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# THE CASE AGAINST PREEMPTION: VACCINES & UNCERTAINTY

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## I. INTRODUCTION

Proponents of expansive federal preemption of state law damages actions begin their critique of state law with the following: federal regulatory bodies, not common law juries, have the expertise to decide the correct balance of risk and benefit that regulated industries should be permitted to pose to the general public. Once a federal agency has decided through the appropriate regulatory structure that a certain drug is approved or a certain product design is permissible, state juries should not be permitted to second-guess that decision. Federal preemption must operate to defeat the inconsistent actions of state juries because they have neither the expertise to understand the complex factors at issue in such a balancing act, nor the ability to see beyond the individual injured plaintiff, or so the argument goes.<sup>1</sup>

This argument has been made successfully over the past twenty years in a wide variety of product liability actions involving drugs and medical devices.<sup>2</sup> The structure and content of the federal preemption doctrine has

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1. See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 325 (2008) (“A jury, on the other hand, sees only the cost of a more dangerous design, and is not concerned with its benefits; . . .”). See generally, Richard C. Ausness, *The Impact of Wyeth v. Levine on FDA Regulation of Prescription Drugs*, 65 *FOOD & DRUG L.J.* 247, 253-59 (2010) (discussing the pro and con preemption arguments in the context of prescription drug labeling before *Wyeth v. Levine*).

2. *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996); *Bucknam v. Plaintiffs Legal Committee*, 531 U.S. 341 (2001); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); *Wyeth, Inc. v. Levine*, 129 S.Ct. 1187 (2010). At the time of the presentation of the AALS panel on the topic of federal preemption in the vaccine injury context, the Supreme Court had not yet

changed remarkably in that time period.<sup>3</sup> From a time of rare findings of federal preemption of state damages actions<sup>4</sup> to the now constant drum beat of the pro-preemption argument in virtually any tort damages action that involves a regulated entity, particularly in the health care field,<sup>5</sup> the question of whether common law tort doctrines *should* continue to play a role in the regulatory framework is more important than ever—I have elsewhere articulated a number of reasons why I conclude that it should.<sup>6</sup> The most important of these is the need for an alternative, complementary mechanism to the typically static administrative regulatory framework to encourage the disclosure of, and promote responses to, constantly evolving risk information. The longstanding role of the states in regulating public health and safety, coupled with the inherent inadequacy of *any* current federal regulatory agency to police fully the acquisition of and proper dissemination of risk information, supports that conclusion.<sup>7</sup>

The National Childhood Vaccine Injury Act<sup>8</sup> (“Vaccine Act”), which is the subject of these remarks, provides a unique administrative structure to form the backdrop for this argument. The Vaccine Act established a national vaccine program “for the development of new vaccines and the improvement of existing vaccines and a program to compensate the victims of vaccine-related injuries and deaths.”<sup>9</sup> Congress established a “no-fault” compensation system under which awards “can be made to vaccine-injured persons quickly, easily, and with certainty and generosity.”<sup>10</sup> The Compensation Program (“Program”) is the first step for those who suffer vaccine-related injuries because the Vaccine Act also permits some claims that do

decided the preemption case involving the National Childhood Vaccine Injury Act of 1986. *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068 (2011). The Court decided the case on February 28, 2011 in favor of preemption. *Id.*

3. For explanations of the changes in preemption doctrine over the past decades, see generally Mary J. Davis, *The “New” Presumption Against Preemption*, 61 HASTINGS L. J. 1217 (2010); Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449 (2008); Mary J. Davis, *Unmasking the Presumption in Favor of Preemption*, 53 S.C. L. REV. 967 (2002).

4. See, e.g., *Abbott v. American Cyanamid Co.*, 844 F.2d 1108 (4th Cir. 1988) (DTP vaccine); *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65 (Mass. 1985) (birth control pills). See also DAVID G. OWEN, *PRODUCTS LIABILITY* 909 (2d ed. 2010).

5. See OWEN, *supra* note 4.

6. Mary J. Davis, *The Battle Over Implied Preemption: Products Liability and the FDA*, 48 B.C. L. REV. 1089, 1148-51 (2008). See also Mary J. Davis, *On Restating Products Liability Preemption*, 74 BROOK. L. REV. 759, 776-79 (2009).

7. For others who arrive at a similar conclusion, see Elizabeth Cabraser, *Due Process Preempted: Stealth Preemption as a Consequence of Agency Capture*, 65 N.Y.U. ANN. SURV. OF AM. L. 449 (2009).

8. National Childhood Vaccine Injury Act, Pub. L. No. 99-660, 100 Stat. 3743, 3756-84 (codified at 42 U.S.C. §§ 300aa-1 to 300aa-34) (1987). See generally 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 (2007).

