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On Restating Products Liability Preemption

Mary J. Davis[†]

The opportunity to reflect on the impact of the *Restatement (Third) of Torts: Products Liability*¹ since its adoption by the American Law Institute in 1998 and its interaction with the ever-changing preemption landscape is a fascinating one. Many have written on the subject of federal preemption of products liability actions generally² and on the narrower subject of preemption by particular federal regulatory action, whether by Congress directly or by an administrative agency.³ As a way of framing the discussion at the symposium celebrating the 10th Anniversary of the *Restatement (Third) of Torts: Products Liability*, (“*Products Liability Restatement*”), our organizers asked the following question: “Now that the Supreme Court has manifested a strong interest in federal preemption of common law personal-injury doctrine, should

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¹ RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. (1998).

² See generally THOMAS O. MCGARITY, THE PREEMPTION WAR: WHEN FEDERAL BUREAUCRACIES TRUMP LOCAL JURIES (2008); Richard C. Ausness, *Preemption of State Tort Law by Federal Safety Statutes: Supreme Court Preemption Jurisprudence Since Cipollone*, 92 KY. L.J. 913 (2004) (surveying Supreme Court preemption doctrine); Mary J. Davis, *On Preemption, Congressional Intent, and Conflict of Laws*, 66 U. PITT. L. REV. 181 (2004) (suggesting a conflict of laws analysis for preemption problems); Mary J. Davis, *Unmasking the Presumption in Favor of Preemption*, 53 S.C. L. REV. 967 (2002) [hereinafter Davis, *Unmasking the Presumption*] (providing an historical grounding in preemption cases and an introduction to the doctrine generally); Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449 (2008) (discussing institutional competence issues in federal preemption by agency action). This list is by no means intended to be exhaustive, but illustrates the richness of the scholarship in this area.

³ Most recently, the subject of preemption by the Federal Food and Drug Administration’s actions has been a popular subject because it involves not express preemption but implied preemption, which the Supreme Court has only addressed occasionally in recent years. The Court has decided an implied preemption case this term in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), involving preemption of state common law failure-to-warn claims based on FDA-approved pharmaceutical labeling. The *Wyeth* case and preemption by the FDA was the subject of lively debate at the Products Liability Restatement 10th Anniversary Symposium. I thank the other panel participants, Professor Robert Rabin, Malcolm Wheeler, and Sheila Birnbaum for the engaging discussion. For my position on that issue, see Mary J. Davis, *The Battle Over Implied Preemption: Products Liability and the FDA*, 48 B.C. L. REV. 1089 (2007) [hereinafter Davis, *The Battle Over Implied Preemption*]. For other writing on that subject, see Richard A. Epstein, *Why the FDA Must Preempt Tort Litigation: A Critique of Chevron Deference and a Response to Richard Nagareda*, 1 J. TORT LAW art. 5 (2006); Richard A. Nagareda, *FDA Preemption: When Tort Law Meets the Administrative State*, 1 J. TORT LAW art. 4 (2006); Peter H. Schuck, *FDA Preemption of State Tort Law in Drug Regulation: Finding the Sweet Spot*, 13 ROGER WILLIAMS UNIV. L. REV. 73 (2008).

this topic (omitted in 1998) join the Restatement?” The Reporters of the *Products Liability Restatement* correctly concluded, in section 4, comment e, dealing with the effect of statutes and regulations on liability, that, “The complex set of rules and standards for resolving questions of federal preemption are beyond the scope of this Restatement.”⁴ After almost two decades of struggle in the Supreme Court over products liability preemption, the subject is still beyond the scope of the *Products Liability Restatement*, or any Restatement project, and is likely to be so for a while.

Many reasons exist for the continuing state of uncertainty in preemption doctrine. Even though the Supreme Court has regularly decided cases involving preemption of products liability actions since its initial foray into the subject in 1992 in *Cipollone v. Liggett Group, Inc.*,⁵ the Court’s keen interest in the subject has not resulted in a predictable doctrinal approach.⁶ In addition, some have questioned the Supreme Court’s motives in addressing the subject so frequently, causing many observers to opine about the “politics of preemption,”⁷ which includes concerns about the doctrine’s relationship to tort reform movements⁸ and the tension, even among pro-preemption advocates, about unwarranted federal intrusion into spheres of traditional state regulation as a matter of respecting principles of federalism.⁹ Before *Cipollone*, the Supreme Court had not decided a products liability preemption case and had only rarely decided any case pitting state common law damages actions against a federal regulatory scheme.¹⁰ Since *Cipollone*, the Court has decided nine products liability preemption cases,¹¹ the most recent the

⁴ RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 4, cmt. e (1998).

⁵ 505 U.S. 504 (1992).

⁶ See *infra* notes 49-72 and accompanying text.

⁷ Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 229 (2000) (noting that “the politics of preemption are complicated”).

⁸ MARGARET H. CLUNE, CTR. FOR PROGRESSIVE REGULATION, STEALTH TORT REFORM: HOW THE BUSH ADMINISTRATION’S AGGRESSIVE USE OF THE PREEMPTION DOCTRINE HURTS CONSUMERS 1 (2004), available at <http://www.progressiveregulation.org/articles/preemption.pdf>; see also Terry Carter, *The Pre-emption Prescription*, 94 ABA J. 42, 46-47 (2008) (discussing the politics surrounding pharmaceutical preemption decisions).

⁹ See, e.g., Davis, *Unmasking the Presumption*, *supra* note 2, at 969 (“[P]reemption is about power and politics because it involves the fundamental balance of Congress’s power in relation to the states. . . . To the extent that the Supreme Court has something to say about the power struggle of federalism, it speaks, partially at least, through its preemption decisions.”); Nelson, *supra* note 7, at 229; Jeffrey Rosen, *Supreme Court Inc.*, N.Y. TIMES, Mar. 16, 2008, § MM (Magazine), at 38; see also Catherine M. Sharkey, *What Riegel Portends for FDA Preemption of State Law Products Liability Claims*, 102 NW. U. L. REV. COLL. 415, 417 & n.12 (2008) (noting that preemption decisions regularly involve policy decisions and describing the policy preference model of Supreme Court decision-making noted by political scientists).

¹⁰ See Davis, *Unmasking the Presumption*, *supra* note 2, at 998.

¹¹ *Wyeth v. Levine*, 129 S. Ct. 1187 (2009); *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008); *Warner-Lambert, Co. v. Kent*, 126 S. Ct. 1168 (2008) (per curiam); *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005); *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002); *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341 (2001); *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000); *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996); *Freightliner Corp. v. Myrick*, 514 U.S. 280 (1995). In addition, the Court decided two cases involving preemption of state tort claims

highly anticipated *Wyeth v. Levine*,¹² involving implied preemption of state law-based pharmaceutical failure-to-warn claims by the Federal Food and Drug Administration's (FDA's) product labeling approval decisions. The number of preemption decisions decided by the Court in the last two decades that involved common law damages actions is extraordinary, a record pace by any measure for a subject that had received only scant attention during the prior century.¹³ Given the Supreme Court's continuing interest in the subject of preemption,¹⁴ the relentless pursuit of preemption by regulated industries as a way to limit liability exposure, and the variety of issues presented by the cases,¹⁵ the continuing substantial uncertainty about the state of the doctrine counsels against any attempt to restate it.

