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The "New" Presumption Against Preemption

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Is there or isn't there a "presumption against preemption"? The Supreme Court continues to mention it, but then does, or does not, apply it in a way that helps us understand what it is. This Article explores the Court's preemption opinions in the last several decades, particularly its most recent pronouncements, and concludes that, indeed, there is a presumption against preemption. It is a "new" presumption in the sense that it is born of the Court's active preemption docket in the last two decades, which has more narrowly defined both express and implied preemption analysis. The "new" presumption is stronger in express preemption cases, operating as a true default rule in the absence of clear and manifest congressional intent to preempt, but is less rigid, or, in other words, more forgiving in implied preemption cases, giving breathing room to the definition of actual conflict while maintaining focus on articulated congressional objectives.

The uncertain course of preemption doctrine in the last two decades has contributed to a substantial increase in preemption arguments being made that perhaps never should have been made. The Court opened the door to many of those arguments by its display of uncertainty over the place of the presumption against preemption. The Court may have closed that door by its recent preemption decisions that clarify the importance of the presumption against preemption in both express and implied preemption cases. This Article explains the "new" presumption against preemption that has resulted, and hopes to reduce the current uncertainty over the role of the presumption in preemption doctrine.

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INTRODUCTION

Is there a presumption against federal preemption of state law? The Supremacy Clause of the United States Constitution declares that "the Laws of the United States . . . shall be the supreme Law of the Land,"[1] a fairly "no frills" statement. To respond to the inevitable doubt about what "supreme" means in the face of the wide variety of federal legislation, the Supreme Court has defined a framework to give content to the Supremacy Clause. That framework, known as preemption doctrine, centers on a search for congressional intent to preempt.

Within the search for congressional intent to preempt, the Supreme Court has recognized the historic role of state law and paid homage to

1. U.S. CONST. art. VI, cl. 2 ("This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any state to the Contrary notwithstanding.").

the role of the states in our federal system of government.[2] That homage comes in part in the form of a "presumption against preemption." This "presumption" is often stated as follows:

> [I]n all pre-emption cases, and particularly in those in which Congress has "legislated . . . in a field which the States have traditionally occupied," . . . we "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress."[3]

The Supreme Court has mentioned this presumption on many occasions.[4] But just as frequently, the Court has decided cases involving preemption and never mentioned the presumption.[5]

State laws are, of course, as various as federal laws. The main focus of this Article, and of the many Supreme Court cases in the last two decades,[6] will be federal preemption of state common law damages actions. An example drawn from products liability, a subject which has been the center of many of the Court's preemption decisions in the past two decades, will illustrate: Assume Congress has legislated to impose its solution to a perceived problem, for example, consumer protection legislation. Congress has created an administrative body to implement its solution; in our example, it would be the Consumer Product Safety Commission.[7] Congress charges that agency with promulgating

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2. *See* Caleb Nelson, *Preemption*, 86 VA. L. REV. 225 (2000) (discussing history of the Supremacy Clause and its meaning).

3. Wyeth v. Levine, 129 S. Ct. 1187, 1194–95 (2009) (second and third alterations in original) (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996) (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947))).

This "presumption" has been part of preemption jurisprudence for almost one hundred years. *See, e.g.*, N.Y. Cent. R.R. Co. v. Winfield, 244 U.S. 147, 155–58 (1917). Much has been written on the presumption. *See, e.g.*, Mary J. Davis, *Unmasking the Presumption Against Preemption*, 53 S.C. L. REV. 967 (2002) [hereinafter Davis, *Unmasking the Presumption*]; Richard Nagareda, *FDA Preemption: When Tort Law Meets the Administrative State*, 1 J. TORT L. (2006), http://www.bepress.com/jtl/vol1/iss1/art4/; Susan Raeker-Jordan, *The Pre-Emption Presumption That Never Was: Pre-Emption Doctrine Swallows the Rule*, 40 ARIZ. L. REV. 1380 (1998); Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 454 (2008); Sandra Zellmer, *Preemption by Stealth*, 45 HOUS. L. REV. 1659, 1666–72 (2009).

Most commentators favor such a presumption as consistent with fundamental notions of concurrent federal and state authority in our federal system of government. *See, e.g.*, Mary J. Davis, *The Battle over Implied Preemption: Products Liability and the FDA*, 48 B.C. L. REV. 1089, 1141–44 (2007) [hereinafter Davis, *Implied Presumption*]; Raeker-Jordan, *supra*, at 1428–29; Nelson, *supra* note 2, at 290. *But see* Viet D. Dinh, *Reassessing the Law of Preemption*, 88 GEO. L.J. 2085, 2112–17 (2000) (criticizing the presumption against preemption).

4. *See* Davis, *Unmasking the Presumption*, *supra* note 3 (chronicling one hundred years of Supreme Court preemption jurisprudence and references to the presumption against preemption).

5. *See* Riegel v. Medtronic, Inc., 128 S. Ct. 999 (2008); Geier v. Am. Honda Motor Co., 529 U.S. 861 (2000).

6. *See generally* Mary J. Davis, *On Restating Products Liability Preemption*, 74 BROOK. L. REV. 759, 762 (2009) (noting recent Supreme Court focus on preemption of state tort laws).

7. The Consumer Product Safety Act (CPSA), which is the basis for this example, can be found at 15 U.S.C. §§ 2051–2082 (2006 & Supp. 2008). The CPSA was originally enacted in 1972, *see* Pub. L.

regulations to implement the legislation. Until Congress entered the field, however, the perceived problem was addressed, if at all, by state law. How does one tell, under the Supremacy Clause, whether those state laws continue to operate once Congress and its delegated agency have entered the field? Is all state law displaced under the Supremacy Clause regardless of how it operates, even if it complements the federal legislative and regulatory scheme? Where there is overlap, what state law survives and what state law is defeated?

In the one hundred plus years that the Supreme Court has addressed preemption issues, it has been inconsistent about the role that the presumption against preemption plays. Most recently, the Court, in *Wyeth v. Levine*, reaffirmed the existence of the presumption against preemption in a case asking whether a common law damages action alleging failure to warn regarding a prescription pharmaceutical was impliedly preempted by a federal Food and Drug Administration approval of the product's warning label.[8] In the immediately preceding term, however, the Court decided an express preemption problem, whether a common law damages action alleging design defect based on a federally approved medical device was preempted, without mentioning the presumption at all.[9]

This Article will identify a trend in Supreme Court preemption cases that can be fairly said to define a "new" presumption against preemption. The "new" presumption is more than a platitude. It plays an important, foundational role in express preemption cases in which Congress's words are central to defining preemptive intent but are considered against the backdrop of the presumption. The presumption has substantial impact in express preemption cases as a meaningful default rule in the absence of congressional clarity. The "new" presumption also brings clarity to implied conflict preemption analysis by informing the construction of the relevant conflict. How the "new" presumption operates in preemption analysis, what its limitations are, and how it will limit the aggressive use of preemption doctrine to restrict state law claims is the subject of the remainder of this Article.

I. THE BASIC PREEMPTION FRAMEWORK: SITUATING THE PRESUMPTION

The Supreme Court has long held that federal laws preempt state laws if, first and foremost, that is Congress's clear and manifest intent: "The purpose of Congress is the ultimate touchstone in every pre-emption case."[10] Preemption doctrine begins with the assumption that

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No. 92-573, 86 Stat. 1207, and was substantially amended in 2008.

8. 129 S. Ct. 1187, 1191 (2009). *Levine* is discussed in more detail *infra* Part III.

9. *See Riegel*, 128 S. Ct. 999.

10. Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996); *see also* Retail Clerks Int'l Ass'n, Local 1625 v. Schermerhorn, 375 U.S. 96, 103 (1963) (stating that "[t]he purpose of Congress is the ultimate

Congress has the power to define the scope of its legislation. Sometimes Congress defines its intent expressly by including in legislation a provision that addresses the legislation's preemptive scope. When that is the case, the preemption provision must be evaluated to determine Congress's intent. As with any legislative provision, the words used are often not clear when applied to situations presented months and years later. Express preemption provisions must be interpreted. A variety of interpretive tools exist to determine congressional intent, including an evaluation of the ordinary meaning of the terms of the statute, its structure, and its purpose as discerned through the legislative history.[11]

When Congress has not expressed its preemptive intent, the Supreme Court has identified two basic doctrines that imply that intent and act as a substitute for Congress's express intent to preempt. These implied preemption doctrines substitute for express intent a judicial determination of what Congress *would have intended* on the facts presented. The two categories are: (1) "occupation of the field" implied preemption, where Congress has legislated so comprehensively in a field that it must have intended national uniformity of regulation, and, therefore, its legislation displaces all state regulation;[12] and (2) "implied conflict preemption," where the federal and state regulations are in such *actual* conflict that state law must yield to the federal because *either* (a) federal and state provisions directly conflict so that it is impossible for a person to comply with both requirements, *or* (b) state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[13]

Implied conflict preemption in its "obstacle" form is exceedingly important because it has the potential to be broadly applied; after all, federal and state objectives are in the eye of the beholder. Justice Thomas has strongly criticized implied obstacle preemption for that reason.[14] Defining the scope of express congressional intent to preempt

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touchstone" in preemption analysis).

11. *See* Altria Group, Inc. v. Good, 129 S. Ct. 538, 543 (2008); Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992). For further discussion of determining congressional intent to preempt, see *infra* Part II.D.

12. For a discussion of occupation of the field preemption, see DAVID G. OWEN, PRODUCTS LIABILITY LAW § 14.4, at 942 (2d rev. ed. 2008). *Accord* THOMAS O. MCGARITY, THE PREEMPTION WAR 109, 264–65 (2008) ("The Supreme Court has applied field preemption sparingly to state common law claims, and the lower courts have followed suit."). The Supreme Court has rarely found Congress to have impliedly occupied a field. *But see* United States v. Locke, 529 U.S. 89 (2000) (finding field preemption of state regulation of oil tankers). Because of its relative rarity to date as a significant facet of preemption doctrine, field preemption will not be discussed in detail in this Article. Some have advocated its use in certain limited contexts, however. *See, e.g.*, Richard A. Epstein, *The Case for Field Preemption of State Laws in Drug Cases*, 103 NW. U. L. REV. 463 (2009).

13. OWEN, *supra* note 12, at 942 n.30 (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)).

14. *See, e.g.*, Wyeth v. Levine, 129 S. Ct. 1187, 1204–17 (2009) (Thomas, J., concurring in the judgment) (arguing against any form of obstacle preemption as contrary to federalism principles); *see*

and implementing implied conflict preemption doctrines have proved to be extremely difficult and lead to widely varying opinions, as the Court's preemption cases in the last twenty years attest. Both often require judges to cut at the joint between competing methods of statutory interpretation and overlapping definitions of federal and state objectives. Implied obstacle conflict preemption doctrine has been the most difficult for courts to apply because of the inherent uncertainty in determining Congress's intent to preempt based on an ex post judicial assessment of congressional objectives. A "presumption against preemption" would be an important tool in applying both types of preemption doctrine and would aid in the resolution of cases on the margins. Its existence as a default rule is important in the most difficult cases.

In a prior article, I chronicled one hundred years of preemption doctrine history and the application of the presumption against preemption in particular.[15] After reviewing the cases, and exploring the twists and turns in the Court's modern preemption cases, it appeared to me that the presumption against preemption was little more than a platitude for the Court to mention before moving with dispatch to find preemption in circumstances when it traditionally had not.[16] While the Court has recently reaffirmed the presumption against preemption in *Levine*,[17] it is unclear whether my earlier conclusion needs revision. The Court's modern preemption decisions lack the clarity that one would have hoped would be produced by so much opinion writing. The Court's recent cases have alternated between express and implied preemption analysis and have inconsistently used the presumption in that analysis. Three cases decided in 2008 and 2009 reiterate some basic tenets of the doctrine,[18] and, while the preemption landscape continues to be difficult terrain, a "new" presumption, more narrowly focused and thus more effective, can be identified.[19]

Also important in the birth of the "new" presumption is the effect of the 2008 presidential election, which produced a change not only in the White House but also in the federal government's position on preemption.[20] That change limits the circumstances in which federal

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also Nelson, *supra* note 2, at 277 (stating that obstacle preemption requires "imaginative reconstruction" of congressional intent).