9. H.R. REP. NO. 99-908 at 1 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6344.

10. *Id.*

not lead to Program compensation to proceed in the traditional way—a civil action for damages “just as he or she may have done prior to the enactment of the legislation.”<sup>11</sup> Congress expressly preempted some tort claims in the Vaccine Act.<sup>12</sup> The question is: which ones? And, more importantly, should such a legislative directive be expected to respond to the natural evolution of scientific understanding of the regulated risk, and, if so, how? Current express preemption doctrine, which requires an assessment of congressional intent as the “ultimate touchstone of preemption analysis,”<sup>13</sup> has not fully explored that question. One component of preemption analysis, the “presumption against preemption,” which has fallen into disfavor at the Supreme Court,<sup>14</sup> seems to accommodate the need to consider changes in scientific understanding of risk. When the presumption against preemption is properly understood, it requires an understanding of the tort system as uniquely equipped to respond to the uncertainty inherent in the understanding of risk.

One way to frame this important question was articulated recently by Judge Guido Calabresi of the United States Court of Appeals for the Second Circuit, a long-time prominent tort law scholar.<sup>15</sup> In his opening remarks for a symposium titled “Tort Law in the Shadow of Agency Preemption,” Judge Calabresi articulated the core issues tort law faces in a world increasingly dominated by administrative regulatory action: (1) “Does national centralized decision-making, as between safety and accidents—and as to who bears the cost of safety or the cost of accidents—work better than local, diverse, and diffuse decision-making?”<sup>16</sup> (2) “What are the benefits of allowing different local decisions? How often in America do we have and want to have different values, different notions of what life is worth, of what things are worth?”<sup>17</sup> and (3) “What does the difference between localized and centralized decision-making tell us about who bears the burden of these decisions?”<sup>18</sup> This article provides a small contribution to these much larger questions by asking how courts should respond to the evolution of scientific understanding of risk in determining who bears the cost of that risk when assessing congressional intent to preempt traditional state com-

11. *Id.* Several new substantive and procedural requirements were established for the recovery of these damages. *Id.*

12. 42 U.S.C. § 300 aa-22 (1987). This provision’s scope has been in issue in recent litigation. The Supreme Court decided that the provision preempted all design defect litigation in *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068 (2011). For a fuller discussion of *Bruesewitz*, see *supra* notes and accompanying text.

13. *White Motor Co. v. Malone*, 435 U.S. 497, 504 (1978).

14. See Davis, *The “New” Presumption*, *supra* note 3, at 1220.

15. Hon. Guido Calabresi, *Keynote Address at the New York Univ. Annual Survey of American Law: Tort Law in the Shadow of Agency Preemption*, 65 N.Y.U. ANN. SURV. AM. L. 435 (2009).

16. *Id.*

17. *Id.*

18. *Id.*

mon law.

First, this article provides a brief recap of the state of current preemption doctrine and how it governs the interaction of federal regulation of product manufacturers and state tort actions related to the actions of those manufacturers. Second, the article provides observations on how that doctrine might apply to vaccine injury litigation. *Bruesewitz v. Wyeth, Inc.*<sup>19</sup> involves the preemptive scope of the Vaccine Act and the unique compensation system Congress created to respond to vaccine injuries. *Bruesewitz* was decided on February 22, 2011, and held that design defect claims are expressly preempted by the Vaccine Act.<sup>20</sup> This article endeavors to explain *Bruesewitz* in the context of express preemption doctrine generally. This article also provides observations on the continuing value of state tort law in the assessment of unreasonable risk. Finally, comments in response to Judge Calabresi's framing question, asking how to address the uncertainty inherent in acquisition of risk information, will build on the preemption analysis from *Bruesewitz* to encourage a narrow application of the scope of preemption doctrine particularly in the case of pharmaceuticals and medical devices.

## II. MODERN PREEMPTION FRAMEWORK

Preemption doctrine requires, under the Supremacy Clause, that courts search for congressional intent to preempt as the ultimate touchstone of preemption analysis.<sup>21</sup> Express preemption provisions are to be mined for their meaning and scope and in the absence of such a provision, limited doctrines of implied preemption act as gap-fillers where Congress's intent can be presumed based on an actual conflict with state law.<sup>22</sup>

The presumption against preemption is one feature of preemption analysis that requires a nuanced understanding. Historically, the presumption requires the conclusion that, absent clear and manifest congressional intent to the contrary, state common law tort actions—as a reflection of the historic police powers of the states—are not preempted by federal regulatory action.<sup>23</sup> Congress must be presumed not to displace such actions out of respect for the concurrent, traditional operation of state police powers. This presumption has been described as a fundamental reflection of federalism principles that prevents preemption analysis from becoming a tool of the

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19. *Bruesewitz v. Wyeth, Inc.*, 561 F.3d 233 (3d Cir. 2009), *aff'd*, 131 S. Ct. 1068 (2011).

