

300. *Id.* at 511. For the Third Circuit opinion using implied preemption, see *Cipollone v. Liggett Group, Inc.*, 789 F.2d 181 (3d Cir. 1986).

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

302. *Freightliner Corp. v. Myrick*, 514 U.S. 280, 288-89 (1995).

303. “[N]o State . . . shall have any authority either to establish, or to continue in effect, with respect to any motor vehicle or item of motor vehicle equipment[,] any safety standard applicable to the same aspect of performance of such vehicle or item of equipment which is not identical to the Federal standard.” *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 867 (2000) (quoting 15 U.S.C. § 1392(d) (repealed 1994)) (alteration in original).

304. The saving clause provided that a manufacturer’s compliance with a standard under the act “does not exempt any person from any liability under common law.” *Id.* at 868 (quoting 15 U.S.C. § 1397(k) (repealed 1994)).

305. *Id.* at 868.

306. *Id.* at 871.

307. *Id.* at 881. Several pages of the Court’s opinion were devoted to examining the history and rationale of the federal standard to justify the conclusion that allowing state tort claims would inhibit the purpose of the federal act and regulations. See *id.* at 875-83.

308. *Id.* at 880-81.

by the Department of Transportation.³⁰⁹ Thus, the Court was able to point to a very direct conflict between the federal standard (no absolute duty to install an airbag) and the plaintiffs' claims if successful (absolute duty to install an airbag).³¹⁰

Conceptually, the Court's approach to implied preemption is intimately tied to its approach to the presumption against preemption³¹¹ in focusing on the degree of the federal interest at stake as an analytical trigger point. In *Buckman*, the fraud-on-the-FDA claims held to be preempted were distinguishable from the product liability claims involved in *Medtronic*.³¹² The fraud claims fell within a narrow area of the FDCA unambiguously carved out for federal treatment. The Court determined that success on the fraud claims under state law would have undermined the FDA's ability to do its job.³¹³ To a large degree, the decision was driven by the policy, expressly articulated in the federal statute, that health care providers should remain free to prescribe off-label uses of medical devices. The Court had a difficult time envisioning any circumstances under which a verdict for the plaintiffs on their claims under state law would not infringe directly on this federal policy. One federal district court, attempting to apply *Medtronic* and *Buckman* consistently to a preemption motion involving tort claims related to a prescription drug,³¹⁴ sought to fashion a litmus test for sufficient federal interest. That court held that the plaintiffs' claims were not preempted because the scope of preemption under the FDCA was defined by the party to whom the duty was owed.³¹⁵ Because the plaintiffs' claims alleged a duty owed by the manufacturers to the plaintiffs—and not a duty owed by the manufacturers to the FDA—implied preemption was not involved.³¹⁶ Thus, that court recognized the very narrow use of implied preemption in *Buckman*.

The contrast between *Medtronic* and *Buckman* may have illuminated the distinction between express preemption and implied preemption in the context of the MDA and the FDCA. But it offered only limited justification for *Geier*, and did so only indirectly. *Sprietsma* provided a more instructive contrast with *Geier*. In *Geier*, the statute and regulations had established a federal plan for the imposition of requirements for passive restraints in motor vehicles.³¹⁷ That plan reflected a federal decision to phase in passive restraints and, specifically, not to impose an airbag requirement at the time

309. *Id.* at 883.

310. *Id.* at 866.

311. See discussion *supra* Part III.B.

312. *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352-53 (2001).

313. See *supra* notes 118-21 and accompanying text.

314. *Brasher v. Sandoz Pharm. Corp.*, Nos. CV-98-TMP-2648-S, CV-98-TMP-2650-S, 2001 U.S. Dist. LEXIS 18364 (N.D. Ala. Sept. 21, 2001).

315. *Id.* at *27.

316. Among other things, this meant that any claims alleged by the plaintiffs that the manufacturer had defrauded them would not be preempted because the matter did not directly involve fraud on the FDA. *Id.* Duties owed directly to the plaintiffs "existed irrespective of the FDCA." *Id.* at *28.

317. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 875-80 (2000).

of the accident giving rise to the lawsuit in *Geier*.³¹⁸ In contrast, while the statute at issue in *Sprietsma* reflected a planned federal scheme, the existing regulations were inchoate, allowing the states to regulate in the area of boating safety.³¹⁹ The decision by the Coast Guard not to require propeller guards was not to be read as a mandate that boats not carry such guards; rather, if guards were to be required, the onus was on the states to make that determination.³²⁰ The court acknowledged that sometimes it is appropriate to infer from regulatory silence “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*.”³²¹ This was not such a situation, however, and the states were free both to regulate and to impose common law duties.³²² The overriding factor was that the regulatory decision “does not convey an ‘authoritative’ message of a federal policy.”³²³ This was in stark contrast to the decision not to require airbags discussed in *Geier*, which embodied a specific federal policy and plan.³²⁴ In *Sprietsma*, even the traditional federal interest in maritime matters invoked earlier in *Locke* did not override the fact that the particular regulatory scheme envisioned state participation in the matter of recreational boat safety.³²⁵

So why did the Court move on to an implied preemption analysis in *Sprietsma* when it determined that no overriding federal policy was involved in the regulatory scheme that included the Coast Guard’s decision not to require propeller guards? By all measures, the question seemed to have been fully resolved by express preemption analysis. One answer to this question may be that the broad saving clause raised questions about whether state common law may conflict with federal requirements under the Act.³²⁶ Another answer may be that the question whether the absence of regulation was itself regulation was sufficiently unique to cause the Court to examine

318. *Id.*

319. The Court stated: “It is quite wrong to view [the Coast Guard’s] decision as the functional equivalent of a regulation prohibiting all States and their political subdivisions from adopting such a regulation.” *Sprietsma v. Mercury Marine*, 537 U.S. 51, 65 (2002).

320. *Id.* at 67.

321. *Id.* at 66 (quoting *Ark. Elec. Coop. Corp. v. Ark. Pub. Serv. Comm’n*, 461 U.S. 375, 384 (1983)).

322. *Id.* at 67.

323. *Id.*

324. *Id.* at 67-68; see Eggen, *supra* note 123, at 170-72. The Court punctuated this distinction with mention of a much earlier implied preemption case. In *Ray v. Atlantic Richfield Co.*, 435 U.S. 151 (1978), the Court held that state regulations were impliedly preempted by a federal statute regulating the safety of oil tankers in navigable waters. The Court concluded that the federal statute was intended to occupy the field, in part because it required the Secretary of Transportation to promulgate regulations on the design, construction, and use of the tankers. *Id.* at 161. The Court repeated this interpretation in *United States v. Locke*, 529 U.S. 89, 103-04 (2000).

325. In *Locke*, the Court cited the traditional federal maritime authority as one of several overriding federal policies, leading to implied preemption of some of the regulations in question in the case. 529 U.S. at 99; see also Joshua S. Force, *Sprietsma v. Mercury Marine: The Supreme Court Misses the Boat on Maritime Preemption*, 27 TUL. MAR. L.J. 389 (2003) (arguing that issues in *Sprietsma* were within the strong federal policy of maritime law and that the Court should have held the plaintiff’s claims preempted).

326. See discussion *infra* notes 371-87 and accompanying text.

it from all angles. Finally, the clue may come from *Myrick*, where the Court dealt with similar arguments and moved from express to implied preemption to resolve the case.³²⁷ Whatever the reason, implied preemption was applied very narrowly in *Sprietsma* so as not to preempt any of the plaintiff's claims. What *Sprietsma* and *Geier* lacked, however, was any clear delineation of the circumstances that trigger implied preemption analysis when the statute contains an express preemption provision.

Contrasting *Bates* may provide some illumination. Even though *Bates* involved only express preemption, the fact that the Court declined (without comment) to move to an implied preemption analysis may offer some clues to matters that the previous cases left ambiguous. Only Justice Thomas, in his partial dissent in *Bates*, addressed the Court's reasons for declining to proceed to an implied preemption analysis. He agreed functionally with the majority's preemption analysis but ultimately disagreed, at least in part, with the result of that analysis.³²⁸ Regarding implied preemption, Justice Thomas stated: "Because we need only determine the ordinary meaning of [the preemption provision], the majority rightly declines to address [the] respondent's argument" that implied preemption barred the claims.³²⁹ Addressing the doctrine more generally, he continued: "Today's decision thus comports with this Court's increasing reluctance to expand federal statutes beyond their terms through doctrines of implied pre-emption."³³⁰ These are powerful words emphasizing the limitations on the use of the doctrine of implied preemption.