15. *See* Davis, *Unmasking the Presumption*, *supra* note 3.

16. *Id.* at 1014–21.

17. 129 S. Ct. at 1194 (noting that preemption analysis is guided by "two cornerstones," one of which is the presumption against preemption).

18. *Id.*; Altria Group, Inc. v. Good, 129 S. Ct. 538 (2008); Riegel v. Medtronic, Inc., 128 S. Ct. 999 (2008).

19. *See Altria Group*, 129 S. Ct. at 538; Geier v. Am. Honda Motor Co., 529 U.S. 861 (2000); Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996); Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992).

20. Preemption: Memorandum for the Heads of Executive Departments and Agencies, 74 Fed. Reg. 24,693 (May 20, 2009) ("The purpose of this memorandum is to state the general policy of my

government agencies within the executive branch are to advance a preemption position. As such, the policy change will affect whether the federal government takes a position on preemption in any particular piece of litigation[21] and, in doing so, may slow the evolutionary speed of preemption doctrine that has occurred in the last twenty years. It may also affect the content of the doctrine just as the preceding administration's aggressive advocacy for preemption spurred more cases that led to decisions favoring preemption.[22]

The pace of preemption cases in the last twenty years, in combination with a renewed government position advocating restraint in seeking preemption, solidify what I am calling the "new" presumption against preemption. The "new" presumption operates against the backdrop of a political climate that, at times, may favor or disfavor preemption as a means of strengthening federal control over a subject. Ultimately, the "new" presumption confirms that it is Congress that has the final word and, absent clarity from Congress, the "new" presumption will operate as a meaningful default rule in express preemption cases. In cases of implied conflict preemption, where loose notions of "objectives" and "purposes" cause concern among those who favor both limited judicial intervention and limited federal control over traditionally state-governed subjects, the "new" presumption acts as one factor in constructing an actual conflict that will serve to defeat state law. The balance struck by the "new" presumption against preemption may bring stability to preemption doctrine, which continues as a most important doctrine determining the relationship between federal and state governments, particularly in this era of rapid federal government expansion.

The following Part provides a brief synopsis of the history of the presumption against preemption, describes its modern treatment by the

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Administration that preemption of State law by executive departments and agencies should be undertaken only with full consideration of the legitimate prerogatives of the States and with a sufficient legal basis for preemption.").

21. *See, e.g.*, Colacicco v. Apotex, Inc., 521 F.3d 253 (3d Cir. 2008), *vacated*, 129 S. Ct. 1578 (2009) (vacating in light of *Levine*, 129 S. Ct. 1187). In response to *Levine*, the United States withdrew as amicus in *Colacicco* and notified the Third Circuit that the United States "does not take a position on whether [the state-law failure-to-warn claims] are preempted" and "has not yet conducted the sort of reexamination of various preemption issues following the Supreme Court's decision in [*Levine*] that would be necessary to inform a position of the United States in this case." Letter from Sharon Swingle, U.S. Dep't of Justice, to Marcia M. Waldron, Clerk, U.S. Court of Appeals (Apr. 28, 2009), *available at* http://www.ahrp.org/cms/index2.php?option=com_content&do_pdf=1&id=583.

22. *See* Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227 (2007) (chronicling the recent trend of federal agencies issuing statements supporting preemption); *see also* Davis, *Implied Preemption*, *supra* note 3, at 1094–96 (discussing the change in position at the FDA in the early 2000s regarding preemption by regulation in the pharmaceutical context).

Court, and explains the current state of the presumption. Part III will explain the "new" presumption against preemption.

II. THE PRESUMPTION AGAINST PREEMPTION: A BRIEF HISTORY

A. FOUNDATIONAL CASES ESTABLISHING THE PRESUMPTION AGAINST PREEMPTION

Several cases from the mid-twentieth century set the stage for modern preemption doctrine. In *Rice v. Santa Fe Elevator Corp.*, the Court emphasized the centrality of discerning congressional intent to preempt and defined the presumption against preemption which is quoted today: when Congress has legislated in a field that the states have traditionally occupied, "we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress."[23] *Rice* involved application of the Federal Warehouse Act, which, though originally leaving state regulation intact, had been amended to provide the Secretary of Agriculture with "exclusive authority" to license federal warehouses.[24] Plaintiff challenged a variety of Illinois warehousing regulations, most of which did not directly conflict with federal regulations, but, rather, were more comprehensive than the federal counterpart.[25]

The Court defined the ways in which Congress's "clear and manifest purpose" might be evidenced. The Court noted that if the federal scheme is pervasive, leaving states no room to supplement it, or the federal legislation involves a field dominated by the federal interest, Congress must have intended to preclude state laws on the same subject, leading to what has been referred to as "field preemption."[26] Finding no dominant federal interest or pervasive federal scheme of regulation, the Court applied a third method of discerning congressional intent: whether state policy is inconsistent with federal objectives.[27] To make that assessment, the Court reviewed the statute's terms and its particular history and found that Congress had intended to displace state regulation entirely in the field even though many areas had been left unregulated by federal legislation.[28]

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23. 331 U.S. 218, 230 (1947).

24. *See* Ch. 13, 39 Stat. 486 (1916) (codified as amended at 7 U.S.C. §§ 241–256 (2006)); *see also Rice*, 331 U.S. at 223–24.

25. *Rice*, 331 U.S. at 224–29 (including such matters as rates, discrimination, mixing grain, and maintenance of elevators).

26. *Id.* at 230 (citing Hines v. Davidowitz, 312 U.S. 52 (1941) (federal immigration laws); N.Y. Cent. R.R. Co. v. Winfield, 244 U.S. 147 (1917) (railroad regulations)).

27. *Id.* at 230, 232.

28. *Id.* at 234–35.

Rice relied on statutory interpretation, statutory scope, and legislative history to discern the clear and manifest congressional intent to overcome the presumption against preemption. *Rice* involved implied preemption of a very specific state business regulation—warehouse licensing requirements. In *San Diego Building Trades Council v. Garmon*, the Court was faced with a different situation: the application of implied preemption doctrine to state common law damages actions and their effect on federal labor laws.[29] In *Garmon*, employers claimed to have been injured by the nonviolent picketing of labor activists.[30] They sued the activists for damages under state tort law, and the activists argued that the National Labor Relations Act (NLRA) preempted the state tort causes of action.[31] The NLRA clearly left room for the states to regulate matters not governed by the federal scheme, so the Court had to determine whether state tort actions survived the federal scheme.[32] The labor activists sought to use preemption as a shield to protect their right to speak freely to educate their fellow workers and encourage organization.[33]

The Court, applying implied conflict preemption,[34] did not speak directly about a presumption against preemption. In ascertaining congressional intent to impliedly preempt, the *Garmon* Court was sensitive to the nature of the regulatory scheme in place—"new and complicated" and "drawn with broad strokes"—that required the Court to carry out Congress's purposes "by giving application to congressional incompletion."[35] The Court was concerned about the potential conflicts that were posed by "inconsistent standards of substantive law and differing remedial schemes."[36] The Court expressed the opinion, often repeated since, that state common law damages actions have a regulatory effect, albeit indirect, making them a proper subject of preemption

29. 359 U.S. 236, 241 (1959).

30. *Id.* at 237.

31. *Id.* at 237–38.

32. *Id.* at 240.

> "By the Taft-Hartley Act, Congress did not exhaust the full sweep of legislative power over industrial relations given by the Commerce Clause. Congress formulated a code whereby it outlawed some aspects of labor activities and left others free for the operation of economic forces. As to both categories, the areas that have been pre-empted by federal authority and thereby withdrawn from state power are not susceptible of delimitation by fixed metes and bounds.... [The Act] leaves much to the states, though Congress has refrained from telling us how much. This penumbral area can be rendered progressively clear only by the course of litigation."

Id. (citation omitted) (quoting Weber v. Anheuser-Busch, Inc., 348 U.S. 468, 480–81 (1955)) (internal quotation marks omitted).

33. *Id.* at 237.

34. *Id.* at 241–43.

35. *Id.* at 240.

36. *Id.* at 242.

analysis: "Such regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy."[37] The Court concluded that state tort law damages were preempted because "to allow the States to control conduct which is the subject of national regulation would create potential frustration of national purposes."[38]

The Court did not discuss the presumption against preemption other than to suggest that the "interests so deeply rooted in local feeling and responsibility" were overcome by a "compelling direction" by Congress that entrusted national labor policy to the National Labor Relations Board.[39] A presumption against preemption would arguably have produced a different result in a case like *Garmon*, in which traditional state law had operated and would have gutted the "compelling direction" by Congress to protect the very conduct the common law damages claims would inhibit. One can imagine that the Court would have found any presumption to be overcome as a result. Nevertheless, the Court did not discuss the presumption and, instead, remarked that common law damages actions have a regulatory effect, a statement that has influenced every subsequent preemption claim involving common law damages actions. The Court's discussion in *Garmon* has driven the analysis of the preemption of common law damages actions.

After *Garmon*, the potential existed that the Court would broadly apply implied obstacle preemption to common law damages actions. The Court did not return to that subject until twenty-five years later in *Silkwood v. Kerr-McGee Corp.*[40] *Silkwood* involved application of the Atomic Energy Act (AEA)[41] to a tort action for personal injuries and property damage filed by the estate of Karen Silkwood, who had become contaminated with plutonium while working at a nuclear power plant operated by Kerr-McGee Corp.[42] The estate's administrator alleged a variety of irregularities in the operation of the facility that led to Silkwood's contamination.[43] He pled negligence and strict liability claims and sought punitive damages.[44]

The AEA was enacted in 1954 to free the nuclear energy industry from total federal control and to provide for some private involvement in the development of nuclear power.[45] In an amendment to that Act,

37. *Id.* at 247.
38. *Id.* at 244.
39. *Id.*
40. 464 U.S. 238 (1984).
41. 42 U.S.C. §§ 2011 to 2297h-13 (2006).
42. *Silkwood*, 464 U.S. at 241–43. She later died in an unrelated car accident. *Id.* at 242.
43. *Id.* at 243.
44. *Id.* at 241, 243, 245.
45. Ch. 724, 68 Stat. 919 (1954) (codified as amended in scattered sections of 42 U.S.C.).

Congress sought to clarify the respective federal and state responsibilities by giving the states limited regulatory authority, but precluded the states from regulating the safety aspects of nuclear material.[46] Congress's decision to prohibit the states from regulating safety was based on its belief that the delegated federal agency, the Nuclear Regulatory Commission, was more qualified to determine what type of safety standards should be enacted in the area.[47] The preemption provision of the AEA thus defined a limited sphere of state authority carved out of federal authority. Nonetheless, the Court concluded unanimously that the AEA did not preempt Silkwood's compensatory damages action.[48] The Justices agreed that such an award may have an "indirect" regulatory impact on a nuclear facility, but Congress's silence on the matter of preemption "takes on added significance in light of Congress' failure to provide any federal remedy for persons injured" by regulated conduct.[49] Consequently, neither implied field nor conflict preemption was established.[50]

The presumption against preemption was not directly implicated because the area being regulated, nuclear energy production and safety, was federal and not one involving the "historic police powers"[51] of the states. Even in that context, however, the Court recognized that Congress would not destroy traditional means of legal recourse without at least acknowledging it openly.[52] Furthermore, Congress's silence on

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46. *See* 42 U.S.C. § 2021(a)(1), (c)(4); *see also* Pac. Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n, 461 U.S. 190, 206 (1983) ("[U]ntil 1954 . . . the use, control, and ownership of nuclear technology remained a federal monopoly.").