20. *Id.*

21. U.S. CONST. art. VI, cl. 2; *Retail Clerks Int'l Ass'n, Local 1625 v. Schermerhorn*, 375 U.S. 96, 103 (1963).

22. See Davis, *The "New" Presumption*, *supra* note 3, at 1221.

23. See *Wyeth v. Levine*, 129 S. Ct. 1187, 1194 (2009). See also Davis, *The "New" Presumption*, *supra* note 3.

courts or agencies—any branch other than Congress—to assess preemptive scope in some freewheeling fashion to displace otherwise applicable state law, regardless of the perceived value or popularity of that law.<sup>24</sup>

The Supreme Court's preemption decisions in the last twenty years have introduced substantial confusion regarding the preemption framework generally and the application of the presumption against preemption specifically. As a result, it seems that there is a tendency for courts to view the topic of preemption very narrowly and to lose many of the nuances that are involved, but that is the world in which courts operate. Courts are looking for a model, a rational framework by which to answer these intractable questions surrounding the concurrent application of state law in an increasingly federalized world of tort duties and obligations. So when the Supreme Court decides a case like *Cipollone v. The Liggett Group, Inc.*,<sup>25</sup> which found preemption of *some* common law tort claims based on the federal cigarette labeling laws prohibition of conflicting state law "requirements,"<sup>26</sup> lower courts, based on expansive pro-preemption arguments of product manufacturers, tended to find other legislative enactments that referred to "requirements" as broadly preemptive in scope.<sup>27</sup> *Cipollone* actually articulated a narrow construction of express preemption provisions in light of the presumption against preemption, but the justices disagreed strongly on the nature of that analysis.<sup>28</sup> I continue to think that *Cipollone*'s determination that "requirements" include common law damages actions in the cigarette labeling statute was misguided. That genie is out of the bottle, however, and the Court has continued to hold that the use of the word "requirements" may indicate congressional intent to defeat common law damages actions.<sup>29</sup> The ensuing turmoil over how to determine the scope of express preemption provisions has led to a hodge-podge of confusing, sometimes conflicting, preemption decisions.

The Court's next preemption opinion, *Medtronic, Inc. v. Lohr*,<sup>30</sup> also focused on express preemption, this time under the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act ("FDCA"),

24. See, e.g., *Wyeth*, 129 S. Ct. at 1205 (Justice Thomas, concurring, criticizing free-wheeling judicial assessment under implied obstacle preemption); see also Brief for Kenneth Starr and Erwin Chemerinsky as Amici Curiae Supporting Petitioner, *Bruesewitz v. Wyeth*, 131 S.Ct. 1068 (2011) (No. 09-142).

25. *Cipollone v. The Liggett Group, Inc.*, 505 U.S. 504 (1992).

26. *Id.* at 515-20.

27. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 483-87 (1996) (discussing the treatment by courts of the term "requirements" in the MDA to the FDCA, and concluding nothing in the legislation or its history suggested that common law damages actions were intended to be requirements).

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

29. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 325 (2008). See also Robert Rabin, *Territorial Claims in the domain of Accidental Harm: Conflicting Conceptions of Tort Preemption*, 74 BROOK. L. REV. 987, 991-994 (2009) (discussing tort duties as "requirements").

30. *Lohr*, 518 U.S. 470 (1996).

which preempted state law “requirements.” Plaintiff alleged common law product defect claims arising out of his use of defendant’s pacemaker, which had been approved under the FDA’s pre-market notification approval regulations, a grandfathering method of approval without the heightened rigor of the more elaborate pre-market approval process.<sup>31</sup> The Court was divided on whether the MDA preempted the plaintiffs’ claims, but all justices again agreed that the express preemption provision controlled the analysis.<sup>32</sup> The majority opinion 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.<sup>33</sup> 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.<sup>34</sup>

Importantly, a majority of justices concluded in *Lohr* that, while general common law obligations were not a threat to the non-device specific federal requirements at issue,<sup>35</sup> where the federal government had weighed the competing interests relevant to the particular requirement in question, 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, an entirely different case would exist for preemption under the statute and implementing regulations.<sup>36</sup> The search for specific federal government “weighing of competing interests” in subsequent regulatory situations becomes a recurring theme in assessing preemption, both express and implied.<sup>37</sup>

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31. *Id.* at 476-81.

32. *Id.* at 484-85; *id.* at 503 (Breyer, J., concurring); *id.* at 509 (O’Connor, J., concurring and dissenting).

33. *Id.* at 476-81. Justice Stevens wrote: “[W]e used a presumption against the preemption of state police power regulations to support a narrow interpretation of such an express command in *Cipollone*. That approach is consistent with both federalism concerns and the historic primacy of state regulation of matters of health and safety.” *Id.* at 485.

34. *Id.* at 487.

35. *Id.* at 501-02.

36. *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 503-05.

37. *Id.* The Court also addressed the FDA’s preemption position articulated in a formally adopted regulation that implemented its statutory preemption authority. *Id.* at 497-98. See also 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”); 21 C.F.R. § 808.1 (d)(1) (no preemption of “state or local requirements of general applicability”). Federal agency action regarding preemption may inform preemptive scope if Congress has delegated to the agency that authority. 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. See *CSX Transp. Inc. v. Easterwood*, 507 U.S. 658, 670 (1993); *Norfolk & Southern Ry. v. Shanklin*, 529 U.S. 344 (2000) (preemption under Federal Railroad Safety

A few years after *Lohr*, the Court decided the effect of an express preemption provision in the National Traffic and Motor Vehicle Safety (“NTMVSA”) in *Geier v. American Honda Motor Corp.*<sup>38</sup> The case involved an allegedly defective automobile that did not have a driver’s side airbag even though the Federal Motor Vehicle Safety Standard 208 permitted manufacturers at the time to choose whether to incorporate such safety systems.<sup>39</sup> *Geier*, which found implied but not express preemption even though the statute contained an express preemption provision, is a watershed case in the Court’s preemption opinions because of its expansive implied preemption analysis. It reflects the power of federal administrative agency position regarding preemption if that position is based on an assessment of whether an actual conflict would “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.”<sup>40</sup> The Court was persuaded in *Geier* 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.