For those seeking a clear distinction between the doctrines of express preemption and implied preemption, however, it is unlikely that the current Supreme Court will provide one. Unless the statute does not contain a preemption provision, there is an organic relationship between the two doctrines. Concepts relevant to implied preemption—for example, whether Congress intended the federal statute to be exclusive in some or all matters related to its subject—inform the process of express preemption analysis when a court is attempting to determine the meaning and scope of the statute's preemption provision. On the other side, if a court has undertaken an express preemption analysis, the information gleaned from that analysis—such as the purpose and scope of the statute—is directly relevant to an implied preemption analysis. Justice Thomas stated an important constraint on the implied preemption doctrine, however, when he referred to the "Court's increasing reluctance to expand federal statutes beyond their terms"³³¹ by making use of implied preemption.³³²

327. *Freightliner Corp. v. Myrick*, 514 U.S. 280, 288-90 (1995); *supra* notes 73-86 and accompanying text.

328. *Bates v. Dow Agrosiences LLC*, 125 S. Ct. 1788, 1805-06 (2005) (Thomas, J., concurring in judgment in part & dissenting in part).

329. *Id.* at 1806.

330. *Id.* at 1807.

331. *Id.*

332. Justice Thomas also stated, rather defensively, "This reluctance reflects that pre-emption analy-

Bates makes clear that the Court does not intend implied preemption analysis to be automatic and that judicial restraint should limit an overzealous use of the doctrine. The caselaw demonstrates that certain factors must converge for the Court to move from express preemption to implied preemption. One such factor is that express preemption analysis does not yield a complete resolution of the preemption question (as it did not yield a satisfactory result in *Geier*).³³³ Another factor is that federal interest must be extremely high in the subject matter of the case. Thus, in *Bates*, the express preemption analysis provided ample evidence of a federal scheme that invited state regulation.

One theory is that the Court may actually prefer any ambiguity it has created in distinguishing between express preemption and implied preemption. The Court may be eschewing the traditional express/implied preemption dichotomy as an artificial distinction that no longer serves its purposes. Yet, there is still a danger that courts may interpret the cases to allow them to draw their own lines where it is most convenient or where it advances their reform agendas. That possibility is deeply unsatisfying. As Justice Thomas stated, it is not appropriate for courts to expand federal statutes beyond their terms by wielding the doctrine of conflict preemption.³³⁴ One thing is certain: The Court must provide further guidance on this troubling point.

D. Standardization of Express Preemption

On a more satisfying note, *Bates* has clarified the framework for express preemption analysis. Express preemption begins with the intent of Congress, but the course of determining Congress's intent may go beyond the plain meaning of the language of the preemption provision, as the cases have demonstrated.

sis is not '[a] freewheeling judicial inquiry into whether a state statute is in tension with federal objectives,' . . . but an inquiry into whether the ordinary meanings of state and federal law conflict." *Id.* (citations omitted) (alterations in original).

333. The Court has yet to provide an explanation of what may constitute a complete resolution. In *Geier*, the Court read the express preemption provision together with the saving clause to draw its conclusion that express preemption did not completely resolve the issues in the case. *See Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 868 (2000). The Court stated that "it is possible to read the pre-emption provision, standing alone, as applying to standards imposed in common-law tort actions, as well as standards contained in legislation or regulations." *Id.* But because "[t]he saving clause assumes that there are a significant number of common-law liability cases to save," the Court decided that an implied preemption analysis was the appropriate means of determining which claims should be saved and which preempted. *See id.* at 861. *Geier* sends a message to Congress that inconsistency, generality, and ambiguity in preemption provisions and saving clauses may invite judicial creativity that could lead—at least under some circumstances—to aberrant results.

334. *Id.*

1. Focus on the Statute

First, the Court has repeatedly emphasized the need to focus on the specific statute relevant to the case, with all of its linguistic and conceptual idiosyncrasies. But do the unique characteristics of each particular statute prevent the development of generalized rules for the doctrine of preemption? To the contrary, the Supreme Court cases on product preemption indicate that while the idiosyncrasies of a particular statute or regulatory scheme are important in making a preemption decision, the analysis is becoming more uniform. Moreover, the underlying norms that have been articulated by the Court give guidance for future cases.