To state the black-letter law of federal preemption would, in truth, be a fairly simple task.¹⁶ Preemption of state law stems from the Supremacy Clause of the United States Constitution¹⁷ which the Court has long held requires an assessment of Congressional purpose.¹⁸ To that end, the Court has defined express and implied preemption doctrines. Express preemption exists when a statutory provision provides the scope of Congress' intent to preempt, and its scope must be evaluated through an assessment of the statutory language, its structure, and, there is disagreement here, its purpose as discerned through the legislative history.¹⁹ Implied preemption doctrines substitute for Congress' express intent to preempt a judicial determination that Congress would have wanted federal laws to govern when state laws create an actual conflict with federal objectives or make it impossible to comply with both federal

by the Federal Railroad Safety Act, *Norfolk Southern Railway Co. v. Shanklin*, 529 U.S. 344 (1999), and *CSX Transportation, Inc. v. Easterwood*, 507 U.S. 658 (1993), and two cases involving preemption of state regulation under the federal cigarette labeling laws, *Altria Group, Inc. v. Good*, 129 S. Ct. 538 (2008) (no express preemption of state fraud-based consumer protection litigation), and *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001) (state cigarette advertising regulations expressly preempted).

¹² *Wyeth v. Levine*, 129 S. Ct. 1187 (2009). For a discussion of *Wyeth*, see *supra* notes 113-128 and accompanying text.

¹³ See Davis, *Unmasking the Presumption*, *supra* note 2, at 998.

¹⁴ See William N. Eskridge, Jr., *Vetogates*, Chevron, *Preemption*, 83 NOTRE DAME L. REV. 1441, 1442 (2008) ("In short, there are few topics relating the Supreme Court's statutory jurisprudence that are as important as agency inputs into preemption decisions, and none that are more important.").

¹⁵ From whether state consumer trade regulations are preempted by express preemption provisions, see *Altria Group, Inc.*, 129 S. Ct. 538, to whether product-specific labeling decisions impliedly preempt common law claims, see *Wyeth*, 129 S. Ct. 1187, it is clear that aggressive preemption arguments can continue to be expected.

¹⁶ See, e.g., DAVID G. OWEN, PRODUCTS LIABILITY LAW § 14.4 (2d ed. 2008).

¹⁷ U.S. CONST. art. VI, cl. 2 ("The Constitution, and laws of the United states which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land. . . .").

¹⁸ See *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963) (stating that "the purpose of Congress is the ultimate touchstone" in preemption analysis).

¹⁹ See *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). For the continuing debate on these seemingly straightforward principles, see *Altria Group, Inc.*, 129 S. Ct. 538 and the debate between the majority opinion of Justice Stevens and the dissenting opinion of Justice Thomas. *Altria Group, Inc.* is discussed *infra* notes 108-112 and accompanying text.

and state obligations.²⁰ Implementing implied preemption doctrines often requires judges to cut at the joint between overlapping federal objectives and important state prerogatives and, therefore, is a sensitive inquiry. A variety of factors has been important to the Court's implied preemption doctrine over the years²¹ and it might be possible to "restate" those in a catalogue-type way if one were so inclined.²²

Our symposium organizers likely asked the framing question rhetorically, however, understanding that the debate over preemption of products liability personal injury actions is about much more than the doctrine itself. It provides a much broader canvas than that. Rather, it provides the opportunity to examine a number of considerations that are not directly related to the details of preemption doctrine or whether that doctrine is ready to be "restated" in the American Law Institute way. That is why this opportunity is such a fascinating one.

The considerations to which I refer are both doctrinal and normative. They relate to the way preemption doctrine has evolved in the past two decades and to the question of whether the current trend in preemption doctrine, toward increased preemption of state common law personal injury actions, strikes the right balance between federal interests in certainty and uniformity of regulation and the interests of those harmed by the unrelenting risks produced by some regulated industries. The Supreme Court's own struggle over this balance supports a narrow vision of preemption doctrine. I also suggest that to restate preemption doctrine that codifies a rule that places the risk of uncertainty on the future victim of that risk, absent *unquestionable* congressional intent to do so, or *clear, focused* analysis that openly takes those victims' interests into account, does not strike that balance appropriately.

This Article provides a brief explanation of the state of preemption doctrine and explains how the Court altered, quite dramatically, its treatment of preemption of common law tort actions in the last two decades. The Court's almost exclusive focus on the interpretation of express preemption provisions, which never specifically address common law tort claims one way or the other, turned "traditional" preemption analysis of common law tort claims on its head. The Court then, almost as suddenly, signaled a retreat from the emphasis on express preemption analysis and returned, awkwardly, to implied preemption doctrine.²³ The Court has only recently begun meaningful

²⁰ See *Cipollone*, 505 U.S. at 516-17.

²¹ See Davis, *Unmasking the Presumption*, *supra* note 2, at 1013-14.

²² See, e.g., Davis, *The Battle Over Implied Preemption*, *supra* note 3, at 1138-51 (applying identified factors in implied conflict preemption to failure-to-warn claims involving pharmaceuticals).

²³ *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 884 (2000). The Court had foreshadowed this result in *Freightliner Corp. v. Myrick*, 514 U.S. 280, 288-89 (1995). For a discussion of *Geier*, see *infra* notes 55-59 and accompanying text.

modern analysis of implied preemption,²⁴ particularly with its decisions *Geier v. American Honda Motor Co.*²⁵ and *Wyeth v. Levine*,²⁶ and that doctrine will require years of fleshing out by the Court's current members.²⁷ After describing the current, uneasy state of preemption doctrine, this Article will provide a few observations about the normative inquiry regarding what preemption doctrine should, and should not, be accomplishing.

The effort to identify congressional intent to preempt has always been central to the preemption inquiry. As mentioned earlier, under the command of the Supremacy Clause of the Constitution,²⁸ the Court has obligated itself to identify and follow the "clear and manifest purpose of Congress"²⁹ to assess the preemptive scope of federal legislation. It must be remembered that before *Cipollone* in 1992, the Court had only rarely found common law tort claims to be contained within the scope of any express preemption provision, much less had it found such claims impliedly preempted.³⁰ With its opinion in *Cipollone*, the Court began in earnest to shift the focus on determining congressional intent by inquiring into the plain or ordinary meaning of the terms of express preemption provisions.³¹

Cipollone is an example of the difficulty of that inquiry as it applies to common law tort claims. The case involved the question of whether the preemption provision of the federal cigarette labeling laws, the Federal Cigarette Labeling Act of 1965, as amended by the Public Health Cigarette Smoking Act of 1969,³² preempted tort claims arising out of cigarette smoking-related health problems.³³ Neither statute

²⁴ *Geier*, 529 U.S. 861, and *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002), both involved express preemption provisions that the Court concluded did not preempt the claims in issue and implied conflict preemption analyses which supported preemption in *Geier* but not in *Sprietsma*. See *infra* notes 55-59, 69-71 and accompanying text; see also Davis, *The Battle Over Implied Preemption*, *supra* note 3, at 1124-27, 1129-30.

²⁵ 529 U.S. 861 (2000).

²⁶ *Wyeth v. Levine*, 129 S. Ct. 1187 (2009).

²⁷ Indeed, watching how the Justices line up on the preemption scorecard has been somewhat of a pastime for many observers of preemption jurisprudence. See, e.g., Sharkey, *supra* note 9, at 419, 428-29 (discussing the unusual 8-to-1 decision in *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008), involving Medical Device Amendments preemption). After attempting to predict how the Court would answer the Federal Boat Safety Act preemption question in *Sprietsma v. Mercury Marine*, I have given up on prognosticating where preemption is concerned. See Davis, *Unmasking the Presumption*, *supra* note 2, at 1025-28.