47. *See* 42 U.S.C. § 2021(c)(4); *see also Pac. Gas & Elec. Co.*, 461 U.S. at 206.

48. *Silkwood*, 464 U.S. at 251; *id.* at 263 (Blackmun, J., dissenting); *id.* at 279–80 (Powell, J., dissenting).

49. *Id.* at 251 (majority opinion); *see also id.* at 263 (Blackmun, J., dissenting) ("Because the Federal Government does not regulate the compensation of victims, and because it is inconceivable that Congress intended to leave victims with no remedy at all, the pre-emption analysis established by *Pacific Gas* comfortably accommodates—indeed it compels—the conclusion that compensatory damages are not preempted whereas punitive damages are." (footnote omitted)).

50. *Id.* at 256 (majority opinion).

51. The term "historic police powers" is not well defined though often used. It can be considered for our purposes to mean general state power to protect the citizenry in its health and welfare. For a discussion of the history of the term and its various meanings, see D. Benjamin Barros, *The Police Power and the Takings Clause*, 58 U. MIAMI L. REV. 471, 484 (2003).

> Judges and legal scholars have made many attempts to define the police power or to draw boundaries around its scope. Writers of early treatises tried to explain the police power in terms of the common law theories reflected in cases that upheld police regulations. Courts have often defined the police power by reference to the acknowledged legitimate ends of the power, such as the promotion of the polity's health, safety, and morals, and some commentators have attempted to limit the police power to the pursuit of these ends. Many more commentators have attempted to define the police power by reference to political theory.

Id.; *see also* Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947).

52. *See Silkwood*, 464 U.S. at 251.

the topic suggested that traditional means of legal recourse indeed would remain.[53] The Court rejected the notion that Congress would implicitly permit the destruction of traditional state tort remedies simply by regulating in a field, even one like nuclear power that requires comprehensive safety standards.[54]

B. The Rise of Express Preemption and the Changing Role of the Presumption Against Preemption

Federal statutes have long been interpreted to determine congressional intent to preempt, but those statutes often either do not contain an express preemption provision or, if one exists, its scope is unclear. Consequently, implied preemption doctrines have been more frequently used to determine preemptive scope. When federal statutes and their implementing regulations do contain preemption provisions, courts, until the last twenty years, had regularly found such provisions to be ambiguous regarding congressional intent to preempt but had applied implied preemption principles anyway.[55] Consequently, express preemption analysis was rarely applied to preempt state common law damages actions.[56]

In the 1980s, however, more and more defendants in products liability actions sought total protection from liability based on the supremacy of federal regulation.[57] Product manufacturers argued that compliance with governmental safety regulations preempted the operation of state tort laws that might find those regulations not to establish due care.[58] Compliance with governmental regulations has always been relevant to the exercise of due care and proof of product defect in tort actions, but it has never strictly been its measure.[59] Regulations that contain standards of conduct have historically been considered to state minimum and not maximum standards. The general consensus by the early 1990s was that "[t]he general approach to tort claims against non-federal actors . . . is to deny any preemptive or

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53. *Id.*

54. *Id.* at 250–51. The primary area of contention in *Silkwood* was whether punitive damages were preempted and, on this issue, the Court was divided. Three Justices—Blackmun, Marshall, and Powell—dissented from the finding of no preemption of the punitive damages claim. *See id.* at 258 (Blackmun, J., dissenting); *id.* at 274 (Powell, J., dissenting).

55. Owen, *supra* note 12, at 945–47; *see also* Davis, *Unmasking the Presumption*, *supra* note 3, at 983–97 (exploring the Court's struggle with implied and express preemption pre-1990).

56. Owen, *supra* note 12, at 947.

57. Examples of this effort resulted in the prominent preemption cases that made their way to the Supreme Court in the 1990s, such as *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), and *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

58. *See generally* Symposium, *Regulatory Compliance as a Defense to Products Liability*, 88 Geo. L.J. 2049 (2000).

59. Owen, *supra* note 12, § 14.3, at 929; *see also* Restatement (Third) of Torts: Products Liability § 4(b) (1998); Restatement (Second) of Torts § 288C (1965).

shielding effect unless there is some specific indication of a congressional intent to preempt state tort law."[60]

Also during the mid-1980s, the Supreme Court decided a number of products liability matters, reflecting a general bias in favor of limited tort liability.[61] The Court's preemption doctrine and its restrictive approach to products liability collided in *Cipollone v. Liggett Group, Inc.*, which involved interpretation of the preemptive effect of the federal cigarette labeling and advertising laws on cigarette products liability actions.[62] *Cipollone* was an action against three cigarette manufacturers on behalf of Rose Cipollone, who died of lung cancer after smoking the defendants' cigarettes for forty years.[63] Her son pled a number of claims centering on the manufacturers' failure to warn of the risks of smoking.[64] The Third Circuit Court of Appeals had concluded that the express preemption provisions in those statutes did not include common law tort claims, but that the claims were impliedly preempted.[65]

The Supreme Court reversed, concluding that when Congress had expressed the preemptive scope of a statute, and that provision provided a "reliable indicium of congressional intent," the express preemption provision controlled.[66] The Court recognized the presumption against federal preemption of matters historically within the states' police powers, and focused on discerning congressional intent.[67] Perhaps *Cipollone*'s focus on the express preemption provisions was not surprising in light of the turmoil in preemption analysis in the 1980s over the role of implied obstacle preemption.[68] Nevertheless, *Cipollone* represented a dramatic shift in emphasis in preemption analysis from implied conflict preemption to express preemption. It also represented a remarkable extension of express preemption doctrine to include common law damages actions.

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60. 2 AM. LAW INST. REPORTERS' STUDY, ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY: APPROACHES TO LEGAL AND INSTITUTIONAL CHANGE 94 (1991).

61. *See generally* Mary J. Davis, *The Supreme Court and Our Culture of Irresponsibility*, 31 WAKE FOREST L. REV. 1075 (1996) (discussing the Supreme Court's products liability cases in the 1980s, particularly *East River Steamship v. Delaval Corp.*, 476 U.S. 858 (1986), and *Boyle v. United Technologies Corp.*, 487 U.S. 500 (1988), both of which limited the reach of tort liability in some federal cases).

62. 505 U.S. at 508–09 (applying Federal Cigarette Labeling and Advertising Act of 1965, Pub. L. No. 89-92, 79 Stat. 282; Public Health Cigarette Smoking Act of 1969, 15 U.S.C. §§ 1331–1341 (1988)).

63. *Id.* at 508.

64. *Id.* at 508–10.

65. Cipollone v. Liggett Group, Inc., 789 F.2d 181, 187 (3d Cir. 1986). State courts had found otherwise. *See, e.g.*, Dewey v. R.J. Reynolds Tobacco Co., 577 A.2d 1239, 1255 (N.J. 1990) (finding no implied obstacle preemption by cigarette labeling laws).

66. *Cipollone*, 505 U.S. at 517 (quoting Malone v. White Motor Corp., 435 U.S. 497, 505 (1978)).

67. *Id.* at 516.

68. *See* Davis, *Unmasking the Presumption*, *supra* note 3, at 995–97.

All the Justices in *Cipollone* agreed that the preemption analysis should proceed by an interpretation of the scope of the express preemption provisions of the statute.[69] The federal cigarette labeling laws, from 1965 and 1969, contained express preemption provisions. The 1965 Act stated: "No statement relating to smoking and health . . . shall be required on any cigarette package."[70] The 1969 Act amended the preemption provision to state: "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."[71] Noting that congressional intent is the "ultimate touchstone" of preemption analysis,[72] the Court described its focus on the express preemption provision:

> Such reasoning is a variant of the familiar principle of *expressio unius est exclusio alterius*: 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 each of those sections.[73]

A majority of the Court found that the 1965 Act did not preempt any state common law damages actions based on the precise words of the provision and the presumption against preemption, which "reinforces the appropriateness of a narrow reading" of the provision.[74] The Justices disagreed about the 1969 Act, however, which prohibited any "requirement or prohibition . . . imposed under State law."[75] The plurality opinion, authored by Justice Stevens (who has become a prominent author of the Court's preemption opinions) used both the text of the provisions and the legislative history to preempt some, but not all, common law damages actions.[76] Justice Stevens read the language of the preemption provision with particularity to conclude that the statute "plainly reaches beyond such [positive] enactments,"[77] because, as stated

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69. *See* 505 U.S. at 516–17; *id.* at 531 (Blackmun, J., concurring in part, concurring in the judgment in part, and dissenting in part); *id.* at 545–46 (Scalia, J., concurring in the judgment in part and dissenting in part).

70. *Id.* at 514 (majority opinion) (quoting Federal Cigarette Labeling and Advertising Act of 1965, Pub. L. No. 89-92, § 5, 79 Stat. 282).

71. *Id.* at 515 (quoting Pub. L. No. 91-222, § 5(b), 84 Stat. 87 (1969)).

72. *Id.* at 516 (quoting Malone v. White Motor Corp., 435 U.S. 497, 505 (1978)).

73. *Id.* at 517.

74. *Id.* at 518. In addition, the Court found that the purposes and the regulatory context of the Act also supported a narrow reading. *See id.* at 519.

75. *Id.* at 515 (quoting Pub. L. No. 91-222, § 5(b)).

76. *Id.* at 521–24 (plurality opinion) (discussing change in preemption provision from the 1965 Act to the 1969 Act).

77. *Id.* at 521 ("The phrase '[n]o requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common-law rules." (alteration in original)).

in *Garmon*,[78] common law damages actions can have a regulatory effect. Justice Blackmun disagreed vehemently with the conclusion that common law damages actions necessarily were precluded under the statute because they constituted some general "requirement or prohibition."[79] *Cipollone* marked an important shift away from the protective treatment of common law damages actions evidenced by *Silkwood*. The conclusion in *Cipollone* is also evidence that *Garmon* has been extended well beyond its legitimate reach in implied preemption analysis.

The ensuing seventeen years have been extraordinarily active ones for the Court in defining express preemption analysis. The Court twice analyzed the express preemption provision of the National Traffic and Motor Vehicle Safety Act (NTMVSA), which provides that states may not maintain "motor vehicle safety standards" that conflict with federal performance standards on the same topic.[80] In the first NTMVSA case, *Freightliner Corp. v. Myrick*, the Court, in a unanimous opinion by Justice Thomas, concluded that because there was no federal standard in issue on the topic of anti-lock brakes for eighteen-wheel trucks, there was neither express nor implied obstacle preemption of state design defect claims based on the absence of such brakes.[81] The Court raised a question about the interaction between express and implied preemption analysis,[82] which it would resolve in the second NTMVSA case, *Geier v. American Honda Motor Co.*, discussed shortly.

The Court's next preemption opinion, *Medtronic, Inc. v. Lohr*,[83] also focused on express preemption, this time under the Medical Device Amendments (MDA) to the Food, Drug and Cosmetic Act.[84] Plaintiff alleged common law product defect claims arising out of his use of defendant's pacemaker. The device had been approved under the FDA's

78. *See supra* notes 29–39 and accompanying text (discussing *Garmon*).