The Court’s treatment of common law damages actions in *Geier* illustrates the Court’s uncertainty about the value of traditional state law’s regulatory value, even in cases where preemption is being implied. The *Geier* Court perceived that common law tort actions might be detrimental to thoughtfully established federal goals,<sup>41</sup> even in the face of congressional intent to the contrary as evidenced by the savings clause. The Court weighed the perceived federal regulatory objectives against the general interest the states have in promoting health and welfare and compensating citizens for injuries suffered by defective products.<sup>42</sup> 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.<sup>43</sup> The Court did not mention the presumption against preemption.<sup>44</sup> The *Geier* analysis, which broadly assessed federal objectives under implied preemption analysis, has

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Act, relevance of agency position debated).

38. *Geier v. American Honda Motor Corp.*, 529 U.S. 861 (2000). *Geier* is a five-to-four opinion; Justice Breyer writing for the majority, joined by Chief Justice Rehnquist, Justices O’Connor, Scalia, and Kennedy. Justice Stevens, the author of both the *Cipollone* and *Medtronic* plurality opinions, dissented in an opinion in which Justices Souter, Thomas, and Ginsberg joined.

39. *Id.* at 865. The National Traffic and Motor Vehicle Safety Act of 1966, Pub. L. No. 89-563, 80 Stat. 718 (codified as amended at 49 U.S.C. 30101-30169).

40. *Geier*, 529 U.S. at 872.

41. *Id.* at 881. See also *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

42. *Geier*, 529 U.S. at 882-83.

43. *Id.* at 871.

44. *Id.* at 894 (Stevens, J. dissenting).

been criticized for its potential to encourage judicial over-reaching of state law prerogatives.<sup>45</sup>

The Court has also relied variously on the federal government's position on preemption, either through agency action or government litigating position, 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.<sup>46</sup> The government's position in *Geier* was found in a wide-ranging assessment of the history of the regulation and the current Secretary's position in the litigation as well as predecessor Secretary's opinions.<sup>47</sup> In the eight years between *Cipollone* and *Geier*, the Court contracted the operation of traditional state tort laws substantially and therefore increased the likelihood that pro-preemption arguments would be made based on federal regulatory action. The Court also resisted discussing the presumption against preemption and increasingly relied on agency assessments of the role of state tort law as complementary to federal regulatory action.<sup>48</sup>

Subsequent cases display the Court's own unease in assessing the scope of express preemption provisions. In *Bates v. Dow Agrosciences LLC*,<sup>49</sup> the Court spoke openly about the delicate balance that must be achieved in determining the scope of express preemption provisions, and about the effect of shifting agency position on that analysis. *Bates* involved preemption under the Federal Fungicide, Insecticide and Rodenticide Act ("FIFRA") and failure to warn claims regarding pesticides whose labels

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45. Indeed, the Court recently decided a second NTMVSA case involving Standard 208 and found that the regulatory history did not impliedly preempt a common law damages claim involving rear lap seat belts. *Williamson v. Mazda Motor of Am., Inc.*, 131 S. Ct. 1131 (2011). In *Williamson*, the Court speaking through Justice Breyer who authored *Geier*, concluded that state tort law did not actually conflict with the then current version of Standard 208 because there was no indication that the federal agency intended to prevent States from "supplement[ing] through state tort law" federal minimum standards. *Id.* at 1139. *See also, id.* at 1140 (Sotomayor, J., concurring) ("I write separately only to emphasize the Court's rejection of an overreading of *Geier* that has developed since that opinion was issued.").

46. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495-96 (1996). Justice Breyer concurred, agreeing that "the relevant administrative agency possess[ed] 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).

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

48. An example is *Sprietsma v. Mercury Marine* involving Coast Guard action under the Federal Boat Safety Act. 537 U.S. 51, 59-60 (2002) (applying 46 U.S.C. §§ 4301-11 (2000)). The Court was faced with whether a Coast Guard decision not to regulate the design of propeller guards preempted common law claims based on a failure to equip with propeller guards, and found neither express nor implied conflict preemption. *Id.* at 64-66. The Court was influenced by Coast Guard regulations, which preserved state authority in the absence of federal action, and the Coast Guard consistently concluded that its regulations did not have preemptive effect, though it had no formal rule on the subject. *Id.* at 66.