²⁸ U.S. CONST. art. VI, cl. 2. For a thorough analysis of the history of this provision and its meaning in historical context, see Nelson, *supra* note 7, at 232-64.

²⁹ *Rice v. Sante Fe Elevator Corp.*, 331 U.S. 218, 230 (1947); *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978) (congressional intent is "the ultimate touchstone" of preemption analysis (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963))).

³⁰ See Davis, *Unmasking the Presumption*, *supra* note 2, at 998.

³¹ *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992) (stating that express preemption controls when it provides "reliable indicium of congressional intent" to be discerned by interpretation of statutory language (quoting *Malone*, 435 U.S. at 505)).

³² 15 U.S.C. §§ 1331-1341 (2006); *Cipollone*, 505 U.S. at 514-15.

³³ *Cipollone*, 505 U.S. at 508-09.

specifically mentioned common law damages claims, but rather stated, respectively, that the states may not impose any “statement” or “requirement or prohibition” “relating to smoking and health” in cigarette packaging or advertising.³⁴ All the Justices in *Cipollone* agreed that the preemption analysis should proceed by an interpretation of the scope of the express preemption provision,³⁵ but that is where the agreement ended.

The majority opinion, authored by Justice Stevens,³⁶ summarized the state of preemption doctrine and then engaged in a “fair[] but . . . narrow[]” interpretation of the provisions in issue with sensitivity to the presumption against preemption where matters historically within the police powers of the state are involved.³⁷ The majority concluded, therefore, that the 1965 Act did not preempt any common law tort actions.³⁸ A plurality of Justices then concluded that the 1969 Act’s language, preempting state law “requirements or prohibitions,” preempted some but not all of the claims.³⁹ Even the plurality was not entirely true to the task of fair but narrow statutory interpretation based on the presumption against preemption: the plurality found that the 1969 Act preempted some claims because of the change in the preemption provision’s language, even though Congress specifically stated in the legislative history of the 1969 Act that it did not intend to alter the scope of the preemption provision from its previous version.⁴⁰

Three concurring Justices found no express preemption at all, resting on the premise that common law damages actions have at most an indirect regulatory effect and, therefore, do not impose either requirements or prohibitions inconsistent with Congress’ intent.⁴¹ Justice Blackmun, speaking for this group, recognized the Court’s long tradition of declining “to find the regulatory effects of state tort law direct or

³⁴ *Id.* at 514-15 (citing 15 U.S.C. § 1334).

³⁵ *See id.* at 516; *id.* at 531 (Blackmun, J., concurring in part and dissenting in part); *id.* at 545-46 (Scalia, J., concurring in part and dissenting in part).

³⁶ Justice Stevens has authored many of the Court’s preemption opinions including, in addition to *Cipollone*, the opinions of the Court in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002), *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), and, most recently, *Altria Group, Inc. v. Good*, 129 S. Ct. 538 (2008), which confirms the viability of the plurality opinion’s analysis in *Cipollone*.

³⁷ *Cipollone*, 505 U.S. at 518, 523 (plurality opinion).

³⁸ *Id.* at 519-20.

³⁹ *Id.* at 521.

⁴⁰ *Id.* (“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.”) (quoting Public Health Cigarette Smoking Act of 1969, 15 U.S.C. § 1334(b) (2006)). The plurality opinion found partial preemption of those damages actions whose predicate is a “requirement or prohibition based on smoking and health.” *Id.* at 524. The Court dismissed Congress’ statement in the legislative history regarding no intended change in scope of the preemption provision as inconsistent with the plain meaning of the statute’s language. *Id.* at 520-21 & n.19.

⁴¹ *Id.* at 535-36 (Blackmun, J., concurring in part and dissenting in part).

substantial enough to warrant pre-emption.”⁴² The two remaining Justices, Scalia and Thomas, found complete preemption based on the “apparent meaning” of the same words.⁴³ So, the stage was set for decades of confusing express preemption analysis and relentless arguments that Congress intended words like “requirements” to include common law damages actions.

The *Cipollone* court also addressed the presumption against preemption of state law in areas involving the historic police powers of the state, including matters of public health and safety.⁴⁴ The Court disagreed about the presumption then, and continues to disagree about it.⁴⁵ The *Cipollone* plurality said that express preemption provisions should be fairly but narrowly interpreted, being informed by an understanding of the value of the long tradition of tort law that complemented federal regulation of public health and safety.⁴⁶ That understanding reflected the federalism balance struck by historical preemption jurisprudence over the previous seventy years.⁴⁷ Implied preemption played no role in *Cipollone*, though the Court had emphasized implied preemption analysis in its discussion of preemption of common law damages actions throughout history.⁴⁸

The Court’s post-*Cipollone* opinions have been similarly fractured, though in differing ways. First, the Court has continued to struggle with determining the scope of express preemption provisions. *Medtronic, Inc. v. Lohr*,⁴⁹ involving the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act, is another example of the Court’s struggle with express preemption principles.⁵⁰ In *Lohr*, the

⁴² *Id.* at 537.

⁴³ *Id.* at 544 (Scalia, J., concurring in part and dissenting in part). Justice Scalia’s dissent figures prominently in Justice Thomas’ dissent in *Altria Group, Inc. v. Good*, 129 S. Ct. 538, 551 (2008) (Thomas, J., dissenting), discussed *infra* note 110 and accompanying text.

⁴⁴ *Cipollone*, 505 U.S. at 518. For a fuller discussion of the “presumption against preemption,” see Davis, *Unmasking the Presumption*, *supra* note 2.

⁴⁵ See Davis, *The Battle Over Implied Preemption*, *supra* note 3, at 1132-34; Davis, *Unmasking the Presumption*, *supra* note 2, at 1013-14.

⁴⁶ *Cipollone*, 505 U.S. at 516.

⁴⁷ See Davis, *Unmasking the Presumption*, *supra* note 2, at 972-97.

⁴⁸ See *id.*

⁴⁹ *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

⁵⁰ The preemption provision of the MDA, added to the FDCA in 1976 and at issue in *Lohr*, stated that states may not impose “requirement[s] . . . different from or in addition to” any federal requirement “relate[d] to safety or effectiveness.” 21 U.S.C. § 360k(a) (2006). The three opinions in *Lohr* revisited the disagreement begun in *Cipollone* over whether “requirement” was intended to mean common law damages actions and how express preemption provisions were to be read, whether neutrally or with an understanding of the presumption against preemption in the case of historic state police powers. See Davis, *Unmasking the Presumption*, *supra* note 2, at 1002-04. Five justices found that the provision did not preempt any claims against the medical device manufacturer, with Justice Breyer’s concurrence being critical to the holding. *Lohr*, 518 U.S. at 503 (Breyer, J., concurring). He suggested that common law damages actions could be requirements, but they were not intended to be so based on the preemption provision’s language and the FDA’s regulation implementing the provision. *Id.* at 503-04. For additional discussion of *Lohr* and MDA preemption, see Richard C. Ausness, “After you, My Dear Alphonse!”: Should the Courts Defer to

manufacturers of a medical device that had been approved under a grandfathering method known as pre-market notification argued that the MDA's preemption provision preempted common law tort claims based on alleged defects in the device's design, warning, and manufacture.⁵¹ The Court was again divided on the meaning of the term "requirements," with a plurality considering that it did not preempt the claims in issue under a narrow interpretation of the statute and its implementing regulations,⁵² but a majority, four in dissent and one concurring in the result, disagreed.⁵³