79. *Cipollone*, 505 U.S. at 536 (Blackmun, J., concurring in part, concurring in the judgment in part, and dissenting in part) ("More important, the question whether common-law damages actions exert a regulatory effect on manufacturers analogous to that of positive enactment . . . is significantly more complicated than the plurality's brief quotation from *San Diego Building Trades Council v. Garmon* would suggest. The effect of tort law on a manufacturer's behavior is necessarily indirect." (citation omitted)). Justice Blackmun recognized that the Court's earlier cases assessing preemption of common law damages actions had "declined on several recent occasions to find the regulatory effects of state tort law direct or substantial enough to warrant preemption." *Id.* at 537 (referring to, among others, *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984)).

80. 49 U.S.C. § 30103(b)(1) (2006).

81. 514 U.S. 280, 289 (1995).

82. *Id.* at 288–89 ("The fact that an express definition of the pre-emptive reach of a statute 'implies'—*i.e.*, supports a reasonable inference—that Congress did not intend to pre-empt other matters does not mean that the express clause entirely forecloses any possibility of implied pre-emption. . . . At best, *Cipollone* supports an inference that an express pre-emption clause forecloses implied pre-emption; it does not establish a rule.").

83. 518 U.S. 470 (1996).

84. Pub. L. No. 94-295, 90 Stat. 539 (1976).

premarket notification approval regulations, a grandfathering method of approval without the heightened rigor of the more elaborate premarket approval process.[85] The Court was divided on whether the MDA preempted the plaintiff's claims, but all Justices again agreed that the express preemption provision controlled the analysis.[86]

The Justices hewed closely to the language of the express preemption provision, which stated that states could not impose "requirement[s] . . . different from, or in addition to" any federal requirement related to safety or effectiveness of the device.[87] The premarket notification process did not require nor approve specific design features.[88] The majority opinion, again authored by Justice Stevens, applied the presumption against preemption and, in doing so, concluded that common law damages actions alleging design defects did not impose "requirements" in this context.[89] Four Justices concluded that nothing in the legislation, its history, or its basic purpose suggested that common law damages actions were intended to be requirements.[90] A majority of Justices agreed that common law obligations were not a threat to the general federal requirements in *Lohr*.[91] That majority also agreed, however, that where the federal government had weighed the competing interests relevant to device-specific requirements, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or products, a case would exist for preemption under the statute and implementing regulations.[92] The specificity of the federal government's "weighing of competing interests" would become a recurring theme.

The Court also addressed the FDA's position on preemption found in a formally adopted regulation that implemented its statutory preemption authority.[93] Federal agency action regarding preemption is

85. *Medtronic*, 518 U.S. at 476–80.

86. *See id.* at 484–85; *id.* at 503 (Breyer, J., concurring in part and concurring in the judgment); *id.* at 509 (O'Connor, J., concurring in part and dissenting in part).

87. 21 U.S.C. § 360k (2006).

88. *Medtronic*, 518 U.S. at 476–80.

89. *Id.* at 493–94. He stated: "[W]e used a 'presumption against the pre-emption of state police power regulations' to support a narrow interpretation of such an express command in *Cipollone*. That approach is consistent with both federalism concerns and the historic primacy of state regulation of matters of health and safety." *Id.* at 485 (citation omitted) (quoting Cipollone v. Liggett Group, Inc., 505 U.S. 504, 518, 523 (1992)).

90. *Id.* at 487 (plurality opinion).

91. *Id.* at 501–02 (majority opinion).

92. *Id.* at 501. Justice Breyer's concurring opinion gave the Court its judgment in the case, and he interpreted the word "requirement" to include common law damages actions in some circumstances, but not in this case. *Id.* at 503–04 (Breyer, J., concurring in part and concurring in the judgment).

93. 21 C.F.R. § 808.1(d)(2) (2008) (no preemption of state or local requirements that are "equal to, or substantially identical to, requirements imposed by or under the [MDA]"); *id.* § 808.1(d)(1) (no

central to these cases because it may inform preemptive scope. All three *Lohr* opinions explored the importance of the agency's position in determining the scope of preemption.[94] The Justices disagreed on the extent to which they should rely on an agency's position on preemption, though in earlier cases the Court had noted that agency regulations could be informative on defining the scope of preemption where consistent with statutory language.[95] The FDA did not consider common law damages actions to be preempted by its device approval regulations at that time.[96]

These two disputed features in *Lohr*—the scope of express preemption provisions (does "requirements" include common law damages actions?), and the treatment of administrative agency opinion on preemptive scope (to defer or not?)—are central to the modern debate about preemption analysis. They also foreshadow the Court's return to a focus on implied preemption doctrine in *Geier v. American Honda Motor Co.* one year later.

C. Coordinating Express and Implied Preemption and the Impact of Savings Clauses

Only a few years after *Lohr*, the Court would muddy the preemption waters again. In *Geier v. American Honda Motor Co.*,[97] the Court was asked to analyze the effect of the express preemption provision in the NTMVSA on a lawsuit alleging that a 1987 Honda was defective in design because it did not have a driver's side air bag.[98] The NTMVSA contains a preemption provision that states that whenever a federal motor vehicle safety standard (FMVSS) (defined elsewhere in the statute as a minimum safety standard)[99] is in effect, states may not establish or continue any "standard applicable to the same aspect of

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preemption of "State or local requirements of general applicability").

94. *See* 518 U.S. at 495–96 (agency regulations "substantially inform" interpretation of statute); *id.* at 505–06 (Breyer, J., concurring in part and concurring in the judgment); *id.* at 511–12 (O'Connor, J., concurring in part and dissenting in part).

95. *See* Norfolk & S. Ry. v. Shanklin, 529 U.S. 344, 356 (2000) (discussing preemption under Federal Railroad Safety Act, and debating relevance of agency position); *see also* CSX Transp. Inc. v. Easterwood, 507 U.S. 658, 670 (1993).

96. *See Lohr*, 518 U.S. at 492–94. *But see* Riegel v. Medtronic, Inc., 128 S. Ct. 999, 1009 (2008). *Riegel* is discussed *infra* regarding the FDA's change in position on this issue.

97. 529 U.S. 861 (2000). *Geier* is a five-to-four opinion; Justice Breyer wrote for the majority and was joined by Chief Justice Rehnquist and Justices O'Connor, Scalia, and Kennedy. Justice Stevens, the author of both the *Cipollone* and *Lohr* plurality and majority opinions, dissented in an opinion in which Justices Souter, Thomas, and Ginsberg joined.

98. *Id.* at 865 (discussing the National Traffic and Motor Vehicle Safety Act of 1966, 80 Stat. 718 (codified as amended at 49 U.S.C. §§ 30101–30169 (2006))).

99. 49 U.S.C. § 30102(a)(9) ("'[M]otor vehicle safety standard' means a minimum standard for motor vehicle or motor vehicle equipment performance.").

performance" that is not identical to the federal standard.[100] The statute also contains a "savings clause," a provision in a federal statute that does just that; it "saves," or preserves, some category of state law from being overtaken by the federal statute. The NTMVSA savings clause states: "Compliance with any Federal motor vehicle safety standard issued under this subchapter does not exempt any person from any liability under common law."[101] The clause appeared quite clearly to preserve the operation of "liability under common law."

The Department of Transportation issued Standard 208 in 1984,[102] after a lengthy administrative process, permitting automobile manufacturers a choice of passive restraints, and culminating in the 1989 requirement that all cars have a driver's side air bag. Ms. Geier's 1987 Honda did not have a driver's side air bag.[103] Justice Breyer wrote the majority opinion and articulated a three-part preemption analysis when faced with an express preemption provision: First, does the express preemption provision preempt the lawsuit?[104] If not, then second, "do ordinary pre-emption principles nonetheless apply?"[105] If so, then third, does the lawsuit "actually conflict" with the federal statute?[106]

The express preemption provision analysis is quite different than that in both *Cipollone* and *Lohr*, which involved close attention to statutory text. The Court in *Geier* concluded that the express preemption provision did not preempt plaintiff's action but did not discuss the terms of the provision with the particularity it had previously.[107] Nor did the Court assess what the term "standard," as opposed to "requirement," might mean. Instead, the Court concluded, with little fanfare, that the "savings clause" made that exercise unnecessary.[108] The Court said that the savings clause assumed "that there are some significant number of common-law liability cases to save."[109] The Court thus concluded that the presence of the savings clause required a narrow reading of the express preemption provision, excluding common law damages actions from its operation, to give actual meaning to the savings clause.[110]

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100. *Id.* § 30103(b)(1).

101. 15 U.S.C. § 1397(k) (1988).

102. 49 C.F.R. § 571.208 (1984). For a discussion of the tortured administrative history, see *Geier*, 529 U.S. at 875–77; *id.* at 889–92 (Stevens, J., dissenting); and see also Ralph Nader & Joseph A. Page, *Automobile-Design Liability and Compliance with Federal Standards*, 64 GEO. WASH. L. REV. 415, 443–46 (1996).

103. *Geier*, 529 U.S. at 865.

104. *Id.* at 867.

105. *Id.*

106. *Id.*

107. *See id.* at 868.

108. *Id.* at 867–68.

109. *Id.* at 868.

110. *Id.*

The majority opinion never mentioned the presumption against preemption. Indeed, the Court suggested that a broad reading of the preemption provision might be appropriate in some circumstances, but that "[w]e have found no convincing indication that Congress wanted to preempt, not only state statutes and regulations, but also common-law tort actions."[111] The Court used the existence of the savings clause to defeat preemption but did not interpret the statute, evaluate its purposes, or consider its legislative history. The Court certainly did not follow the ordinary meaning of the savings clause—to preserve common law liability principles.

After finding no express preemption, the Court concluded that the express preemption provision, coupled with the savings clause, reflected a neutral congressional policy toward the operation of implied preemption doctrine when an actual conflict may exist. Thus, the Court answered its second question in the affirmative—implied conflict preemption principles continued to operate to the extent that they prohibited *actual conflict*—reasoning that it would be impermissible to "take from those who would enforce a federal law the very ability to achieve the law's congressionally mandated objectives that the Constitution, through the operation of ordinary preemption principles, seeks to protect."[112] The Court was persuaded to apply implied conflict preemption principles out of concern for the "careful regulatory scheme" established by NTMVSA, despite the arguably plain meaning of the savings clause.[113] The Court did not want to be confined to the traditional categories of implied preemption—obstacle and impossibility—and instead stated that it "assumed that Congress would not want either kind of conflict."[114] Thus, the Court did not distinguish among types of federal-state conflict. The Court had been badly splintered on how to interpret express preemption provisions, so it is not entirely surprising that it would revert to application of implied conflict preemption principles to resolve ambiguity over congressional intent to preempt.

In answering the final question of whether an actual conflict existed, the Court clearly perceived that common law tort actions might be detrimental to thoughtfully established federal goals,[115] even in the face of congressional intent to the contrary (i.e., the savings clause). In *Geier*, the federal goals with which state law was found to conflict were located not in the statute but in the air bag regulation, FMVSS 208.[116] The Court

111. *Id.*

112. *Id.* at 872.

113. *See id.* at 870.

114. *Id.* at 873–74.

115. *Id.* at 881. A similar concern was raised in *Medtronic, Inc. v. Lohr*, 518 U.S. 418, 495–97 (2000).