49. 544 U.S. 431 (2005). *Bates* involved application of the express preemption provision of the Federal Insecticide, Fungicide, and Rodenticide Act, Pub. L. No. 80-103, 61 Stat. 163 (1947) (codified at 7 U.S.C. §§ 134-36).

were EPA.<sup>50</sup> The Court reiterated, however, its adherence to the presumption against preemption because tort litigation “provide[s] an incentive to manufacturers to use the utmost care in the business of distributing inherently dangerous items.”<sup>51</sup> The Court narrowly analyzed the express preemption provision, as it had done in *Cipollone*, specifically rejecting the conclusion that common law jury verdicts are the equivalent of “requirements” simply because they may influence decision-making.<sup>52</sup> The Court also expressed a sense of frustration at the way the lower courts had read the term “requirements” broadly after *Cipollone*, and chastised the “too quick conclusion”<sup>53</sup> that tort claims were always preempted under statutes that used that term. The Court concluded that the express preemption provision preempted very few claims,<sup>54</sup> stating, “if Congress had intended to [prevent the operation] of a long available form of compensation, it surely would have expressed that intent more clearly.”<sup>55</sup> 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.”<sup>56</sup>

Three years later, the Court returned to express preemption under the FDCA MDA. *Riegel v. Medtronic, Inc.*<sup>57</sup> involved allegations of design defect in devices approved through the pre-market approval process.<sup>58</sup> The Court was quite critical of the role of common law tort claims in regulating product safety, unlike its position in *Bates*, and was quite expansive in its

50. *Bates*, 544 U.S. 431.

51. *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)).

52. *Id.* at 445 (reasoning that “[a] requirement is a rule of law that must be obeyed[, whereas] an event, such as a jury verdict, that merely motivates an optional decision is not a requirement”).

53. *Id.* at 446.

54. *Id.* at 451-52.

55. *Id.*

56. *Id.* (stating that the Defendant and EPA’s concern that “tort suits led to a ‘crazy-quilt’ of FIFRA standards or otherwise created [a] real hardship for manufacturers” was unpersuasive because, as the Court observed, “for much of this period EPA appears to have welcomed these tort suits.”).

57. *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008).

58. *Id.* The second MDA preemption case was *Bucknam Co. v. Plaintiffs’ Legal Committee* 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. 531 U.S. 341 (2001).

description of the scope of express preemption.<sup>59</sup> The Court, speaking through Justice Scalia, seemed less interested in assessing congressional intent to preempt, which it had done in two prior cases, than in re-affirming its own understanding of the statute's term "requirements."<sup>60</sup> 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."<sup>61</sup> This conclusion, which seems contrary to *Bates*' analysis and sentiment, is the kind of inconsistency that makes express preemption analysis so fraught with uncertainty.

While thus defining the term "requirement" for future congresses, the Court reiterated its pre-*Bates* distrust over the operation of common law tort actions. Justice Stevens, the originator of modern preemption analysis in *Cipollone*, had come to speak positively about the general value of state tort law as a complement to federal regulation, as indicated by his opinion in *Bates*. Justice Scalia, the author of *Riegel*, on the other hand, finds tort law as applied by juries to be "less deserving of preservation" than other state regulations. His stated rationale is that 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.<sup>62</sup> The *Riegel* Court found it "implausible" that Congress would create the "perverse distinction" that grants greater power to a single state jury than to state officials.<sup>63</sup> There is no mention of the "presumption against preemption." There is certainly little regard in these remarks for tort law's historic place in contributing to public safety or for its "catalyzing" effect to increase access to risk information as discussed in *Bates*.<sup>64</sup>

The final pre-*Bruesewitz* express preemption case meriting discussion is *Altria Group, Inc. v. Good*,<sup>65</sup> decided after *Riegel*, which involved the

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59. 128 S.Ct. 999, 1007.

60. *Id.*

61. *Id.* For a different assessment of Congress's intent, see 128 S.Ct. 999, 1013 (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 *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). 128 S. Ct. 999, 1011-13 (Stevens, J., concurring in part and dissenting in part).

62. *Id.* at 1007.

63. *Id.*

64. 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*, 518 U.S. 470 (1996). See Catherine M. Sharkey, Colloquy, *What Riegel Portends for FDA Preemption of State Law Products Liability Claims*, 102 NW. U. L. REV. 415 nn. 3-4 (2008). See *contra* Davis, *On Restating Products Liability Preemption*, *supra* note 6 (discussing the importance of the debate in *Riegel* to the larger discussion of the continuing value of tort law).

65. 129 S.Ct. 538 (2008).

continuing validity of *Cipollone* in defining the claims that survived express preemption under the cigarette labeling laws.<sup>66</sup> After *Riegel* and its eight-to-one opinion in favor (in dicta, at least) of a more expansive reading of express preemption provisions, one would have expected that Justice Stevens' plurality opinion in *Cipollone* had been outgrown. On the contrary, the Court held that the *Cipollone* plurality controls the express preemption analysis of the statute.<sup>67</sup> The majority, authored by Justice Stevens, rejected the broader scope of preemption analysis proposed by Justice Scalia in *Cipollone*, and advocated in *Altria Group* by Justice Thomas for the dissent,<sup>68</sup> 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."<sup>69</sup> Justice Stevens' opinion confirmed the validity of the presumption against preemption in conjunction with a fair but narrow reading of the scope of express preemption.<sup>70</sup>

*Bates*, *Riegel*, and *Altria Group*, as the most recent express preemption opinions until *Bruesewitz*, give contrary signals about the role of the presumption against preemption and determining the scope of congressional intent to preempt as found in express provisions. Justice Stevens retired in 2010. A different majority may be about to emerge on the scope of preemption of traditional state tort laws. The *Bruesewitz* contribution to express preemption analysis is found in Part III.