With such disagreement, it is no wonder that commentators opined that *Medtronic, Inc. v. Lohr* was a "veiled implied preemption analysis"⁵⁴ in express preemption clothing, because the Justices continued to debate whether Congress intended to include common law damages actions within the meaning of the term "requirement." Those commentators might be called prescient. Four years later in *Geier v. American Honda Motor Co.*,⁵⁵ the Court found that an express preemption provision, arguably clearer than that involved in *Lohr*, which prohibited state "standards" that were not identical to the statutorily-defined minimum federal standards in issue, did *not* expressly preempt a design defect claim based on failure to include an air bag, but that implied conflict preemption principles did bar the claim.⁵⁶ This result is even more remarkable given that the legislation in issue, the National Traffic and Motor Vehicle Safety Act (NTMVSA),⁵⁷ contains a savings clause, which states that compliance with a federal standard "does not exempt a person from liability at common law."⁵⁸ The majority opinion in *Geier* said nothing about the presumption against preemption nor did it engage in a particularly meaningful evaluation of the actual terms of the express preemption provision, as one would have expected after *Cipollone* and *Lohr*.⁵⁹

the FDA's New Interpretation of § 360k(a) of the Medical Device Amendments?, 80 TUL. L. REV. 727, 767-75 (2006); Davis, *Unmasking the Presumption*, *supra* note 2, at 1002-04.

⁵¹ *Lohr*, 518 U.S. at 480-83.

⁵² *Id.* at 492-94.

⁵³ *Id.* at 508 (Breyer, J., concurring in part and concurring in the judgment); *id.* at 509 (O'Connor, J. concurring in part and dissenting in part).

⁵⁴ See Davis, *Unmasking the Presumption*, *supra* note 2, at 1004.

⁵⁵ 529 U.S. 861 (2000).

⁵⁶ *Id.* at 865-87.

⁵⁷ The NTMVSA of 1966, 15 U.S.C. §§ 1381-1431 (1988) (repealed 1994), is currently codified at 49 U.S.C. §§ 30101-30169 (2000).

⁵⁸ 15 U.S.C. § 1397(k) (1988). I am delighted to have been able to discuss *Geier* with Malcolm Wheeler, Wheeler Trigg Kennedy LLP, at the symposium. Malcolm successfully argued *Geier* for the defendants. I happen to agree with the dissent in *Geier* that neither express nor implied preemption were justified. *Geier*, 529 U.S. at 886 (Stevens, J., dissenting). See generally Ralph Nader & Joseph A. Page, *Automobile-Design Liability and Compliance with Federal Standards*, 64 GEO. WASH. L. REV. 415 (1996) (arguing against preemption under NTMVSA).

⁵⁹ See Davis, *Unmasking the Presumption*, *supra* note 2, at 1006-07.

The implied preemption analysis from *Geier* is an important modern exploration by the Court of implied conflict preemption and for that reason is likely to be very influential going forward.⁶⁰ The Court did not discuss the presumption against preemption *per se*⁶¹ but did identify features of the air bag regulatory scheme and its history that informed the assessment of actual conflict. The Court reviewed a wide range of factors in determining actual conflict: the history of the regulation, the views of the various Secretaries of Transportation on the objectives of the standard, as well as the published comments to the various versions of the standard.⁶² The obvious effort by Department of Transportation officials to balance the interests of the regulated industry and the consuming public during the evolution of the standard influenced the Court in its determination that state tort laws would have an impermissible impact on the implementation of those objectives.⁶³ The Court also discussed the relevance of the Secretary's position on preemption and how much weight to place on the Department of Transportation's assessment of conflict.⁶⁴ The lack of a formal statement on preemption was not determinative, though the Court seemed uneasy about how to treat less-than-formal expressions of agency position.⁶⁵

In the eight years between *Cipollone* and *Geier*, then, the Court's preemption doctrine stood on shifting sand. With every new case, the Court resisted discussing the "presumption against preemption" and struggled with how to balance the historic role of state tort law in regulating product safety. Subsequent cases continued to reflect that conflict. In *Buckman Co. v. Plaintiffs Legal Committee*,⁶⁶ the Court conducted an implied preemption analysis under the Medical Device Amendments, after quickly concluding that the plaintiff's fraud-on-the-FDA claims were not expressly preempted.⁶⁷ Because policing fraud on a federal agency was uniquely federal and not traditionally governed by the states, the Court concluded that the presumption against preemption

⁶⁰ See Davis, *The Battle Over Implied Preemption*, *supra* note 3, at 1124-27. The Court discussed *Geier* at length in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), in applying implied preemption principles to the pharmaceutical labeling claims involved there. The FDCA does not have an express preemption provision related to its pharmaceutical approval provisions. See *Wyeth*, 129 S. Ct. at 1195-96 (discussing history of FDCA and noting that Congress did not include an express preemption provision for pharmaceutical approvals when it added the express preemption provision in the Medical Device Amendments in 1976); see also Caraker v. Sandoz Pharm. Corp., 172 F. Supp. 2d 1018, 1035 (S.D. Ill. 2001) (explaining that the portion of FDCA dealing with pharmaceuticals does not contain a preemption provision).

⁶¹ *Geier*, 529 U.S. at 869-72; see also *id.* at 894 (Stevens, J., dissenting).

⁶² *Id.* at 877-85.

⁶³ *Id.* at 882-83. For a more elaborate discussion of the *Geier* implied conflict preemption analysis, see Davis, *The Battle Over Implied Preemption*, *supra* note 3, at 1124-27.

⁶⁴ *Geier*, 529 U.S. at 883.

⁶⁵ *Id.* at 884-85.

⁶⁶ 531 U.S. 341 (2001).

⁶⁷ *Id.* at 347-48.

did not operate and that the state-law based claims were preempted.⁶⁸ In *Sprietsma v. Mercury Marine*,⁶⁹ the Court similarly concluded that the Federal Boat Safety Act of 1971 did not expressly preempt design defect claims based on a failure to equip a recreational vessel with a propeller guard even though the Coast Guard had studied the matter and declined to require the guards.⁷⁰ The Court also found no implied preemption because the Coast Guard regulations preserved state authority in the absence of federal action, and the Coast Guard previously had been in favor of permitting state common law claims.⁷¹ The Court in *Sprietsma* *unanimously* concluded that the more prominent safety objective in the federal statutory scheme justified maintaining complementary common law remedies.⁷² The unanimity was remarkable in itself for a subject about which the Court had been so fractured.

At this point, it would be well to highlight the importance of federal agency position on preemption analysis.⁷³ One of the main issues in preemption analysis present in virtually every case, except *Cipollone*, is how much weight to give the relevant federal agency's position on the matter. An agency position articulating the federal objectives at stake and assessing whether those objectives preempt state tort claims might properly inform the preemption analysis as a substitute for congressional intent when determining whether an actual conflict exists. The Court has recognized the need, in some cases, to defer to agency interpretations of statutes and administrative regulations, but whether to defer to agency position on preemption of state common law has proved more troublesome. *Medtronic, Inc. v. Lohr*, involved an FDA regulation implementing the statutory preemption provision; the majority opinion was "substantially informed" by that regulation because it had been formally adopted and because of the agency's "unique role" enforcing the statute.⁷⁴ *Geier v. American Honda Motor Co.*, "place[d] some weight" on the position of the Department of Transportation, DOT, in favor of preemption, but did not defer to it.⁷⁵ The Court in *Sprietsma*, as just mentioned, was heavily influenced by the Coast Guard's position

⁶⁸ *Id.*

⁶⁹ 537 U.S. 51 (2002).