116. *See* 529 U.S. at 881.

discussed at some length the federal objectives behind the regulation.[117] The Court relied extensively on the administrative history of the regulation, as well as the Department of Transportation's (DOT) contemporaneous comments about the purposes of the regulation.[118] The Court was influenced by comments to the original standard and the Secretary of Transportation's position, described in an amicus brief, that the standard "embodies the Secretary's policy judgment that safety would best be promoted if manufacturers installed *alternative* protection systems in their fleets rather than one particular system in every car."[119] The Court noted the DOT's effort to balance a variety of concerns and, therefore, concluded that the standard was neither a minimum nor a maximum standard, but one representing a unique balance of considerations.[120]

The Court did not mention the presumption against preemption.[121] The Court weighed the perceived federal regulatory objectives against the states' general interest in promoting health and welfare, and in compensating citizens for injuries caused by defective products.[122] It was somewhat sympathetic to state concerns of compensating victims and enhancing product safety, but concluded that jury-assessed standards would lead to unpredictability and uncertainty in the standard of care.[123] The Court did not describe the burden necessary to establish implied conflict preemption, but rejected any "special burden" on the proponent of preemption.[124]

Finally, the Court discussed the role of the federal agency's position on the federal objectives behind the standard and its conclusion that tort suits would stand as an obstacle to those objectives.[125] The Court gave "some weight" to the agency's interpretation because of the technical nature of the subject matter, the complexity of the statutory scheme, and the agency's expertise and "unique" qualification to comprehend the likely impact of state requirements on that scheme.[126] In addition, the Court was influenced by the Secretary's consistent position on

117. *Id.* at 874–80.

118. *Id.* at 875–77.

119. *Id.* at 881 (quoting Brief for the United States as Amicus Curiae Supporting Affirmance at 25, *Geier*, 529 U.S. 861 (No. 98-1811)).

120. *See id.* at 877–81.

121. *See id.* at 906–07 (Stevens, J., dissenting).

122. *See id.* at 881–82 (majority opinion).

123. *See id.* at 871.

124. *See id.* at 874. The idea of a "special burden" stemmed from Justice Stevens's dissenting opinion, in which he criticized the Court's overly broad implied obstacle preemption analysis. *See id.* at 898–99 (Steven, J., dissenting).

125. *Id.* at 880–81 (majority opinion). Many scholars have discussed the importance of agency position in preemption analysis. *See generally, e.g.*, Nina Mendelson, Chevron *and Preemption*, 102 MICH. L. REV. 737 (2004); Sharkey, *supra* note 22.

126. *Geier*, 529 U.S. at 883.

preemption.[127] The Court recognized that it should not readily find conflict preemption in the absence of clear evidence of a conflict, but that to require a formal agency statement on preemption was too restrictive.[128]

As mentioned earlier, federal agency position on preemption has become increasingly important as a tool for litigants seeking to establish intent to preempt. *Lohr* involved a specific agency rule promulgated to define the scope of the MDA preemption provision prior to litigation, and the Court was "substantially informed" by it.[129] The agency's position in *Geier* was found in the history of the regulation and the Secretary of Transportation's position in the litigation, which displayed some consistency over time with predecessor opinions.[130] After *Geier*, federal agency statements articulating federal objectives and assessing whether those objectives might be thwarted by state law increased as federal agencies sought greater and greater preemption of state law, particularly common law tort claims.[131]

D. POST-*GEIER* EXPRESS PREEMPTION ANALYSIS: AN EMERGING STASIS?

In the eight years between *Cipollone* and *Geier*, the Court emphasized express preemption in a wholly new way, resisted discussing the presumption against preemption, and struggled with how to balance the historic role of state tort law with federal regulatory action. After *Geier*, it was unclear what role express preemption analysis would continue to play. Subsequent cases emphasized the search for congressional intent but returned gradually to the presumption against preemption.

In *Sprietsma v. Mercury Marine*,[132] the Court followed *Geier* and interpreted an express preemption provision with a savings clause *not* to expressly preempt a product liability claim under the Federal Boat Safety Act.[133] *Sprietsma* involved a Coast Guard assessment of the need for propeller guards on recreational vessels that did not result in any regulation.[134] The Court was faced with whether that failure to regulate

127. *See id.*

128. *Id.* at 884–85.

129. *See* 518 U.S. 470, 495–96 (1996). Justice Breyer concurred, agreeing that "the relevant administrative agency possesse[d] a degree of leeway to determine which rules, regulations, or other administrative actions will have pre-emptive effect." *Id.* at 505 (Breyer, J., concurring in part and concurring in the judgment).

130. *See* 529 U.S. at 883.

131. *See generally* Samuel Issacharoff & Catherine Sharkey, *Backdoor Federalization*, 53 UCLA L. REV. 1353 (2006) (describing trend toward limiting operation of state tort law by federal agency action); Sharkey, *supra* note 22.

132. 537 U.S. 51, 62–63 (2002).

133. 46 U.S.C. §§ 4301–4311 (2006).

134. 537 U.S. at 60–61.

preempted common law claims based on a failure to equip with propeller guards, and found neither express nor implied conflict preemption.[135] The Court was influenced by the Coast Guard regulations that preserved state authority in the absence of federal action, and the fact that the Coast Guard consistently concluded that its regulations did not have preemptive effect, even though it had no formal rule on the subject.[136] *Sprietsma* was a unanimous opinion.[137]

In *Bates v. Dow Agrosciences LLC*,[138] the Court was presented with another express preemption provision, this time from the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).[139] The Court, speaking through Justice Stevens, attended closely to the language of the express preemption provision—as in both *Cipollone* and *Geier*—and was also informed by the history of the legislation as well as the importance of tort litigation as a complement to the regulatory scheme.[140] The Court did not describe the role of the presumption against preemption until it had evaluated these three components of assessing Congress's intent. Before concluding that analysis, and finding most claims not preempted by the language of FIFRA,[141] the Court noted that courts have "a duty to accept the reading [of an express preemption provision] that disfavors pre-emption."[142] The Court also noted that the "long history of tort litigation against manufacturers of poisonous substances adds force to the basic presumption against pre-emption."[143] It reiterated its adherence to the presumption against preemption because tort litigation "provid[es] an incentive to manufacturers to use the utmost care in the business of distributing inherently dangerous items."[144]

The Court employed the narrow express preemption analysis described in *Cipollone*, specifically rejecting the conclusion that common law jury verdicts are the equivalent of "requirements" simply because

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135. *Id.* at 64–66.

136. *Id.* at 65–66.

137. *Id.* at 53.

138. 544 U.S. 431 (2005).

139. 7 U.S.C. § 136 (2006).

140. *Bates*, 544 U.S. at 440–42 (noting the importance of the history of the legislation and the role of tort litigation as a "common feature of the legal landscape").

141. *Id.* at 452.

142. *Id.* at 449.

143. *Id.* at 450. The Court continued: "If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly." *Id.* (citing Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 251 (1984)).

144. *Id.*; *see also id.* at 459 (Thomas, J., concurring in the judgment in part and dissenting in part) ("Today's decision thus comports with this Court's increasing reluctance to expand federal statutes beyond their terms through doctrines of implied pre-emption. This reluctance reflects that pre-emption analysis 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." (alteration in original) (citations omitted) (quoting Gade v. Nat'l Solid Wastes Mgmt., 505 U.S. 88, 111 (1992) (Kennedy, J., concurring in part and concurring in the judgment)).

they may influence manufacturer decisionmaking.[145] The Court reasoned, "A requirement is a rule of law that must be obeyed," whereas "an event, such as a jury verdict, that merely motives an optional decision is not a requirement."[146] The Court concluded that the express preemption provision preempted very few claims.[147] The Court also expressed a sense of frustration at the way the lower courts had broadly read the term "requirements" after *Cipollone*, and chastised those courts for "too quickly conclud[ing]" that tort claims were therefore also preempted under FIFRA.[148] While the Court did not describe its express preemption provision analysis as a narrow one, informed by the presumption against preemption, such a conclusion can certainly be drawn from the analysis in *Bates*.

Bates also addressed the importance of agency position on express preemption. The regulating agency, the Environmental Protection Agency, had shifted its position from being against preemption to being in favor of it within the previous five years.[149] The Court was not influenced by that shift in position, describing the result of the Government's analysis as "particularly dubious given that just five years ago the United States advocated the interpretation that we adopt today."[150] The Court endorsed the parallel operation of common law tort claims, stating they "would seem to aid, rather than hinder, the functioning of FIFRA[,] . . . [which] contemplates that pesticide labels will evolve over time, as manufacturers gain more information about their products' performance in diverse settings. . . . [T]ort suits can serve as a catalyst in this process."[151] The concern expressed by the defendant and the EPA that "tort suits led to a 'crazy-quilt' of FIFRA standards or otherwise created any real hardship for manufacturers" fell on deaf ears, as the Court observed that "for much of this period EPA appears to have welcomed these tort suits."[152] There was remarkable agreement in *Bates*; Justice Breyer concurred and Justices Thomas and Scalia concurred in the judgment but dissented over the failure of the majority to focus on the ordinary meaning of the preemption provision.[153]

Riegel v. Medtronic, Inc.[154] also represents remarkable agreement among the Justices, but in contrary ways to the agreement in *Bates*. The

145. *Id.* at 445 (majority opinion).
146. *Id.*
147. *Id.* at 452.
148. *Id.* at 446.
149. *See id.* at 436–37 & n.7, 449.
150. *Id.* at 449.
151. *Id.* at 451.
152. *Id.* at 451–52.
153. *Id.* at 454 (Breyer, J., concurring); *id.* at 455, 457 (Thomas, J., concurring in the judgment in part and dissenting in part).
154. 552 U.S. 312 (2008).

Court in *Riegel* was asked to address for a third time express preemption under the Medical Device Amendments, this time regarding claims involving devices approved under the premarket approval process.[155] The Court, in an opinion by Justice Scalia, held that the MDA expressly preempts such claims.[156] The Court was critical of the role of common law tort claims and expansive in its description of the scope of express preemption,[157] unlike in *Bates*. The Court's express preemption analysis did not emphasize congressional intent to preempt; instead, it reaffirmed its own understanding of the term "requirements."[158] The Court declared that "requirements" includes common law tort claims, stating: "Congress is entitled to know what meaning this Court will assign to terms regularly used in its enactments. Absent other indication, reference to a State's 'requirements' includes its common-law duties."[159] This contrary conclusion to both the sentiment and discussion in *Bates* about "requirements" is, at the least, an unusual turnabout in so short a time.

While thus defining the term "requirement" for future Congresses, the Court displayed its distrust of the operation of common law tort actions. According to the *Riegel* Court, tort law as applied by juries is "less deserving of preservation" than other state regulations because juries are incapable of balancing costs and benefits adequately as they "see[] only the cost[s] of a more dangerous design, and [are] not concerned with [the] benefits" consumers reap by the manufacturer's design choices.[160] It is "implausible," according to the Court, that Congress would create the "perverse distinction" that grants greater power to a single state jury than to state officials.[161] These remarks leave little, if anything, left of the historic place that state tort law held in regulating public safety, and certainly have little in common with Justice Stevens's remarks on that score in *Bates*. There was no mention of the "presumption against preemption."

The *Riegel* Court also discussed, at some length, the effect of the FDA's changing position on preemption, even though it acknowledged that the position was not relevant to the case because the statutory

155. *Id.* The second time was in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 352 (2001), involving a so-called fraud-on-the-agency theory that the Court found was not expressly preempted by the MDA's express preemption provision but was impliedly preempted because policing fraud on an agency is a uniquely federal matter.

156. *Riegel*, 552 U.S. at 322–26.

157. *See id.* at 324–25.

158. *Id.*

159. *Id.* at 325. For a more thorough discussion regarding Congress's intent, see *id.* at 333 (Ginsburg, J., dissenting). Justice Stevens, the author of *Cipollone*, *Lohr*, *Sprietsma*, and *Bates*, concurred on the scope of "requirements" because he considered it consistent with the result in *Lohr*. *See id.* at 330–33 (Stevens, J., concurring in part and concurring in the judgment).

160. *Id.* at 325 (majority opinion).

161. *Id.*

language was clear.[162] The FDA had recently changed its position on the scope of the MDA preemption provision as it applied to the premarket approval process.[163] While largely dicta, the Court's statements displayed some sympathy for the proposition that *recent* agency position might be relevant to an assessment of preemptive scope, despite longstanding agency position to the contrary.[164] These statements are quite different than those by the Court on this issue in *Geier* and *Bates*.