Preemption analysis, whether express or implied, focuses closely on the language and purpose of the underlying statute and regulatory scheme. Express preemption is invoked when the statute contains a preemption provision; in *Cipollone*, the plurality conducted a narrow analysis that focused specifically on the two cigarette labeling statutes.³³⁵ Justice Stevens stated that the Court “must fairly but—in light of the strong presumption against pre-emption—narrowly construe the precise language of [the preemption provision] and we must look to each of petitioner’s common-law claims to determine whether it is in fact pre-empted.”³³⁶ The process used by the Court involved a textual exegesis of the preemption provisions in the 1965 and 1969 cigarette labeling acts, with most of the attention going to the change in language from preemption of “statements” to preemption of state “requirement[s] or prohibition[s].”³³⁷

In *Medtronic*, the Court was confronted with “requirement” language in the MDA preemption provision that was similar to the language in the 1969 cigarette labeling act. But the Court made a point of distinguishing both the linguistic context and the statutory context of *Cipollone*.³³⁸ The preemption provision in the 1969 cigarette labeling act contained limiting language, referring to “requirements or prohibitions”³³⁹ that are “based on smoking and health”³⁴⁰ and that involve the “advertising or promotion”³⁴¹ of cigarettes.³⁴² The language of the MDA preemption provision, however, was more general. Moreover, the Court’s examination of the purpose and history of the MDA resulted in the Court’s conclusion that the preemption provision “was primarily concerned with the problem of specific, conflicting state statutes and regulations rather than the general duties enforced by common-law actions.”³⁴³

335. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 523 (1992) (plurality opinion).

336. *Id.*

337. 15 U.S.C. § 1334(b) (2000).

338. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 488 (1996).

339. § 1344(b).

340. *Id.*

341. *Id.*

342. *Id.*

343. *Medtronic*, 518 U.S. at 489.

Another distinction between the cigarette labeling acts and the MDA involved the role of the FDA in implementing the MDA. The labeling and advertising requirements set forth in the cigarette labeling acts were self-executing in the sense that no agency action was required to give them full force and effect.³⁴⁴ The MDA not only granted authority to the FDA to promulgate regulations, but the FDA had issued a regulation construing the preemption provision,³⁴⁵ thus adding another layer to the Court's analysis.³⁴⁶ Both the language of the MDA preemption provision and the surrounding history and regulation supported the Court's interpretation of the provision as intended to preempt only "device-specific enactments of positive law by legislative or administrative bodies."³⁴⁷

In *Bates*, the Court gleaned the meaning of the preemption provision not just from the language of the provision, but also from the statutory and regulatory context of FIFRA. Thus, the Court found it significant that EPA had published a notice in 1996 stating "that it had 'stopped evaluating pesticide efficacy for routine label approvals almost two decades ago.'"³⁴⁸ This allowed the Court to say with certainty that FIFRA was not intended to be the final word on the safety and efficacy of pesticides.³⁴⁹ The Court's examination of the legislative and regulatory history of FIFRA was expansive. The Court began with FIFRA's 1910 predecessor statute and followed it through FIFRA's enactment in 1947 and two major amendments, added in 1972 and 1978, on the way to determining the scope of the preemption provision.³⁵⁰ Of special interest were the misbranding regulations, which demonstrated that the proper labeling of a pesticide is a matter left to the responsibility of the manufacturer in the first instance.³⁵¹ EPA policy was not to make a determination of the accuracy of the label and not to evaluate the efficacy of the product, but to leave those tasks primarily to the manufacturer.³⁵²

The methodology of the Court's express preemption analysis in *Bates* was very similar to the Court's detailed analysis of the preemption provisions in both *Cipollone* and *Medtronic* with respect to the manner in which the Court analyzed the preemption provision in relation to the statute, its

344. See *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 513-14 (1992).

345. See 21 C.F.R. § 808.1(d) (2005).

346. Four justices were of the opinion that the Court's use of the FDA's regulation explaining the preemption provision was inappropriate. See *Medtronic*, 518 U.S. at 509 (O'Connor, J., concurring in part & dissenting in part). Justice Breyer formed a majority with the plurality of justices in favor of using the FDA regulation to explain the preemption provision. See *id.* at 505-07 (Breyer, J., concurring in judgment & concurring in part).

347. *Id.* at 489.

348. *Bates v. Dow Agrosciences LLC*, 125 S. Ct. 1788, 1796 (2005) (quoting PESTICIDE REGISTRATION NOTICE 96-4, at 3 (1996)).

349. In an earlier case, *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597 (1991), the Court had ruled that FIFRA was not intended to occupy the field on the matter of pesticide use and safety. *Id.* at 607.