⁷⁰ *Id.* at 59-60.

⁷¹ *Id.* at 64-66. Like the NTMVSA, the FBSA had both an express preemption provision and a savings clause. *Id.* at 62-63 (applying 46 U.S.C. §§ 4301-4311 (2000)).

⁷² *Id.* at 69-70.

⁷³ Many have discussed the importance of agency position in preemption analysis. *See generally* Eskridge, *supra* note 14; Nina Mendelson, *Chevron and Preemption*, 102 MICH. L. REV. 737 (2004); Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227 (2007); *see also* Ausness, *supra* note 50, at 767-75.

⁷⁴ *Medtronic, Inc. v. Lohr*, 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 505-06 (Breyer, J., concurring).

⁷⁵ *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 881-83 (2000).

against preemption. The importance of agency position on preemption, and the uncertainty regarding the Court's position on the matter, has compounded the uneasiness of preemption analysis.

*Bates v. Dow Agrosciences LLC*⁷⁶ offered hope that stability might have come to the Court's express preemption analysis. The Court was presented with an express preemption provision, this time from the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).⁷⁷ The Court, speaking through Justice Stevens, made some important general observations about the delicate balance that must be achieved in determining the scope of such provisions, and about the effect of shifting agency position on preemption analysis. First, the Court gave an uncharacteristic endorsement of the longstanding value of tort law as a catalyst in the effort to enhance public safety.⁷⁸ I say "uncharacteristic" because the Court's opinions had most recently failed even to discuss the presumption against preemption, much less the value of tort law in enhancing public safety.⁷⁹ The Court employed the narrow express preemption analysis it described in *Cipollone*, specifically rejecting the conclusion that common law jury verdicts are the equivalent of "requirements" simply because they may influence decision-making.⁸⁰ The Court also rejected as irrelevant speculation over whether a jury verdict might affect a manufacturer's conduct,⁸¹ and described the proper inquiry as an examination of the predicate "common-law dut[ies] in issue" to determine whether Congress intended that they be preempted.⁸²

The Court concluded that the express preemption provision preempted very few claims.⁸³ The Court 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."⁸⁴ The Court also expressed a sense of frustration at the way the lower courts had broadly read the term

⁷⁶ 544 U.S. 431 (2005).

⁷⁷ 7 U.S.C. § 136 (2006).

⁷⁸ *Bates*, 544 U.S. at 449-51.

⁷⁹ *Id.* at 441. The Court also observed that it was not until *Cipollone* that preemption arguments based on the notion that "requirements" includes common law tort claims began to flood the courts. *Id.*

⁸⁰ *Id.* at 445.

⁸¹ *Id.* ("This effects-based test finds no support in the text of § 136v(b), which speaks only of requirements. A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement.") (internal quotation marks omitted).

⁸² *Id.* ("The inducement test is unquestionably overbroad . . .").

⁸³ *Id.* at 451-52.

⁸⁴ *Id.* at 449; *see also id.* at 459 (Thomas, J., concurring 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 preemption. This reluctance reflects that preemption 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.") (citations omitted) (also endorsing a narrow view of cases in which implied preemption is permitted).

“requirements” after *Cipollone*, and chastised the “too quick conclusion”⁸⁵ that claims were also, therefore, preempted under FIFRA.

Bates also raised the importance of agency position on preemption. The regulating agency, the Environmental Protection Agency, had shifted its position on preemption in the previous five years from being against it to being for it.⁸⁶ The Court was not influenced by that shift in position.⁸⁷ Rather, the Court noted that “if Congress had intended to [prevent the operation] of a long available form of compensation, it surely would have expressed that intent more clearly.”⁸⁸ The Court endorsed the notion that common law tort claims, enforced by private parties, “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.”⁸⁹ The concern expressed by the defendant and the EPA that “tort suits led to a ‘crazy-quilt’ of FIFRA standards or otherwise created a 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.”⁹⁰ The Court’s skepticism about the sincerity of agency position on preemption after such a shift is palpable.

By 2005, one could fairly describe the Court’s preemption personality as a bit Jekyll-and-Hyde-like. Which analysis will apply, express or implied preemption? If express preemption analysis applies, will it be fair but narrow, or something else? Does a presumption against preemption exist or not? What is the role of agency position on preemption? Even with such open questions, I might have suggested that federal preemption doctrine was approaching stasis. After *Bates*, it looked as if express preemption analysis was taking a more certain shape, and, after *Geier* and *Sprietsma*, that implied preemption had the same potential. But in its 2007-08 term, in *Riegel v. Medtronic, Inc.*,⁹¹ by finding express preemption under the Medical Device Amendments for devices that satisfied the pre-market approval process, the Court again reflected an aggressive pro-preemption inclination in spite of *Sprietsma* and *Bates*.⁹² Some observers describe *Riegel* as a fairly narrow application of the MDA express preemption provision and a logical extension of *Medtronic, Inc. v. Lohr*.⁹³ As to the application of the MDA preemption provision to the pre-market approval process, that may be so.

⁸⁵ *Bates*, 544 U.S. at 446 (majority opinion).

⁸⁶ *Id.* at 436-37 & n.7, 449.

⁸⁷ *Id.* at 449.

⁸⁸ *Id.*

⁸⁹ *Id.* at 451.

⁹⁰ *Id.* at 451-52.

⁹¹ 128 S. Ct. 999 (2008).

⁹² *Id.* at 1006-11.

⁹³ See Sharkey, *supra* note 9, at 415 nn.3-4.

The Court's language, however, is gratuitous in its criticism of the role of common law tort claims and expansive in its description of the scope of express preemption where it had not been before.

There are several reasons that I consider *Riegel* to be an unwarranted extension of preemption doctrine, and these reasons support my position that the time has not come to "restate" products liability preemption doctrine. First, *Riegel* purports to be yet another statement on how to read express preemption provisions, but it is much broader than its predecessors. It is an example of the bankruptcy of the idea that express preemption analysis is a search for the clear and manifest intent of Congress. In interpreting, now for the second time, the MDA express preemption provision which preempts state "requirements" different from or in addition to those required by federal regulations, there is little discussion of Congress' intent. The Court's discussion of the issue in *Lohr* had been badly fractured and so *Riegel* provided an opportunity to explore and clarify the matter. Instead, the Court failed to continue the dialogue begun in *Lohr* about the regulatory effect of common law damages actions within the structure of the MDA.⁹⁴ I realize that some members of the Court are reluctant to explore legislative purposes and history in statutory interpretation, but even under an "apparent" meaning analysis, the Court could have explored what Congress' intent was in this regard, as it had in prior cases. The Court appears committed to the position that "requirements" includes common law tort claims, so I will not tarry too long expressing my disagreement with this conclusion. I will, however, direct all readers to Justice Ginsburg's persuasive dissent in *Riegel* on this point.⁹⁵

In lieu of an analysis of congressional intent as the touchstone of preemption analysis, the Court states: "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."⁹⁶ Of course, the MDA was written in 1976 long before the Court's current dictionary of definitions was taking shape. Nevertheless, it is fair to say that the Court's pronouncement, which was joined by eight Justices, stands in stark contrast to the decision in *Bates*, just three years earlier, that was significantly more circumspect on the meaning of the term "requirement." One is left to wonder what meaning

⁹⁴ *Riegel*, 128 S. Ct. at 1007-08. Instead, the Court explains its conclusion about what "requirements" means from its own discussion of the term, in *Bates* involving a statute written in the 1940s, and in *Cipollone* involving statutes written in the 1960s. *Id.*

⁹⁵ *Id.* at 1013 (Ginsburg, J., dissenting). Justice Stevens, the author of *Cipollone*, *Medtronic, Inc.*, *Sprietsma*, and *Bates*, concurred on the scope of "requirements" because it is consistent with the result in *Medtronic, Inc.* See *Riegel*, 128 S. Ct. at 1011-13 (Stevens, J., concurring in part and dissenting in part). Prof. Rabin's remarks on this topic at the symposium are relevant as well. See Robert L. Rabin, *Territorial Claims in the Domain of Accidental Harm: Conflicting Conceptions of Tort Preemption*, 74 BROOK. L. REV. 987 (2009).