Some observers have described *Riegel* as a fairly narrow application of the MDA express preemption provision and a logical extension of *Medtronic, Inc. v. Lohr*.[165] The lack of respect for the traditional longstanding role of state tort law and the failure to mention the presumption against preemption is inconsistent with recent cases and, therefore, unsettling.[166] The discussion of agency position on preemption is also inconsistent with prior cases.[167]

The final express preemption case meriting discussion is *Altria Group, Inc. v. Good*. Decided after *Riegel*, *Altria Group* involved the continuing validity of *Cipollone* in defining the claims that survived express preemption under the cigarette labeling laws after the ensuing sixteen years of preemption doctrine.[168] After *Riegel* and its eight-to-one opinion in favor (in dicta, at least) of a more expansive reading of express preemption provisions and of the meaning of "requirement," one might have expected that Justice Stevens's plurality opinion in *Cipollone* had been outgrown. In a stunning turn of events, however, Justice Stevens, joined by Justices Breyer, Ginsburg, Kennedy, and Souter, held that the more moderate approach of the plurality opinion of *Cipollone* does indeed control the express preemption analysis of the Federal Cigarette Labeling and Advertising Act.[169] The majority rejected the broader scope of preemption analysis proposed by Justice Scalia in

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162. *See id.* at 326.

163. *Id.* at 326–27.

164. *Id.* at 327 ("But of course the agency's earlier position . . . is even more compromised, indeed deprived of all claim to deference, by the fact that it is no longer the agency's position.").

165. *See, e.g.*, Catherine M. Sharkey, *What* Riegel *Portends for FDA Preemption of State Law Products Liability Claims*, 102 NW. U. L. REV. COLLOQUY 415, 415 nn.3–4 (2008), http://colloquy.law.northwestern.edu/main/2008/07/what-riegel-por.html.

166. *See* Davis, *supra* note 6, at 771–73 (2009) (discussing importance of the debate in *Riegel* to the larger discussion of the importance of tort law).

167. The discussion in *Riegel* may now also be moot because of an effort in Congress to undo the result. *See Legislation: Supporters, Opponents Debate Measure To Overturn High Court's Preemption Ruling*, 37 Prod. Saf. & Liab. Rptr. (BNA) 866 (Aug. 10, 2009).

168. 129 S. Ct. 538, 542 (2008).

169. *Id.* at 549 ("In sum, we conclude now, as the plurality did in *Cipollone*, that 'the phrase "based on smoking and health" fairly but narrowly construed does not encompass the more general duty not to make fraudulent statements.'" (quoting Cipollone v. Liggett Group, Inc., 505 U.S. 504, 529 (1992) (plurality opinion))).

Cipollone,[170] and advocated by Justice Thomas in dissent in *Altria*,[171] stating: "Justice Scalia's approach was rejected by seven Members of the Court, and in the almost 17 years since *Cipollone* was decided Congress has done nothing to indicate its approval of that approach."[172] Justice Stevens's opinion in *Altria Group* confirmed the presumption against preemption and a fair but narrow reading of the scope of express preemption provisions.[173]

Bates, *Riegel*, and *Altria Group*, as the most recent express preemption opinions, give contrary signals about the role of the presumption against preemption and determining express congressional intent to preempt. It appears that, for the time being, Justice Stevens's approach to express preemption fashioned in *Cipollone*, *Bates*, and *Altria Group* carries the day.

III. IMPLIED CONFLICT PREEMPTION POST-*GEIER*: *WYETH V. LEVINE*

In March 2009, the Court decided *Wyeth v. Levine*,[174] the much-anticipated implied preemption case involving whether common law tort claims challenging the adequacy of federally approved pharmaceutical labeling are preempted under the federal Food, Drug and Cosmetic Act (FDCA).[175] The FDCA does not have an express preemption provision relating to pharmaceutical approvals, so the case required an application of implied preemption.[176] The Court had not decided a pure implied preemption case (one not involving any express preemption provision) in recent history. In addition, the FDA, which had for years been in favor of the concurrent operation of state common law damages actions, had changed its position on preemption: first, in a series of amicus briefs in cases beginning in 2004, and then in a 2006 preamble to new pharmaceutical labeling regulations.[177] The lower courts had struggled with implied preemption doctrine in these cases and whether to consider the FDA's changed position in the analysis.[178]

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170. 505 U.S. at 552–54 (Scalia, J., concurring in the judgment in part and dissenting in part).

171. 129 S. Ct. at 552–54 (Thomas, J., dissenting); *see also id.* at 545 n.7 (majority opinion).

172. *Id.* at 545 n.7.

173. *See id.* at 543.

174. 129 S. Ct. 1187, 1191 (2009).

175. Ch. 675, 52 Stat. 1040 (1938) (codified as amended in scattered sections of 21 U.S.C.).

176. *See Levine*, 129 S. Ct. at 1195–96.

177. *See* 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006); Davis, *Implied Preemption*, *supra* note 3, at 1090 (chronicling the history of the change in FDA preemption policy); *see also* Sharkey, *supra* note 22, at 238–42.

178. *See, e.g.*, Colacicco v. Apotex, Inc., 521 F.3d 253 (3d Cir. 2008), *vacated*, 129 S. Ct. 1578 (2009) (vacating in light of *Levine*, 129 S. Ct. 1187); Knipe v. SmithKline Beecham, 583 F. Supp. 2d 553 (E.D. Pa. 2008); Tucker v. SmithKline Beecham Corp., 596 F. Supp. 2d 1225 (S.D. Ind. 2008).

Levine involved the anti-nausea drug Phenergan, which had been approved in 1955.[179] Ms. Levine had been injected with the drug to alleviate symptoms from a migraine headache.[180] Through inadvertent injection into an artery, gangrene, a known side effect, resulted and her arm eventually had to be amputated.[181] Wyeth, Phenergan's manufacturer, knew about the risk of intra-arterial injection, and had warned about it in a section of the labeling; that labeling had been approved over the years by the FDA.[182] Ms. Levine claimed that the labeling inadequately warned of the risk of gangrene, and the jury agreed.[183] The Vermont Supreme Court affirmed a lower court ruling that Ms. Levine's claims were not impliedly preempted by the FDA's labeling approvals.[184]

Wyeth made two separate implied conflict preemption arguments: first, that it would have been impossible for it to comply with the state law duty to warn without violating federal law; and second, that recognition of the plaintiff's claims would act as an obstacle to the accomplishment of federal objectives because it would substitute a lay jury's decision for the expert judgment of the FDA.[185] The Court, speaking through Justice Stevens in a six-to-three majority opinion, found that the FDA's product labeling approvals did not impliedly preempt Levine's tort claims under either argument.[186]

A. Reaffirming the Presumption Against Preemption

The Court began by reaffirming the "two cornerstones of [its] pre-emption jurisprudence": first, that "the purpose of Congress is the ultimate touchstone in every pre-emption case"; and second, in "all pre-emption cases," and particularly those involving fields traditionally occupied by states, the analysis begins with the presumption against preemption.[187] The Court rejected Wyeth's argument that the presumption should not apply in implied preemption cases, stating: "This Court has long held to the contrary."[188]

The Court also responded to Wyeth's argument that, because the federal government had long regulated drugs, the presumption should not operate.[189] The Court rejected this argument, stating that it

179. *See* 129 S. Ct. at 1191.
180. *Id.*
181. *Id.*
182. *Id.* at 1192.
183. *Id.* at 1193.
184. Levine v. Wyeth, 944 A.2d 179, 194 (Vt. 2007).
185. *See Levine*, 129 S. Ct. at 1193–94.
186. *Id.* at 1191.
187. *Id.* at 1194–95 (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996)).
188. *Id.* at 1195 n.3.
189. *Id.*

"misunderstands" the presumption which "accounts for the historic presence of state law but does not rely on the absence of federal regulation."[190]

B. Impossibility Conflict Preemption Analysis

The Court's discussion of impossibility conflict preemption is one of the most thorough it has ever written. Wyeth argued that it would be subject to misbranding liability under FDA regulations if it altered its label, as plaintiff claimed it should have, because the FDA must approve all labeling.[191] The Court disagreed after a thorough exploration of the labeling approval regulations that permit pharmaceutical manufacturers to alter their warning labels, after initial product approval, to add or strengthen a warning.[192] The Court emphasized that "through many amendments to the FDCA and to FDA regulations, it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times."[193]

Implied conflict preemption based on the impossibility of complying with both federal and state law has only rarely been applied, and the Court rejected it in this instance, too.[194] The Court noted that impossibility preemption is "a demanding defense"[195] and that it would require "clear evidence" of impossibility to succeed.[196]

The Court found no "clear evidence" after an intense assessment of the federal regulatory scheme and a searching review of the record.[197] The Court described the type of evidence that might suffice: "[Wyeth] does not argue that it attempted to give the kind of warning required by the Vermont jury but was prohibited from doing so by the FDA."[198] There was no evidence that the FDA gave more than "passing attention" to the issue and certainly no affirmative decision to prohibit Wyeth from strengthening its warning.[199] The Court focused on the "central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times."[200] Only proof of a direct federal prohibition of conduct that state law requires would seem to establish an

190. *Id.*
191. *Id.* at 1197.
192. *Id.*
193. *Id.* at 1197–98.
194. *Id.* at 1198–99.
195. *Id.* at 1199.
196. *Id.* at 1198 ("But absent clear evidence that the FDA would not have approved a change to Phenergan's label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements.").
197. *Id.*
198. *Id.*
199. *Id.* at 1198–99.
200. *Id.* at 1197–98.

impossible conflict justifying preemption and, perhaps, overcome the presumption against preemption.[201]

C. Implied Obstacle Preemption Analysis

The *Levine* Court's discussion of implied obstacle preemption is important because of its contrast with *Geier*. It will be helpful to break down the Court's response to Wyeth's arguments of obstacle conflict preemption. Implied obstacle preemption, according to the Court, requires two things: (1) an identification of the congressional purposes or objectives which support the federal law;[202] and (2) a rigorous assessment of whether *Congress*, not just the agency charged with effectuating Congress's intent, considered state law claims to pose an obstacle to the accomplishment of those objectives.[203]

Borrowing from the successful obstacle conflict preemption analysis in *Geier*, Wyeth argued that Levine's tort claims were preempted because "they interfere with 'Congress's purpose to entrust an expert agency to make drug labeling decisions that strike a balance between competing objectives.'"[204] The Court rejected these arguments because they relied on an "untenable interpretation" of congressional intent and "an overbroad view" of an agency's power to preempt state law.[205]

Wyeth contended that once the FDA approves a drug's label, that decision reflects both a floor and a ceiling for regulation, and state law may not hold that decision inadequate.[206] The Court summarily rejected this assessment of federal objectives because it was contrary to all evidence of Congress's purposes.[207] The Court explored the history of federal regulation of pharmaceutical approvals and was influenced by Congress's failure to expressly preempt, stating: "If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history."[208] The Court found congressional silence, in the face of "awareness" of concurrent state tort litigation, to be "powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness."[209]

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201. *Id.* at 1199.

202. *Id.* at 1199; *see also* Davis, *Implied Preemption*, *supra* note 3, at 1132–34 (synthesizing implied conflict preemption principles).

203. *Levine*, 129 S. Ct. at 1200.

204. *Id.* at 1199 (quoting Brief for Petitioner at 46, *Levine*, 129 S. Ct. 1187 (No. 06-1249)).