350. See *Bates*, 125 S. Ct. at 1794-97.

351. See *id.* at 1795.

352. See *id.* at 1796.

history, and its purpose. The statute-specific nature of preemption analysis may lead to widely divergent results in cases involving different statutes, containing preemption provisions with identical language. Yet, *Bates* embodies a consistency of approach that applies across the board.

2. *The Scope of "Requirement"*

Is the term "requirement" in a preemption provision always to be read broadly enough to include common law duties?³⁵³ Barring some further language in the provision to the contrary, the answer is a firm "probably." In *Bates*, the Court explicitly referenced *Cipollone* on this point, saying that "the term 'requirements' in § 136v(b) reaches beyond positive enactments, such as statutes and regulations, to embrace common law duties. Our decision in *Cipollone* supports this conclusion."³⁵⁴ The Court was quick to say, however, that "the use of 'requirements' in a pre-emption clause may not invariably carry this meaning,"³⁵⁵ but it seems certain that in any express preemption analysis in which the preemption provision contains a reference to "requirements," the Court will begin with a working assumption that "requirement" includes common law duties, unless such duties are expressly excluded. Of course, in *Bates*, the Court went on to demonstrate that the language of the preemption provision, along with the legislative and regulatory history of FIFRA, led to the conclusion that Congress intended only a very narrow category of common law claims to be preempted.³⁵⁶

That the term "requirement" may include at least some common law duties was also the position of a majority of the justices in *Medtronic*. With substantial discussion of *Cipollone*—as the authority on the meaning of the term "requirement"³⁵⁷—Justice O'Connor, in a partial dissent joined by Chief Justice Rehnquist and Justices Scalia and Thomas, stated: "I conclude that state common-law damages actions do impose 'requirements' and are therefore pre-empted where such requirements would differ from those imposed by the FDCA."³⁵⁸ There was no question that Justice O'Connor was making her statement in very broad terms. Justice Breyer, in his concurring opinion in *Medtronic*, stated that "the MDA will sometimes pre-empt a state-law tort suit,"³⁵⁹ language that was far from the absolute statement

353. As the cases demonstrate, many preemption provisions prohibit at least some state "requirements" or employ similar language such as "standards." See, e.g., 7 U.S.C. § 136v(b) (2000) (pesticides; "requirements"); 46 U.S.C. § 4306 (recreational boats; "safety standard"); 15 U.S.C. § 1334(b) (cigarette packages; "requirement or prohibition").

354. *Bates*, 125 S. Ct. at 1798.

355. *Id.*

356. See discussion *supra* Part II.

357. Justice O'Connor's references to *Cipollone* included the following: "[The] rationale [of *Cipollone*] is equally applicable in the present context," *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 510 (1996) (O'Connor, J., concurring in part and dissenting in part); "[The plurality] fails to refute the applicability of the reasoning of *Cipollone*." *Id.* at 511; and "*Cipollone* declared," *id.* at 510, suggesting that *Cipollone* provided irrefutable principles.

358. *Id.* at 509 (O'Connor, J., concurring in part & dissenting in part).

359. *Id.* at 503 (Breyer, J., concurring in judgment & concurring in part).

made by Justice O'Connor. Justice Breyer also spoke of *Cipollone* as the authority on this issue: "[I]n *Cipollone* . . . , the Court made clear that similar language 'easily' encompassed tort actions."³⁶⁰

Further, merely because the term "requirement" encompasses common law duties does not necessarily mean that all common law claims impose requirements within the meaning of the preemption provision. This was made clear in *Bates*, when Justice Stevens stated: "A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement."³⁶¹ And, therefore, such an "event" would not be expressly preempted by the FIFRA preemption provision.³⁶² Citing *Cipollone*, he emphasized that "[t]he proper inquiry calls for an examination of the elements of the common-law duty at issue; it does not call for speculation as to whether a jury verdict will prompt the manufacturer to take any particular action."³⁶³ Justice Stevens determined, however, that the plaintiffs' warning claims, if based on duties that were not parallel to FIFRA requirements, could be preempted under this test.³⁶⁴ His line-drawing was far from clear.

Geier offers some amplification of this point. The plaintiffs' common law claims, if successful, would have imposed a clear requirement—the requirement to equip the manufacturer's motor vehicles with airbags.³⁶⁵ The federal scheme thus established what amounted to a maximum standard, which was intended to preclude state regulation of any sort that would create more stringent duties in the area of passive restraints. In *Bates*, by way of contrast, the Court determined that most of the FIFRA requirements were essentially minimum, or general, standards beyond which the states were free to establish their own duties.³⁶⁶ Extrapolating beyond FIFRA, Justice

360. *Id.* at 504.