⁹⁶ *Riegel*, 128 S. Ct. at 1008.

words will have ten, twenty, or thirty years from now, shorn of their connection either to ordinary meaning or congressional intent.

Second, while defining the “normal meaning” of the term “requirement” for future congresses, the Court displayed its contempt for common law tort actions. According to the *Riegel* court, tort law as applied by juries is simply unfit to regulate. It is “less deserving of preservation” than other state regulations.⁹⁷ Juries are incapable of balancing costs and benefits adequately as they “see[] only the costs of a more dangerous design, and [are] not concerned with [the] benefits” consumers reap by the manufacturer’s design choices.⁹⁸ 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.⁹⁹ Whether one agrees or disagrees with these remarks, there is certainly little, if anything, left of the historic place that state tort law held in regulating public safety in them, and certainly little in common with Justice Stevens’ remarks on that score in *Bates*. Such comments also seem to have no place in an opinion analyzing the meaning of a term used by a Congress, writing in 1976, in response to the design and warning labeling failures of the medical device industry which had prompted enactment of the legislation.¹⁰⁰ Remarks such as these also give credence to the criticism that the Court is taking a political and policy position in its preemption doctrine, rendering its opinions unnecessarily activist.

Third, the *Riegel* court discusses, 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 language was clear.¹⁰¹ The FDA had recently changed its position on the scope of the MDA preemption provision as it applied to the pre-market approval process.¹⁰² It has also done so in a high-profile way in the pharmaceutical labeling implied preemption cases.¹⁰³ While largely dicta, the Court’s statements displayed some sympathy for the proposition that *recent* agency position may be relevant to an assessment of current preemptive scope, despite longstanding contrary agency position.¹⁰⁴ Some of the Court’s earlier pronouncements on this matter differ from its

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ *Id.* at 1003; *see also id.* at 1014-15 (Ginsburg, J., dissenting) (chronicling the history of the MDA and the Dalkon Shield intrauterine device litigation which prompted it).

¹⁰¹ *Id.* at 1009 (majority opinion).

¹⁰² *Id.*

¹⁰³ *See Davis, The Battle Over Implied Preemption, supra* note 3, at 1108-11.

¹⁰⁴ *Riegel*, 128 S. Ct. at 1009 (“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.”).

discussion in *Riegel*.¹⁰⁵ Both opinions in *Riegel* recognize the centrality of the issue to implied preemption doctrine, and to the pharmaceutical labeling case of *Wyeth v. Levine* in particular.¹⁰⁶

Riegel does not display the search for balance in preemption doctrine reflected in the Court's other opinions. The respect for the traditional longstanding role of the common law is absent. Express preemption doctrine has some semblance of predictability and stability though that predictability is not sufficiently connected to congressional intent as it is supposed to be. An example of this disconnect in express preemption analysis may be found in *Altria Group, Inc. v. Good*,¹⁰⁷ decided after *Riegel* and which involved whether the plurality opinion in *Cipollone*, defining the claims that survived express preemption under the cigarette labeling laws, had continuing validity after the ensuing sixteen years of preemption doctrine.¹⁰⁸ I would have expected, after *Riegel* and its 8-to-1 opinion in favor (in dicta, at least) of a more expansive reading of express preemption provisions, that Justice Stevens' plurality opinion in *Cipollone* was destined for extinction, but I would have been wrong. In what can only be described as a stunning turn of events in preemption doctrine, Justice Stevens, joined by Justices Breyer, Ginsburg, Kennedy, and Souter, held that the plurality opinion of *Cipollone* does, indeed, control the express preemption analysis of that statute.¹⁰⁹ The majority opinion rejected the broader scope of preemption analysis proposed by Justice Scalia in *Cipollone*, and advocated in *Altria Group* by Justice Thomas for the dissent,¹¹⁰ 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."¹¹¹ Justice Stevens returned in *Altria Group* to his opinion in *Bates* and endorsed the presumption against preemption and a fair but narrow reading of the scope of express preemption.¹¹² One is also left to wonder what to make of the continuing validity of the definition of the term "requirements," fashioned by the majority opinion in *Riegel*.

As if the Court's recent flurry of preemption decisions was not enough to digest, the Court agreed to decide in its 2008-09 term an implied preemption case involving claims challenging the adequacy of

¹⁰⁵ See discussion of *Bates v. Dow Agrosciences LLC*, *supra* notes 76-88 and accompanying text; see also Sharkey, *supra* note 9, at 423.

¹⁰⁶ *Riegel*, 128 S. Ct. at 1009; *id.* at 1017-19 (Ginsburg, J., dissenting).

¹⁰⁷ 129 S. Ct. 538 (2008).

¹⁰⁸ *Id.* at 541-42.

¹⁰⁹ *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*, 505 U.S. 504, 529 (1992)).

¹¹⁰ *Id.* at 545 n.7; see *id.* at 552-54 (Thomas, J., dissenting).

¹¹¹ *Id.* at 545 n.7 (majority opinion).

¹¹² See *id.* at 543.

federally approved pharmaceutical labeling, *Wyeth v. Levine*.¹¹³ The FDA's high profile change in position in favor of preemption of common law tort claims based on its labeling approval decisions began to make its way into briefs on the issue in 2004.¹¹⁴ Many lower courts had struggled with implied preemption doctrine in these cases, and what to make of the FDA's recent position shift in that analysis.¹¹⁵ The FDA also described that shift in a very controversial discussion in the preamble to a 2006 pharmaceutical labeling regulation.¹¹⁶ After *Riegel* and the open debate between Justice Scalia in the majority and Justice Ginsburg in dissent over the scope of implied preemption in pharmaceutical labeling cases and the relevance of agency position on preemption, many observers, including several at the symposium, expected the Court to find a narrow ground on which to preempt the claims in issue in *Wyeth*. But, again, the Court's preemption decisions defy prediction. The Court, speaking through Justice Stevens with a six-to-three majority, found that the FDA's product labeling approvals did not impliedly preempt Levine's tort claims.¹¹⁷

Wyeth involved the anti-nausea drug Phenergan which was approved in 1955.¹¹⁸ Ms. Levine had been injected with the drug to alleviate symptoms from a migraine headache and, through inadvertent injection into an artery, gangrene, a known side effect, resulted and her arm eventually had to be amputated.¹¹⁹ Wyeth knew about the risk of intra-arterial injection, had warned about it in a section of the labeling, and that labeling had been approved over the years by the FDA.¹²⁰ Ms. Levine claimed that the labeling inadequately warned of the risk of gangrene, and the jury agreed.¹²¹ The Vermont Supreme Court affirmed a lower court ruling that Ms. Levine's claims were not impliedly preempted by the FDA's labeling approvals.¹²²

Wyeth made two separate preemption arguments: first that it would have been impossible for it to comply with the state law duty to warn without violating federal law.¹²³ Wyeth argued that it would have been a violation of federal regulations to alter the Phenergan label

¹¹³ 129 S. Ct. 1187 (2009).