205. *Id.*

206. *Id.*

207. *Id.*

208. *Id.* at 1200. Congress had not expressly preempted state tort law claims as it had in other contexts, such as in the Medical Device Amendments. *See id.*

209. *Id.* Further, "[Congress] may also have recognized that state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate

Wyeth argued that the FDA's position in favor of preemption by its labeling decisions, as set forth in the preamble to its 2006 labeling regulation, was powerful evidence that the agency had precisely balanced the risks and benefits of the labeling and, thus, state tort jury verdicts should not interfere with that balance.[210] The Court acknowledged that an agency regulation "with the force of law" can preempt conflicting state requirements, but it held that the Court performs its own conflict determination when deciding such cases, as it had in *Geier*.[211]

The Court rejected reliance on the FDA's "mere assertion" that state law posed an obstacle.[212] Instead, it confirmed that "[t]he weight we accord the agency's explanation of state law's impact on the federal scheme depends on its thoroughness, consistency, and persuasiveness."[213] The FDA's position did not deserve deference in this instance because (1) the FDA stated its position on preemption after having earlier stated that the rule would not "have federalism implications," (2) the agency finalized the rule without giving states an opportunity to comment, and (3) the position was at odds with the available evidence of Congress's purposes and the agency's own longstanding position in favor of the operation of state tort law.[214] The Court explored the many ways that tort law acts as a complement to federal drug regulation.[215]

The Court distinguished *Geier*, upon which Wyeth had relied. First, *Geier* involved formal agency rulemaking that embodied the government's policies, not an individualized product approval as in *Levine*.[216] Second, in *Geier*, the Court assessed the preemptive effect of the rule independently, *informed* by the agency's explanation, not *driven* by it.[217] The Court in *Levine* found the FDA's "newfound opinion" to be inconsistent with the "longstanding coexistence of state and federal law and the FDA's traditional recognition of state-law remedies" and thus unpersuasive on assessing a current conflict with federal objectives.[218]

The Court recognized that the FDA's drug regulations could potentially impliedly preempt state tort law claims, but that this was not

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warnings." *Id.* at 1199–1200.

210. *Id.* at 1200.

211. *Id.* at 1200–01.

212. *Id.* at 1201.

213. *Id.*

214. *Id.* at 1201–02.

215. *Id.* at 1202 ("State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. Failure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times.").

216. *Id.* at 1203.

217. *Id.*

218. *Id.* at 1203–04.

such a case.[219] Justice Breyer, in concurrence, reminded readers that "lawful specific regulations" that establish a ceiling and a floor might have preemptive effect.[220] Justice Thomas strongly criticized obstacle conflict preemption, calling for its abandonment as inconsistent with constitutional federalism principles and likely to result in overreaching.[221]

Levine represents a narrower implied obstacle conflict preemption analysis after *Geier*. The Court seems to have settled into a more balanced approach to the value of state common law tort actions within its implied conflict preemption analysis. The "new" presumption against preemption has its greatest impact in this analysis.

IV. A SYNTHESIS OF PREEMPTION ANALYSIS: REVEALING THE "NEW" PRESUMPTION AGAINST PREEMPTION

The Court has made it clear that the presumption against preemption of historic state police powers continues to operate in cases of both express and implied preemption. Only clear and manifest intent of Congress to the contrary will defeat the presumption. The question remaining is what type of evidence will support that conclusion. That is where the "new" presumption against preemption plays its role.

A. THE NEW PRESUMPTION AS DEFAULT IN EXPRESS PREEMPTION ANALYSIS

When an express preemption provision provides "clear and manifest" evidence of Congress's intent, it will control. Justice Stevens, in *Cipollone*, *Lohr*, *Bates*, *Altria Group*, and, to a lesser extent, in his concurrence in *Riegel*, provides the best statement of the current manner of interpreting express preemption provisions to discern congressional intent: narrowly based on the ordinary meaning of the statute's terms, its structure, purposes, and history, with an understanding that Congress would not defeat the operation of traditional, historic police powers of the states without quite explicitly saying so. All of this seems to suggest that a "new" presumption against preemption operates as a meaningful default rule when interpreting congressional intent to preempt. For the Court to state, as it did in *Bates*,[222] that courts should accept a reading of an express preemption provision that disfavors preemption strongly suggests a presumption with teeth. The *Riegel* Court did not mention the presumption, however. I offer two reasons for that omission: (1) the Court had analyzed preemption under the Medical Device Amendments

219. *Id.*

220. *Id.* at 1204 (Breyer, J., concurring).

221. *Id.* at 1205 (Thomas, J., concurring in the judgment). Justice Alito dissented in an opinion in which the Chief Justice and Justice Scalia joined. *See id.* at 1217–31 (Alito, J., dissenting).

222. *See* 544 U.S. 431, 449 (2005).

twice before, in *Lohr* and *Buckman*, and had found the express preemption language at issue to clearly indicate Congress's intent; and (2) the regulatory scheme in *Riegel* was more rigorous and device-specific than that in *Lohr* and, therefore, arguably consistent with congressional intent to preempt under the statute. While I would take issue with that assessment, and would agree with Justice Ginsburg's evaluation of that intent,[223] the Court in *Riegel* seemed anxious to close the door on preemption under the Medical Device Amendments. Justice Stevens's majority opinion in *Altria Group*, on the heels of *Riegel*, may be the most useful explanation of how to treat *Riegel*; the *Altria Group* majority clearly endorsed a strong role for the presumption in express preemption cases.

The Court seems intent on assessing statutory language with particularity, to discern whether the terms used, such as "requirements," "statements," or "standards," fairly include state common law claims under the relevant statute's history alone, and not with reference to use of the terms in other statutory schemes. This statute-centered focus comes after years of proponents of preemption trying to stretch the meaning of "requirements." The *Riegel* Court tried to define that term for future Congresses, though Congress could still undo the Court's definition. The "new" presumption against preemption puts overreaching of statutory definitions in its place by requiring a tighter fit between statutory context and language.

If the Court's analysis of express preemption provisions teaches anything, it is that statutes are unique and so is the search for congressional intent. Relying on the interpretation of language from one statute runs the risk of proving too much in the interpretation of similar language in another statute. I hesitate to single out any one statute as an example of express preemption analysis, but cases involving the National Childhood Vaccine Injury Act[224] may serve as good examples.

The National Childhood Vaccine Injury Act established a Vaccine Injury Compensation Program (the "Program") that provides a no-fault

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223. *See* Riegel v. Medtronic, Inc., 128 S. Ct. 999, 1014–19 (2008) (Ginsburg, J., dissenting).

224. 42 U.S.C. §§ 300aa-1 to -34 (2006). For additional history on the National Childhood Vaccine Injury Act, see Lainie Rutkow et al., *Balancing Consumer and Industry Interests in Public Health: The National Vaccine Injury Compensation Program and Its Influence During the Last Two Decades*, 111 PENN ST. L. REV. 681, 683–84 (2007).

> With the swine flu episode a not-so-distant memory, Congress fashioned a no-fault, ideally non-adversarial system to compensate the families of children who were injured after receiving a vaccination. It took Congress over three years to pass the final legislation that created the National Vaccine Injury Compensation Program (VICP); the program has remained in effect for nearly twenty years. During the last few years, when the government has considered massive vaccine campaigns for seasonal influenza and smallpox, the VICP has served as a model program for congressional members.

Id. (footnotes omitted).

compensation system as an alternative to tort litigation against vaccine manufacturers for personal injuries that result from vaccines.[225] The Program defines the vaccines covered and the injuries compensated; "if certain predetermined conditions are met, a person will automatically receive an award from the [Program]."[226] Fault by the vaccine manufacturer need not be demonstrated.[227] A victim can directly sue a vaccine manufacturer if the petition for compensation is denied, the person rejects the compensation granted, or the vaccine is not covered by the Program.[228]

In two recent cases, courts have disagreed about how to interpret the following provision in the Act that addresses the preemption of certain state common law tort claims: "Except as provided in subsections (b), (c), and (e) . . . State law shall apply to a civil action brought for damages for a vaccine-related injury or death."[229] Subsection (b) states:

> No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.[230]

The question, of course, is how much state law did Congress intend to displace by this language? Congress established a compensation scheme that expressly displaces some state law while also defining the types of state law claims that survive. There would be no need to say that "state law shall apply" if no state law claims survive. The question then remains, how much, and what, state law survives?

Plaintiffs in *American Home Products Corp. v. Ferrari* argued that their son suffered neurological damages caused by vaccines made with a mercury-laden preservative for which a substitute was then available and, therefore, that the child's injury was avoidable.[231] The Georgia Supreme Court affirmed a finding of no express preemption of the design defect claim, concluding that a case-by-case basis of determining whether a side effect was unavoidable was required.[232] The *Ferrari* court based its

225. 42 U.S.C. § 300aa-11(a)(2)(A); *see also* Rutkow et al., *supra* note 224, at 684–87 (describing the Program); Mary Beth Neraas, Comment, *The National Childhood Vaccine Injury Act of 1986: A Solution to the Vaccine Liability Crisis?*, 63 WASH. L. REV. 149, 156–58 (1988) (explaining the compensation mechanism). For the history and structure of the Act, see *Bruesewitz v. Wyeth, Inc.*, 561 F.3d 233, 235–36 (3d Cir. 2009), *cert granted*, 78 U.S.L.W. 3521 (U.S. Mar. 8, 2010) (No. 09-152).

226. Rutkow et al., *supra* note 224, at 684–86 (describing the Program in detail).

227. 42 U.S.C. §300aa-11(c); *see also* Rutkow et al., *supra* note 224, at 684.

228. Rutkow et al., *supra* note 224, at 688.

229. 42 U.S.C. §300aa-22(a).

230. *Id.* § 300aa-22(b)(1).

231. 668 S.E.2d 236, 237–38 (Ga. 2008).

232. *Id.* at 240.

decision on a review of the statute's text, its legislative history, and the presumption against preemption.[233]

The Third Circuit Court of Appeals, in *Bruesewitz v. Wyeth Inc.*,[234] disagreed. The Third Circuit found that the statute preempted *all* design defect claims, and that a case-by-case analysis of such claims would defeat Congress's intent in establishing the compensation scheme, part of which was to promote the availability of vaccines.[235] The vaccine manufacturers in *Ferrari* petitioned for certiorari to the Supreme Court, but the Ferraris dismissed their claims in state court without prejudice.[236] The Bruesewitzes' petition for certiorari was granted.[237]

The statute's terms appear on their face to carve out some design defect claims that are not preempted.[238] The statute is complex and its structure and history seem to admit different conclusions regarding the scope of the preemption provision. The case presents a unique federal compensation scheme, which clearly displaces the operation of a substantial amount of state common law by its very terms. At the same time, Congress endorsed the parallel operation of some state law by borrowing language from comment k to section 402A of the *Restatement (Second) of Torts*, which recognizes that unavoidably unsafe products should not be subject to strict liability.[239] The Supreme Court asked for an opinion from the Solicitor General on the Government's position on preemption in *Ferrari*.[240] Governing agencies may assist in assessing

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233. *See id.* at 238–39.

234. 561 F.3d 233, 245–46 (3d Cir. 2009), *cert granted*, 78 U.S.L.W. 3521 (U.S. Mar. 8, 2010) (No. 09-152).

235. *Id.* at 246–47.

236. *See* Brief for the United States as Amicus Curiae at 21, Am. Home Prods. Corp. v. Ferrari, No. 08-1120 (Jan. 29, 2010).

237. 78 U.S.L.W. 3521.

238. *See* 42 U.S.C. § 300aa-22(b)(1) (2006).

239. The *Restatement of Torts* states, "There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use," one of which is a vaccine, for which sellers cannot be held liable if they are "properly prepared and marketed" and accompanied by a "proper warning." RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965); *cf.* Lars Noah, *This Is Your Products Liability Restatement on Drugs*, 74 BROOK. L. REV. 839, 842–43 (2009) (describing case law under comment k as "unintelligible" and having produced confusion among courts and commentators).