### III. A FEW LESSONS FROM IMPLIED PREEMPTION AND *WYETH V. LEVINE*

While implied preemption doctrine is not applicable to Vaccine Act preemption, the Court's opinion in 2009 in *Wyeth v. Levine*,<sup>71</sup> which involved the application of implied preemption under the FDCA to pharmaceutical labeling claims, is an important contribution to the continuing debate over the value of state tort law in the regulatory framework for pharmaceuticals. The Court had not decided an FDCA implied preemption case since *Hillsborough County v. Automated Medical Laboratories, Inc.*<sup>72</sup> in 1985. In addition, the FDA which had for years been in favor of the concurrent operation of state common law damages actions had changed its

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66. *Id.* at 541-42.

67. *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)).

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

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

70. See *id.* at 543.

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

72. *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707 (1985).

position on preemption, first in a series of amicus briefs in cases beginning in 2004 and then in a now discredited 2006 Preamble to new pharmaceutical labeling regulations.<sup>73</sup> A number of issues had confounded the lower courts, which needed guidance on the modern state of implied preemption analysis.<sup>74</sup>

*Levine* involved the anti-nausea drug Phenergan that had been approved in 1955.<sup>75</sup> Plaintiff lost her arm as a result of inadvertent injection of the migraine drug into an artery, which resulted in gangrene, a risk of which Wyeth was aware and which had been warned about in the product's labeling.<sup>76</sup> Ms. Levine claimed that the labeling inadequately warned of the risk of gangrene, and the jury agreed.<sup>77</sup> The Vermont Supreme Court affirmed a lower court ruling that Ms. Levine's claims were not impliedly preempted by the FDA's labeling approvals.<sup>78</sup>

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 substitutes a lay jury's decision for the expert judgment of the FDA.<sup>79</sup> The Court, again 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 under either impossibility or obstacle implied preemption.<sup>80</sup> The Court re-affirmed the "two cornerstones of our pre-emption jurisprudence"<sup>81</sup> first, that the purpose of Congress is the "ultimate touchstone in every pre-emption case"<sup>82</sup> and, second, "in all pre-emption cases,"<sup>83</sup> but particularly those involving fields which the states have traditionally occupied, the analysis begins with the presumption against preemption. The Court rejected Wyeth's argument that the presumption should not apply in implied preemption cases, stating,

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73. See Davis, *The Battle Over Implied Preemption*, *supra* note 6, at 1090 (chronicling the history of the change in FDA preemption policy). The Preamble is found in Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg., 3922, 3934 (Jan. 24, 2006). See also Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227 (2007).

74. See, e.g., *Colacicco v. Apotex, Inc.*, 521 F.3d 253 (3d Cir. 2008), *vacated by Colacicco v. Apotex, Inc.*, 129 S. Ct. 1578 (U.S. 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).

75. *Levine*, 129 S.Ct. at 1191.

76. *Id.* at 1191-92.

77. *Id.* at 1193.

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

79. *Wyeth v. Levine*, 129 S. Ct. at 1193-94.

80. *Id.* at 1190-91.

81. *Id.* at 1194.

82. *Id.* (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)).

83. *Id.* (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)).

“this Court has long held to the contrary.”<sup>84</sup>

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.”<sup>85</sup> The Court required “clear evidence” before an impossible conflict is established.<sup>86</sup> 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.<sup>87</sup>

The Court’s discussion of implied obstacle conflict preemption principles is important because of the contrast with the discussion in *Geier*. Implied obstacle preemption, according to the *Levine* Court, requires two things: (1) an identification of the congressional purposes or objectives which support the federal law and, (2) a rigorous assessment of whether Congress considered state law claims to pose an obstacle to the accomplishment of those objectives, not just the agency charged with effectuating Congress’ intent. Borrowing from the successful obstacle conflict preemption analysis in *Geier*, Wyeth had 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.’”<sup>88</sup>

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 pre-empt state law.”<sup>89</sup> Relying on an argument that had been successful in *Geier*, 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.<sup>90</sup> The Court summarily rejected this assessment of federal objectives because it was contrary to all evidence of Congress’s purposes.<sup>91</sup> 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.”<sup>92</sup> 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

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84. *Id.* at 1195, n.3.

85. *Id.* at 1197-98.

86. *Id.* at 1198.

87. *Id.* at 1198-99.

88. *Id.* at 1199.