¹¹⁴ See Davis, *The Battle Over Implied Preemption*, *supra* note 2, at 1090.

¹¹⁵ See, e.g., Colacicco v. Apotex, Inc., 521 F.3d 253 (3d Cir. 2008), *vacated*, No. 08-437, 2009 WL 578682 (Mar. 9, 2009); Tucker v. SmithKline Beecham, 596 F. Supp. 2d 1225 (S.D. Ind. 2008); Knipe v. SmithKline Beecham, 583 F. Supp. 2d 553 (E.D. Pa. 2008).

¹¹⁶ Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3922, 3934 (Jan. 18, 2006).

¹¹⁷ *Wyeth*, 129 S. Ct. at 1191.

¹¹⁸ *Id.* at 1192.

¹¹⁹ *Id.* at 1191.

¹²⁰ *Id.* at 1192.

¹²¹ *Id.* at 1192-93.

¹²² *Levine v. Wyeth*, 944 A.2d 179 (Vt. 2007).

¹²³ *Wyeth*, 129 S. Ct. at 1193, 1196.

without first obtaining FDA approval.¹²⁴ The Court disagreed after a thorough exploration of the labeling approval regulations which permitted pharmaceutical manufacturers to alter product labels to add or strengthen a warning.¹²⁵ 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.¹²⁶ The Court noted that impossibility preemption is “a demanding defense”¹²⁷ and that it would require “clear evidence” of impossibility to succeed.¹²⁸ This guidance on implied conflict preemption involving arguments of impossibility will be a welcome addition to the Court’s jurisprudence in this area.

Of greater importance, however, is the Court’s discussion of general implied preemption principles relating to obstacle conflict preemption. Borrowing from the analysis in *Geier* which supported implied conflict preemption, Wyeth had argued that plaintiff’s tort claims are 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,’”¹²⁹ and that set both a floor and a ceiling for drug regulation.¹³⁰ The Court emphatically rejected these arguments, noting they rely on an “untenable interpretation” of congressional intent and “an overbroad view” of an agency’s power to preempt state law.¹³¹

After *Riegel*, the Court could not have been expected to so boldly embrace the regulatory value of state tort law, but it did, reiterating adherence to the presumption against preemption.¹³² It explored congressional purposes behind the labeling provisions by reviewing how the history of those provisions illuminated Congress’ attitude toward complementary state tort litigation. The Court concluded that, “If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express preemption provision at some point during the FDCA’s 70-year history.”¹³³ Adding to its conclusion that Congress did not consider state tort law to be an obstacle

¹²⁴ See *id.* at 1197.

¹²⁵ *Id.* at 1196-97.

¹²⁶ *Id.* at 1196-99.

¹²⁷ *Id.* at 1199.

¹²⁸ *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 requirement.”).

¹²⁹ *Id.* at 1199 (quoting Brief for Petitioner at 46, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249)).

¹³⁰ *Id.*

¹³¹ *Id.*

¹³² *Id.* at 1194-95; see also *id.* at 1195 n.3 (“We rely on the presumption because respect for the States as ‘independent sovereigns in our federal system’ leads us to assume that ‘Congress does not cavalierly preempt state-law causes of action.’” (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996))).

¹³³ *Id.* at 1200.

to achieving federal objectives in the area of pharmaceutical labeling, the Court rejected as irrelevant the FDA's "mere assertion" that state law poses an obstacle.¹³⁴ Finding this position at odds with the available evidence of Congress' purposes, the Court explored the many ways that tort law acts as a complementary form of drug regulation.¹³⁵

After the discussion in *Riegel* about the negative impact that tort verdicts have on regulated industries, the discussion in *Wyeth* seems to be coming from an entirely different court. Compare the following language from *Wyeth* with earlier remarks from *Riegel*:

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.¹³⁶

These comments sound like those of Justice Stevens in *Bates* and are a welcome return to greater balance between the role of state tort law and the need to give federal regulation the breathing room that Congress intended, but no more.

Finally, because *Wyeth* had relied on *Geier* for many of its implied preemption arguments, the Court distinguished *Geier* by noting the significant differences in the two regulatory schemes.¹³⁷ *Geier* involved a formal agency rule-making with a contemporaneous plan to implement the defined objectives.¹³⁸ *Wyeth* did not. On this point, Justice Breyer noted in concurrence that "it is also possible that state tort law will sometimes interfere with the FDA's desire to create a drug label containing a specific set of cautions and instructions"¹³⁹ similar to the regulation in *Geier*, an opinion authored by Justice Breyer. The future of implied obstacle preemption will likely be defined, therefore, by the thoroughness of federal agency assessment of "lawful specific regulations" and not on hindsight case specific evaluations.

So where does that leave us? Trying to make sense of preemption opinions reminds one of being on a roller coaster and, while enjoying the ride, getting off is a welcome relief. The uncertainty of where the coaster will go, while exhilarating for the time, is also exhausting and frustrating. This coaster ride is over for the time being though much work is left to be done after *Wyeth* in deciphering labeling approval decisions to identify those that may preempt state tort claims.

¹³⁴ *Id.* at 1201. The Court discussed the FDA's 2006 drug regulation preamble in which the preemption position was most recently articulated and found it did not deserve deference under an assessment of its "thoroughness, consistency, and persuasiveness." *Id.*

¹³⁵ *Id.* at 1202-03.

¹³⁶ *Id.*

¹³⁷ *Id.* at 1203.

¹³⁸ *Id.*

¹³⁹ *Id.* at 1204 (Breyer, J. concurring).

Two cases were remanded by the Court for further ruling in light of *Wyeth*¹⁴⁰ and many others are likely to be reconsidered in its wake. For the time being, it is important to point out that under *Geier* and *Wyeth* opportunities remain to argue for implied preemption in the pharmaceutical labeling context, and under other regulatory regimes.

Building on this assessment of the current, uncertain state of the doctrine of preemption, this Article will now identify some of the normative concerns that counsel against endorsing preemption doctrine in the current preemption climate. First, the Court's express preemption doctrine continues to raise questions about the defining congressional intent to preempt. After *Riegel*'s diatribe against tort law as implemented by juries, preemption doctrine would have been fairly criticized as being more concerned about reducing the role that tort law will play in the world of regulated products than about fairly assessing congressional intent to preempt. Whether the historic respect for the role of a robust state tort law in enhancing product safety continues or not remains an important open question in express preemption cases. *Bates* and *Riegel* provide inconsistent answers, but they at least openly engage the debate.

I am in the camp of those who believe that state tort law has an important role to play in regulating product safety and that it does not create perverse incentives in doing so. Tort law is not of a piece and the Court's suggestion to the contrary in *Riegel* dismisses the reality that the measured evolution of tort doctrines has already incorporated many limits to address its alleged excesses. Many states have adopted regulatory compliance defenses,¹⁴¹ causation-limiting doctrines and apportionment mechanisms,¹⁴² limits on non-economic damages,¹⁴³ and other doctrines that limit the potential for excess liability. It also bears repeating, as the Court noted in *Wyeth*, that tort law fundamentally serves goals other than regulating conduct: compensation, enhancing the availability of risk information, and corrective justice concerns are also fundamental to tort law.¹⁴⁴ These important objectives should not be blithely ignored.