240. *See* Brief for the United States as Amicus Curiae, *supra* note 236, at 1. The White House's recently announced position restricting executive agencies to preemption positions "with full consideration of the legitimate prerogatives of the States and with a sufficient legal basis," Preemption: Memorandum for the Heads of Executive Departments and Agencies, 74 Fed. Reg. 24,693 (May 20, 2009) (citing Exec. Order No. 13,132, 3 C.F.R. 206 (1999), *reprinted in* 5 U.S.C. § 601)), is relevant but does not take a very strident position either for or against preemption generally. The United States's brief in *Ferrari*, filed January 29, 2010, takes the position that Congress did intend to preempt design defect claims in the vaccine cases and has asked the Court to accept certiorari in *Bruesewitz*. *See* Brief for the United States as Amicus Curiae, *supra* note 236, at 7.

congressional intent but the Court has made quite clear that it is *Congress's* intent that controls.[241]

Ferrari may have the better analysis because it recognizes that the compensation scheme Congress created did not specifically articulate those claims that may be deemed unavoidable. Because the allegation in *Ferrari* was that an alternative formulation was available, rendering the defect avoidable, the preemption provision arguably does not control. The presumption against preemption, requiring a narrow reading of the terms of a statute with a view to maintain state law absent clear evidence to the contrary, supports, in principle, the result in *Ferrari*—not all design defects in vaccines are the result of unavoidable conditions. Proof of Congress's intent will also, of course, be assessed by reference to the legislative history and the purposes behind the compensation scheme. If clear preemptive intent can be derived, it will control. The "new" presumption against preemption, which acts as a default in express preemption cases in which Congress's clear intent to preempt has not been established, supports the conclusion that some set of design defect claims survived preemption by the Vaccine Injury Act.

Finally, the Consumer Product Safety Act (CPSA), mentioned in the introduction to this Article, has an express preemption provision with a savings clause.[242] Cases interpreting the CPSA found no express preemptive intent, because of the savings clause, and also held that implied preemption defeated some claims.[243] The operation of savings clauses should be reexamined in light of a refocus on clear congressional intent grounded in the presumption against preemption. The analysis in *Geier*, which did not consider the presumption against preemption, is inconsistent with the "new" presumption against preemption which requires a narrow view of Congress's express preemptive language and a default to state law absent clear intent to preempt.

B. The New Presumption as Restricting the Definition of Conflict Preemption

Implied conflict preemption similarly incorporates the presumption against preemption, though how the presumption operates in such cases is more uncertain than within express preemption analysis. Conflict preemption requires that the proponent establish an actual conflict between federal and state law, either because of impossibility of compliance with both, or because state law frustrates federal objectives. When the Court applies either kind of implied conflict preemption, it

241. *See supra* notes 172–86 and accompanying text.

242. 15 U.S.C. § 2074(a).

243. *See, e.g.*, Moe v. MTD Prods., Inc., 73 F.3d 179 (8th Cir. 1995) (applying 15 U.S.C. § 2075); BIC Pen Corp. v. Carter, 251 S.W.3d 500 (Tex. 2008) (same).

rarely discusses how the presumption operates in the establishment of actual conflict. The Court tends to be very situation-specific and fact-driven in determining what constitutes an actual conflict. *Geier* is a classic example of that. The Court discusses the value of the relevant state law in its determination of actual conflict but it does not otherwise describe how the presumption against preemption operates in these cases.

The "new" presumption against preemption in implied conflict preemption restricts the definition of actual conflict. For example, when assessing implied impossibility conflict, the Court acknowledged in *Levine* that it is a "demanding" defense, and thus unlikely to be established without substantial evidence of actual impossibility.[244] Because the Court has so rarely seen a case of impossibility, only a circumstance where federal law affirmatively prohibits what state law affirmatively requires should suffice. A common law tort judgment requiring a defendant to pay damages would, therefore, typically not constitute an affirmative state law obligation that would make it impossible to comply with a contrary federal obligation. *Levine* teaches that an agency position on impossibility will not suffice to create an impossible conflict.[245]

Another pharmaceutical labeling case may be a test for impossibility conflict preemption. *Colacicco v. Apotex, Inc.*[246] involved failure-to-warn claims based on the increased risk of suicidality from taking the anti-depressant drug Paxil.[247] Mrs. Colacicco had taken Paxil and committed suicide, allegedly as a result.[248] Her estate sued both the manufacturer of the generic drug she had taken and the manufacturer of the brand name drug, Glaxo SmithKline.[249] The FDA, according to the Court of Appeals, had

> repeatedly rejected the scientific basis for the warnings that Colacicco and [a companion plaintiff] argue should have been included in the

244. *See supra* notes 194–201 and accompanying text.

245. *See supra* notes 210–13 and accompanying text.

246. 521 F.3d 253 (3d Cir. 2008), *vacated*, 129 S. Ct. 1578 (2009) (vacating in light of *Wyeth v. Levine*, 129 S. Ct. 1187 (2009)).

247. *Id.* at 256; *see also* Davis, *Implied Preemption*, *supra* note 3, at 1095–98 (exploring history of warnings on selective serotonin re-uptake inhibitors, or SSRIs, like Paxil).

248. *Colacicco*, 521 F.3d at 256.

249. *Id.* Cases against generic pharmaceutical manufacturers are pending nationwide and involve claims of implied conflict preemption similar to those involving the brand name manufacturers. *See, e.g.*, Kellogg v. Wyeth, 612 F. Supp. 2d 437, 441 (D. Vt. 2009) ("Thus, although the *Levine* decision did not definitively dispose of the issues in this case, its statement that '[f]ailure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times,' *Levine* does not appear to permit the caveat, 'except for generic drug manufacturers.'" (citation omitted) (quoting *Levine*, 129 S. Ct. at 1202) (citing Stacel v. Teva Pharms., 620 F. Supp. 2d 899, 906–07 (N.D. Ill. 2009); Schrock v. Wyeth, Inc., 601 F. Supp. 2d 1262, 1265–66 (W.D. Okla. 2009))).

> labeling. The FDA has actively monitored the possible association between SSRIs and suicide for nearly twenty years, and has concluded that the suicide warnings desired by plaintiffs are without scientific basis and would therefore be false and misleading.[250]

The Court of Appeals thus sustained a finding of implied conflict preemption on the narrow ground that the FDA had "clearly and publicly stated its position prior to the prescriptions and deaths at issue."[251] Consequently, a state law duty to warn of such an association would render the label misbranded under federal law based on the "FDA's oft-repeated conclusion that the evidence did not support such an association" requiring a warning.[252]

The plaintiffs argued that "nothing less than the FDA's explicit rejection of a drug manufacturer's request to add a contested warning to its drug labeling should suffice to establish conflict preemption."[253] The Supreme Court has clearly stated that the manufacturer is responsible for its labeling under the FDCA.[254] One could make the argument, after *Levine*, that only an affirmative decision by the FDA to prohibit a manufacturer's proposed labeling change will support impossibility conflict preemption of a state common law duty. I am not aware of a circumstance where a pharmaceutical manufacturer has asked to enhance a warning and been affirmatively rebuffed by the FDA after full assessment of the data. *Colacicco* does not present that situation, though it is a stronger case than *Levine* because of the history of the FDA's involvement with SSRI labeling.[255] Nevertheless, the "new" presumption against preemption would focus on the manufacturer's control of the evidence of post-approval risks and the absence of an affirmative FDA prohibition against altering the labeling. Prior FDA determinations of labeling adequacy may not create an impossible conflict with a state law warning obligation under the "new" presumption against preemption.[256]

Implied obstacle conflict preemption requires an assessment of congressional objectives with which state common law may conflict, and an evaluation of whether the state common law indeed frustrates those objectives. The "new" presumption against preemption has its greatest importance, in my estimation, in obstacle conflict preemption. The

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250. *Colacicco*, 521 F.3d at 269.

251. *Id.* at 271.

252. *Id.*

253. *Id.* at 272.

254. Wyeth v. Levine, 129 S. Ct. 1187, 1197–98 (2009).

255. *See Colacicco*, 521 F.3d at 268, 268–71 ("The FDA has actively monitored the possible association between SSRIs and suicide for nearly twenty years.").

256. *See* Davis, *Implied Preemption*, *supra* note 3, at 1148–51. For a case involving SSRIs finding no implied conflict preemption post-*Levine*, consistent with application of the presumption against preemption articulated in this Article, see Mason v. SmithKline Beecham Corp., 596 F.3d 387 (7th Cir. 2010).

"new" presumption is represented by the Court's emphasis, in *Levine*, on congressional, not agency, intent when assessing federal objectives and its implicit rejection of a broader assessment of those objectives in *Geier*. As in *Garmon* and *Silkwood*, *Levine* reaffirmed that congressional silence on preemption in the face of awareness of the longstanding operation of tort laws is persuasive evidence against a finding that state common law poses an obstacle to accomplishing federal objectives.[257] Reasoned agency explanations on preemption, as opposed to political or policy shifts in position or generalized statements of federal objectives, may be useful in assessing federal objectives, but the courts must make an independent assessment. Shifts in agency position on preemption are inherently suspect and should be met with skepticism. Consequently, deference to agency pronouncements on preemption is unwarranted, absent formal rulemaking on the subject. These features of the "new" presumption, primarily from *Levine* but born of the Court's struggle with implied obstacle preemption generally, give it significant teeth.

Recent cases involving FDA rules regarding food safety are good examples of the "new" presumption against preemption in implied obstacle conflict preemption. In *Fellner v. Tri-Union Seafoods, L.L.C.*, plaintiff argued that defendant should have warned of the risk of mercury poisoning from eating its canned tuna.[258] Defendant sought preemption based on various FDA actions amounting to a decision not to regulate and an FDA letter opining about the preemptive effect of its prior actions.[259] The Court of Appeals reminded us that it is *federal law* that preempts, not any federal action.[260] While formal rulemaking is not required, the informal agency positions taken regarding mercury in tuna did not suffice.[261] *Fellner* is an excellent example of a court aggressively challenging whether the proposed federal objectives that supposedly preempt state law reflect congressional intent.[262]

CONCLUSION

The presumption against preemption is part of the landscape of preemption jurisprudence, perhaps now more than at any time in recent memory. The Court has reaffirmed the presumption in several recent cases. While uncertainty remains about how it operates, this Article has identified a "new" presumption against preemption. A court must always be mindful of the "touchstone" of preemption: congressional intent. If a proponent of preemption has not established the "clear and manifest"

257. *See supra* notes 205–07 and accompanying text.
258. 539 F.3d 237, 241 (3d Cir. 2008).
259. *Id.* at 241–42.
260. *Id.* at 250.
261. *Id.* at 251–55.
262. *Id.* at 245.

intent to preempt in areas involving the historic police powers of the states, a case for preemption has not been made.

That intent can be established, first, through an express preemption provision. Such a provision should be narrowly interpreted in light of the presumption against preemption, which operates as a meaningful default rule in the absence of that clear and manifest intent. A court should be attentive to the legislative scheme, its structure, and purpose, all the while focusing on *congressional* intent, not the intent of those federal actors and others who profess a substitute for it.

Implied conflict preemption is a substitute for express congressional intent and, therefore, should be met with suspicion. The "new" presumption against preemption operates as a fundamental analytical backdrop, particularly in implied conflict preemption cases, to insure that traditionally operating state law is appropriately preserved. Conflict preemption analysis, either impossibility or obstacle, should maintain a laser-like focus on only those federal statutory objectives, or federal regulatory actions, with which state law purportedly conflicts. The line-drawing that creates a preemptive conflict must be precise. The Court's preemption doctrine demands it.