361. *Bates v. Dow Agrosciences LLC*, 125 S. Ct. 1788, 1799 (2005).

362. This view was reminiscent of the opinion of Justice Blackmun in his partial dissent in *Cipollone*. There, Justice Blackmun stated:

The effect of tort law on a manufacturer's behavior is necessarily indirect. Although an award of damages by its very nature attaches additional consequences to the manufacturer's continued unlawful conduct, no particular course of action (e.g., the adoption of a new warning label) is required. A manufacturer found liable on, for example, a failure-to-warn claim may respond in a number of ways. It may decide to accept damages awards as a cost of doing business and not alter its behavior in any way Or, by contrast, it may choose to avoid future awards by dispensing warnings through a variety of alternative mechanisms, such as package inserts, public service advertisements, or general educational programs. The level of choice that a defendant retains in shaping its own behavior distinguishes the indirect regulatory effect of the common law from positive enactments such as statutes and administrative regulations.

Cipollone v. Liggett Group, Inc., 505 U.S. 504, 536-37 (1992) (plurality opinion) (Blackmun, J., concurring in part & dissenting in part) (citations omitted). In *Bates*, Justice Stevens did not go so far, even though he agreed with the basic premise. The *Bates* decision was consistent with the plurality in *Cipollone*, however, holding that warning-related claims could be preempted as requiring a particular course of action, if the state common law duties were "in addition to or different from" the FIFRA requirements. *Bates*, 125 S. Ct. at 1800 (quoting 7 U.S.C. § 136v(b) (2000)).

363. *Bates*, 125 S. Ct. at 1799 (citation omitted).

364. *See id.* at 1803.

365. *See Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 864-65 (2000).

366. Later in the *Bates* opinion, Justice Stevens commented that allowing jury verdicts on matters

Stevens's position on common law duties suggests that many, if not most, jury verdicts—or the threat of jury verdicts—will not be deemed to be the equivalent of legal standards that may conflict with federal statutory or regulatory standards. Again, this reflects a normative decision regarding the role of state common law as an important remedial and deterrent force in the American legal system.

3. *Broad Analytical Framework*

Finally, after *Bates*, there is no doubt that the Court is advocating—indeed insisting upon—a broad analysis of all matters related to the preemption provision's scope and the statute's purpose. In *Medtronic*, Justice Stevens, focusing on interpreting the language of the preemption provision in the statute and “‘identify[ing] the domain expressly pre-empted’ by that language,”³⁶⁷ emphasized that the Court's “‘interpretation of that language does not occur in a contextual vacuum.’”³⁶⁸ Justice Stevens moved beyond the language of the preemption provision to allow a consideration of broader matters of policy and purpose, stating the importance of “‘the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law.’”³⁶⁹ In *Bates*, another case in which the Court conducted only an express preemption analysis, the Court undertook a similarly broad contextual analysis of FIFRA in relation to the preemption provision.³⁷⁰

E. *The Role of Saving Clauses in Preemption Analysis*

In several product preemption cases decided by the Supreme Court, the existence of a saving clause has been instrumental in the Court's analysis, particularly in its decision to move from express preemption to implied preemption. Where a saving clause accompanies a preemption provision, it is a complement to the preemption provision and should be interpreted with it

related to FIFRA would be unlikely to create conflicting standards, at least with regard to matters related to the misbranding of pesticides. *See id.* at 1803. The Court stated:

While it is true that properly instructed juries might on occasion reach contrary conclusions on a similar issue of misbranding, there is no reason to think such occurrences would be frequent or that they would result in difficulties beyond those regularly experienced by manufacturers of other products that everyday bear the risk of conflicting jury verdicts.

Id. Justice Thomas, however, disagreed with this characterization of common law duties. He argued that a common law action under state law based upon the labeling of a pesticide “adds some supplemental requirement of truthfulness to FIFRA's requirement that labeling statements not be ‘false or misleading.’” *Id.* at 1805 (Thomas, J., concurring in judgment in part & dissenting in part).

367. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 484 (1996) (quoting *Cipollone*, 505 U.S. at 517). Of course, Congress could solve these interpretation problems in the first instance by drafting clear legislation. *See, e.g.*, OWEN, *supra* note 1, § 14.4, at 920; Grey, *supra* note 1, at 615-18. That solution, while preferable, does not appear to be forthcoming.