Second, as confirmed in *Wyeth*, the presence of a parallel tort law regime fulfills the constant and critical need for oversight of the

¹⁴⁰ *Colacicco v. Apotex, Inc.*, No. 08-437, 2009 WL 578682 (U.S. Mar. 9, 2009); *Pa. Employees Benefit Trust Fund v. Zeneca*, No. 07-822 (U.S. Mar. 9, 2009).

¹⁴¹ See generally Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J. L. REFORM 461 (1997); see also Carl Tobias, *FDA Regulatory Compliance Reconsidered*, 93 CORNELL L. REV. 1003, 1025-27 (2008).

¹⁴² See generally RESTATEMENT (THIRD) OF TORTS: APPORTIONMENT OF LIAB. (2000) (describing the wide variety of reform measures apportionment of responsibility).

¹⁴³ See DAN B. DOBBS, *THE LAW OF TORTS* § 384 (2000).

¹⁴⁴ See generally John C.P. Goldberg, *Twentieth Century Tort Theory*, 91 GEO. L. J. 513 (2003) (describing the wide variety of theories that support tort law); John C.P. Goldberg, *The Constitutional Status of Tort Law: Due Process and the Right to a Law for the Redress of Wrongs*, 115 YALE L.J. 524 (2005) (discussing the view of tort law as a combination of redress of private wrongs and regulatory policy).

regulatory process.¹⁴⁵ Many have expressed the concern that our federal agencies are simply ill-equipped to act as the “one-stop shop” for insuring product safety.¹⁴⁶ One need only look at the failures of weak regulatory regimes in recent months to recognize the value of shining a light on the dark recesses of our regulatory systems. Those recesses result from a host of problems in the way our federal agencies operate: from a lack of staffing and funding to insure regulatory compliance to an inability to produce complete risk information (either pre- or post-regulatory decision-making) because the regulated industry is largely in charge of that information, to the influence of shifting political winds on agency positions.¹⁴⁷ These are concerns that stem from the inherent limits of the regulatory process. While faith in the expertise and good judgment of our regulators is certainly justified, that faith should not be blinded by the limitations that the process imposes on them.

Finally, as a policy matter, a choice has to be made about where the risk of uncertainty in the regulatory decision-making process should be placed: on the future victim of that uncertainty or the creator of it. Reasonable, rational, good faith decisions will be made that will produce real and significant harms alongside the benefits of those decisions. Inherent uncertainty exists in the current regulatory system because of, among other things, information-gathering and enforcement limitations. That uncertainty may or may not produce unreasonable risks from conduct that leads to common law products liability. If it does, however, the traditional tort system should not be prohibited from operating in its traditional way without the unquestionably clear intent of our federal legislators and regulators that such a result was, in fact, consciously considered, contemplated, and desired.

Much has been written on the effect of limitations on information gathering, and that ignoring those limitations can lead to analyses that “diverge in significant ways from reality.”¹⁴⁸ Questions about the character of scientific knowledge and its relationship to the law

¹⁴⁵ For a discussion of the need for regulatory oversight regarding the FDA and its effect on implied conflict preemption, see Davis, *The Battle Over Implied Preemption*, *supra* note 3, at 1148-51.

¹⁴⁶ See Wendy Wagner, *When All Else Fails: Regulating Risky Products Through Tort Litigation*, 95 GEO. L.J. 693, 695 (2007). Wagner explains:

[P]rotective regulation is plagued by a variety of important information costs that slow and even halt regulatory progress. . . . In some settings, the tort system can be more effective than the regulatory system in accessing the various types of information needed to inform regulatory decisions. Thus, in addition to its critical role in compensating victims, the tort system plays an indispensable role in supplementing agency regulation of risky products and activities.

Id.; see also Carter, *supra* note 8, at 42 (“The FDA is claiming total responsibility for drug and medical device safety. Some think it’s a bad idea.”).

¹⁴⁷ See *id.* at 44-45.

¹⁴⁸ Wagner, *supra* note 146, at 695.

abound.¹⁴⁹ Scientific certainty and legal certainty are often in conflict; it has been said that “[s]cience aims at truth without ever being certain.”¹⁵⁰ Regulatory action based on scientific inquiry suffers from the same problem. The limits of human knowledge belie the certainty with which the Court tends to view regulatory action. The tort system places the risk of uncertainty on the creator of that risk, providing a necessary incentive for regulated industries to reduce reasonably the risk of uncertainty by understanding, acknowledging, managing, and disclosing that risk.

Many scholars have weighed in recently on the debate over whether tort law or administrative law should govern the risk inherent in the discovery of products and processes that benefit a large percentage of the population but, nevertheless, have inherent risks that will inevitably burden a smaller percentage of that population.¹⁵¹ These discussions include a variety of institutional comparisons and competency assessments, noting the differing goals served by the different regimes including uniformity, application of technical expertise, the viability of optimal safety regulation, the desirability of compensatory remedies and the need for oversight and accountability, among others. This larger debate over the role of federal agency regulatory action as it relates to traditional, state law-based private rights and responsibilities must continue. The Court’s preemption doctrine is only one part of this debate.

The evolution of preemption doctrine since *Cipollone* in 1992 is marked by aggressive efforts to expand its applicability to limit the operation of tort laws and to further the reach of uniform federal regulation. The relentless pursuit of preemption in the last two decades strikes me more as an effort to overcome dissatisfaction with the tort liability system than a sincere attempt at discerning congressional intent under a particular legislative scheme. The object of modern preemption doctrine seems to vacillate between discerning the scope of congressional intent, and creating it.

No Congress writing in the last seventy years can rationally be found to have intended to displace the central role that common law tort doctrines have held in the goal of enhancing public safety yet such arguments are often made. If state product liability and tort doctrines are to be re-evaluated because of the perceived limitations they place on

¹⁴⁹ The use of scientific expert testimony in litigation and the uneasy relationship between that testimony and proof of legal facts has made a cottage industry out of testifying as an expert. For the seminal case discussing the relationship between science and the law, see *Daubert v. Merrell Dow Pharm. Inc.*, 509 U.S. 579 (1993).

¹⁵⁰ PHILIP WIENER, *THE DICTIONARY OF THE HISTORY OF IDEAS* 323 (1973).

¹⁵¹ See Richard A. Epstein, *Why the FDA Must Preempt Tort Litigation: A Critique of Chevron Deference and a Response to Richard Nagareda*, 1 J. TORT L. art. 5, at 15 (2006); David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA’s Efforts to Preempt Failure-to-Warn Claims*, 96 GEO. L.J. 461 (2008); Richard A. Nagareda, *FDA Preemption: When Tort Law Meets the Administrative State*, 1 J. TORT L. art. 4, at 3 (2006); Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449 (2008); Peter H. Schuck, *FDA Preemption of State Tort Law in Drug Regulation: Finding the Sweet Spot*, 13 ROGER WILLIAMS L. REV. 73 (2008).

innovation or some generalized notion of societal welfare, expanding preemption doctrine is not the way to accomplish it. That debate should be held in the full light of day and not hidden behind the cloud of preemption.

Preemption doctrine is out of balance, uncertain, and unwieldy in application. Though the result in *Wyeth* is consistent with my own position on the application of implied preemption doctrine to pharmaceutical labeling cases,¹⁵² many questions remain about implied preemption analysis generally. Now is certainly not the time to restate products liability preemption; perhaps by the time we have a Restatement (Fourth) of Products Liability.

¹⁵² See Davis, *The Battle Over Implied Preemption*, *supra* note 3, at 1151-54.