89. *Id.*

90. *Id.*

91. *Id.*

92. *Id.* at 1200. Congress had not expressly preempted state tort law claims as it had in other contexts, such as in the MDAs. *Id.*

drug safety and effectiveness.”<sup>93</sup> The Court explored the many ways that tort law acts as a complement to federal drug regulation,<sup>94</sup> and found the FDA’s “newfound opinion” to the contrary to be inconsistent with the “longstanding coexistence of state and federal law and the FDA’s traditional recognition of state-law remedies”<sup>95</sup> and, thus, unpersuasive on assessing a current conflict with federal objectives.

*Wyeth v. Levine* represents a narrower implied obstacle conflict preemption analysis than *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 if not so clearly in its express preemption analysis.

#### IV. SYNTHESIS OF PREEMPTION ANALYSIS

The Court has at times stated that the presumption against preemption of historic state police powers continues to operate in cases of both express and implied preemption. The Court has also evaluated express preemption provisions without reference to the presumption, as in *Riegel*. In *Cipollone*, *Lohr*, *Bates*, and *Altria Group*, the Court required clear and manifest intent of Congress to the contrary to defeat the presumption. The presumption was also important in *Wyeth v. Levine*. The question remaining is whether the presumption will, indeed, operate as a default in express preemption cases where the statutory language of preemption does not lend itself to a finding of clear congressional intent. *Bruesewitz* provides an answer to that question though it is unclear what the extent of *Bruesewitz*’s reach will be.

When an express preemption provision provides “clear and manifest” evidence of Congress’s intent, it will control.<sup>96</sup> 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 explicitly

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93. *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 warnings.” *Id.* at 1199-1200 (alteration in original). The Court rejected reliance on the FDA’s “mere assertion” that state law poses an obstacle. *Id.* at 1201. 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.” *Id.*

94. *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.” *Id.*

95. *Id.* at 1203.

96. See Davis, *The “New” Presumption*, *supra* note 3, at 1247.

saying so.<sup>97</sup> All of this seems to suggest that a “new” presumption against preemption operates as a meaningful default rule when interpreting congressional intent to preempt.<sup>98</sup> Clarity is in the eyes of the beholder, as the different results in *Riegel* and *Altria Group* suggest. Even though the Court did not mention the presumption in *Riegel*, the discussion in *Altria Group* on the heels of *Riegel* might portend that a majority has rejected a lesser 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.”<sup>99</sup> This text-centered focus has arisen after years of attempting to force terms from one statute, such as “requirements,” to apply to the meaning of the same term in a different statute.<sup>100</sup> The presumption against preemption as default may reduce the overreaching of statutory definitions by requiring a tighter fit between context and language.<sup>101</sup>

#### V. VACCINE ACT PREEMPTION: *BRUESEWITZ V. WYETH LLC*

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 based on statutory text. Relying on the interpretation of terms from one statute runs the risk of proving too much in the interpretation of similar language in another statute. In an earlier article, I proposed that recent Vaccine Act cases, including *Bruesewitz*, would put this analysis to the test.<sup>102</sup> The Court has now answered the question by finding preemption in a hyper-textual analysis which does not refer to the presumption against preemption, or to other elements of preemption doctrine for that matter.

There is no question that vaccination of children has been spectacularly successful in eradicating the disastrous consequences of many childhood illnesses. There is also no question that vaccinating a child introduces a toxin into the child’s system that may cause a devastating side effect. Those side effects are inevitable in some portion of the vaccinated population. The Vaccine Act was intended to compensate, under a no-fault regime, children who were injured from a vaccination, and the only question

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97. See Davis, *The “New” Presumption*, *supra* note 3, at 1247.

98. *Id.*

99. *Id.* at 1248.

100. *Id.* at 1247.

101. *Id.*

102. See generally *id.*

is which state tort laws survived the creation of the compensation scheme and which ones did not.<sup>103</sup>

Tort laws historically have been seen as a complement to federal drug regulation by courts and federal regulators.<sup>104</sup> Tort actions uncover unknown 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 and uncover information about previously undisclosed or under-disclosed risks. The FDCA's "central premise" is that manufacturers bear primary responsibility for their drug labeling at all times.<sup>105</sup> The same is true of vaccine manufacturers who are regulated under the Public Health Service Act,<sup>106</sup> the FDCA,<sup>107</sup> and the Vaccine Act.<sup>108</sup>

Vaccine licenses are granted if vaccine manufacturers meet standards designed "to insure the continued safety, purity, and potency" of vaccines.<sup>109</sup> Since 1972, the FDA has regulated vaccines and other biologics under the New Drug Application process.<sup>110</sup> To obtain approval, the manufacturer need not establish that the vaccine is the safest possible, nor that there are no feasible alternative formulations.<sup>111</sup> Rather, the FDA is not involved in initiating or conceptualizing the structure of a vaccine. The FDA is not a drug or vaccine design agency: it is an approval agency. It has limited authority to require post-marketing monitoring which is "not a top priority."<sup>112</sup> The FDA relies on the Vaccine Adverse Event Reporting System ("VAERS"), a passive reporting system that relies on voluntary reporting of adverse events that are inevitably underreported.<sup>113</sup> Nor does it have authority to require a manufacturer to adopt a safer alternative for a licensed

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103. *See generally* National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to 300aa-33 (2006).