368. *Medtronic*, 518 U.S. at 485.

369. *Id.* at 486.

370. *See Bates*, 125 S. Ct. at 1794-96.

under an express preemption analysis. One question arising from the Court's treatment of saving clauses is whether the presence of a broad saving clause automatically triggers an implied preemption analysis. Is it possible for a saving clause to be too broad, in essence neutralizing its own force?

In *Myrick*, the Court had an opportunity to address this question, but evaded it. The Court directly held that where the analysis of a preemption provision in the relevant statute resulted in no preemption of the plaintiffs' common law design defect claims, implied preemption was not foreclosed.³⁷¹ In that case, the Court went on to hold, with little analysis, that the plaintiffs' claims were not impliedly preempted because no conflict existed with federal law.³⁷² The Court essentially chose to ignore the saving clause, stating, in a footnote, that it was unnecessary to address it because the Court had determined that no federal safety standard on point existed.³⁷³ Thus, leading up to *Geier*, the role played by the saving clause in relation to implied preemption was not clear.

In *Geier*, the Court filled the gap created by *Myrick* but still left many questions unanswered.³⁷⁴ *Geier* involved the same preemption provision and saving clause as *Myrick*. The saving clause in the National Traffic and Motor Vehicle Safety Act stated that a manufacturer's compliance with standards promulgated under the act "does not exempt any person from any liability under common law."³⁷⁵ On the one hand, the saving clause illuminated the Court's analysis of the express preemption provision, which prohibited a state from establishing or continuing in effect "any safety standard applicable to the same aspect of performance."³⁷⁶ Read together, the preemption provision and the saving clause led the Court to conclude that the preemption provision should be read narrowly as not applying to state common law tort actions.³⁷⁷ Extending *Myrick*, the Court held that the existence of a broad saving clause does not prevent a court from proceeding to an implied preemption analysis to determine if conflict preemption applied.³⁷⁸ This decision led to the now-infamous language in *Geier* that fueled the debate over the viability of the presumption against preemption: "Neither do we believe that the pre-emption provision, the saving provision, or both together, create some kind of 'special burden' beyond that inherent in ordinary pre-emption principles—which 'special burden' would specially disfavor pre-emption here."³⁷⁹ Circling back to the preemption provision,

371. *Freightliner Corp. v. Myrick*, 514 U.S. 280, 288 (1995).

372. *Id.* at 289-90.

373. *Id.* at 287 n.3.

374. *See, e.g., Raeker-Jordan, supra* note 24, at 25-29; Carroll, *supra* note 126, at 819-28; Haas, *supra* note 41, at 1943-47.

375. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 868 (2000) (quoting 15 U.S.C. § 1397(k) (repealed 1994)).

376. *Id.* at 867 (quoting 15 U.S.C. § 1392(d) (repealed 1994)).

377. *See Geier*, 529 U.S. at 867.

378. *See id.* at 871-72.

379. *Id.* at 870.

the Court observed that the provision's explicit language in barring all state standards of the sort described in the provision demonstrated a congressional "intent to avoid the conflict, uncertainty, cost, and occasional risk to safety itself that too many different safety-standard cooks might otherwise create."³⁸⁰ The result in *Geier* was that the plaintiffs' claims were preempted because they posed an obstacle to the accomplishment of the federal goals of the detailed federal regulatory scheme.³⁸¹

The saving clause presents a classic issue of checks and balances. When Congress, using broad plain language, chooses to exempt common law claims from the preemption clause, the common law may occasionally be in conflict with the requirements and purposes of the federal statutory scheme. The doctrine of preemption allows the courts to determine the extent to which nonconforming state standards will be tolerated. That process will involve examining the unique characteristics of the federal statute, as well as the relationship of the state standard to the federal scheme.

Does a saving clause automatically trigger an implied preemption analysis? The answer to that question should be "no," relying on the presumption against preemption. The Supreme Court, however, seems to answer that question with a qualified "sometimes." A sensible, and appropriately cautious, rule deriving from the Court's decisions would give substantial deference to the congressional saving statement. If the saving clause is arguably very broad, the court should start with the assumption that Congress intended all common law claims to be exempt from preemption. If the federal scheme reflects a strong overriding federal interest that cannot be reconciled by the express terms of the statute and the preemption provision, then the court may conduct an implied preemption analysis to determine whether the plaintiff's common law claims are barred. Both factors were present in *Geier*.³⁸²

In *Sprietsma*, the saving clause also broadly preserved liability under the common law.³⁸³ Justice Stevens emphasized the important role of a broad saving clause, stating that "compensation is the manifest object of the saving clause, which focuses not on state authority to regulate, but on preserving 'liability at common law or under State law.'"³⁸⁴ It was somewhat odd that the Court felt the need to consider the matter under implied pre-

380. *Id.* at 871.

381. *See id.* at 881-82.

382. The Court stated:

[T]he saving clause reflects a congressional determination that occasional nonuniformity is a small price to pay for a system in which juries not only create, but also enforce, safety standards, while simultaneously providing necessary compensation to victims. That policy by itself disfavors pre-emption, at least some of the time. But we can find nothing in any natural reading of the two provisions that would favor one set of policies over the other where a jury-imposed safety standard actually conflicts with a federal safety standard.

Id. at 871. This excerpt demonstrates that the Court was aware of the need for caution in applying conflict preemption where the statute contains a broad saving clause. The Court found the justification for conflict preemption in the specific federal scheme for phasing in passive restraints. *See id.* at 879-81.

383. *Sprietsma v. Mercury Marine*, 537 U.S. 51, 63 (2002).

384. *Id.* at 64 (quoting *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984)).

emption, after firmly determining that express preemption did not bar the plaintiff's claims. As suggested earlier, this may have been a function of several factors. The Court disagreed with the manufacturer that the Coast Guard's decision not to regulate boating safety by requiring propeller guards constituted a "regulation" under the act within the meaning of the preemption provision.³⁸⁵ The very fact that the manufacturer was asking the Court to *imply* a regulation may have been sufficient to invoke principles of implied preemption. Also, there was no doubt that the federal government had planned a comprehensive set of regulations for boating safety, thus evidencing a strong federal interest, but those regulations were being developed incrementally.³⁸⁶ Finally, Justice Stevens may have been determined to show how implied preemption should be used so as not to be a freewheeling analysis that pushes preemption beyond the bounds of congressional intent or that permits courts to impose their own unrestrained predisposition on a case.³⁸⁷ Indeed, *Sprietsma* leaves the reader with the sense that any notion of expansive preemption generated by *Geier* is patently incorrect. Rather, implied preemption is to be conducted under very narrow circumstances and applied in an even narrower manner.

CONCLUSION

Until the United States Supreme Court's decision in *Bates v. Dow Agrosciences LLC* in 2005, the preemption doctrine, particularly as applied in product liability cases, appeared confusing and, at times, inconsistent. This confusion was compounded by the fact that some of the Supreme Court cases on product preemption had been plurality decisions, with the justices split on the application of the doctrine in the context of various statutes. More recently, in *Bates* and *Sprietsma v. Mercury Marine*, the Court has incorporated certain normative principles into the product preemption doctrine and established clearer boundaries to prevent preemption from becoming "[a] freewheeling judicial inquiry."³⁸⁸

Bates established that the presumption against preemption, although somewhat bruised, is alive and thriving. It also illuminated the Court's approach to implied preemption and the circumstances under which a court considering a preemption motion may move from an express preemption analysis to an implied preemption analysis. Perhaps most importantly, the Court emphasized more strongly than in earlier decisions that state tort law

385. *Id.* at 65-66.

386. *See Force, supra* note 325, at 417 ("The legislative history of the FBSA reveals that Congress plainly intended the FBSA to establish *uniform* national safety standards for recreational boats and associated equipment.").

387. Dissenting in *Geier*, Justice Stevens expressed this sentiment: "[I]t is . . . clear that the Supremacy Clause does not give unelected federal judges *carte blanche* to use federal law as a means of imposing their own ideas of tort reform on the States." *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 894 (2000) (Stevens, J., dissenting).

388. *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 111 (1992) (Kennedy, J., concurring in judgment & concurring in part).

may play a valuable role in supplementing federal statutory schemes and in deterring the kinds of undesirable activities that the federal statutes address.

Bates undoubtedly will not be the Supreme Court's final word on product preemption. But it evinces a trend toward normalizing product preemption doctrine and providing increased predictability of preemption results. Courts may now render product preemption decisions with a greater sense of certainty that their decisions reflect the doctrinal norms that the Supreme Court embraces and serve the values of consumer health and safety.