104. *Wyeth v. Levine*, 129 S. Ct 1187, 1202 (2009).

105. *Id.* at 1197-98.

106. *See generally* Public Health Service Act of 1944, ch. 373, 58 Stat. 682 (codified as amended, beginning at 42 U.S.C. § 201).

107. *See generally* 21 U.S.C. § 352.

108. *See generally* 42 U.S.C. §§ 300aa-1 to 300aa-34.

109. *See* 21 C.F.R. § 600.3(n) (2011).

110. *See* 21 C.F.R. § 312.2(a), 312.20-312.38. Like the proponent of a new drug, the sponsor of a vaccine must prove, among other things, that the vaccine is safe and effective. *See* 42 U.S.C. § 262 (2006).

111. *See Hurley v. Lederle Labs, Inc.* 863 F.2d 1173, 1177 (5th Cir. 1988) (noting that the FDA is a "passive agency"). *See also* Thuy D. Pham & Annette Martinez, *The Polio Vaccine and the Restatement (Third) of Torts: Why the Controversies*, 11 DEPAUL J. HEALTH CARE L. 125, 158-59 (2008).

112. *See* Brief for Petitioners at 11, *Bruesewitz v. Wyeth LLC*, 131 S.Ct. 1068 (2011) (No. 09-152) (quoting OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH AND HUMAN SERVICES., FDA'S MONITORING OF POSTMARKETING STUDY COMMITMENTS ii-iii (June 2006)), available at 2010 WL 2130598.

113. Final Order on Categorization of Anthrax Vaccine Absorbed, 70 Fed. Reg. 75,180, 75,190 (Dec. 19, 2005).

vaccine.<sup>114</sup> The Vaccine Act creates a no-fault compensation system for victims of certain vaccine-related injuries while encouraging vaccine manufacturers to continue vaccine production at reasonable cost.<sup>115</sup>

None of the statutes which have been the subject of express preemption analysis have involved a congressionally mandated compensation scheme that supplements, or displaces, state tort actions. When Congress created the Vaccine Act administrative compensation scheme, specifically designed to further the compensation of injured victims of vaccinations, did Congress essentially take over the world of vaccine injury compensation? The Supreme Court says it did.<sup>116</sup>

The Vaccine Act preemption provision is found in a section titled “Standards of Responsibility.” That provision states: “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.”<sup>117</sup> Subsection (b)(1) 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.<sup>118</sup>

Subsection (e), titled “Preemption” prohibits states from foreclosing any other civil actions against manufacturers if they are not already barred by this part.<sup>119</sup>

Hannah Bruesewitz suffered seizures in 1992 almost immediately upon taking the third dose of a five-dose regimen of the DTP (diphtheria, tetanus and pertussis) vaccine Tri-Immunol, a whole cell pertussis vaccine.<sup>120</sup> The whole-cell pertussis vaccine had been linked to a variety of adverse events which led to efforts to produce an acellular vaccine.<sup>121</sup> The acellular vaccine was not available for Hannah’s third dose in 1992, but it became available shortly thereafter.<sup>122</sup> Wyeth, the successor to Lederle Labs which

114. See 21 C.F.R. 601.5.

115. See *id.* See also *Bruesewitz v. Wyeth, Inc.*, 561 F.3d 233, 235-36 (3d Cir. 2009) (discussing history and structure of Act).

116. *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068, 1082 (2011).

117. 42 U.S.C. § 300aa-22 (2006).

118. 42 U.S.C. § 300aa-22(b)(1).

119. 42 U.S.C. § 300aa-22(e).

120. *Bruesewitz v. Wyeth, Inc.*, 561 F.3d 233, 236 (3d Cir. 2009). Hannah’s particular vaccine came from a lot that generated sixty-five reports of adverse reactions. *Id.* at 237.

121. *Id.* at 236.

122. *Id.* at 237.

made Hannah's vaccine, voluntarily discontinued making the whole-cell pertussis vaccine in 1998.<sup>123</sup> Hannah's parents sought compensation from the Vaccine Court in April 1995 for Hannah's injuries which, until one month before, had been Table Injuries, signifying that they were compensable in Vaccine Court upon a showing of injury and proximity of onset of injury to the administration of the vaccine.<sup>124</sup> Hannah's parents' claims were denied seven years later in 2002.<sup>125</sup> Hannah's parents rejected the court's judgment and filed suit in state court, however, the case was removed to federal court, which dismissed the claim as preempted.<sup>126</sup> The Third Circuit Court of Appeals affirmed.<sup>127</sup>

In an earlier article, I opined that the Court should find that the statute did not preempt all design defect litigation.<sup>128</sup> The statute appears on its face to carve out some design defect claims that are not preempted by using the term "unavoidable." The statute is complex and its structure and history seem to admit of different conclusions regarding preemptive intent. The case presents a unique federal compensation scheme, however, which clearly displaces the operation of a substantial amount of state common law by its very terms.

The Supreme Court, in an opinion by Justice Scalia, finds preemption based entirely on an analysis of the text.<sup>129</sup> After explaining the impetus for the Act, and describing the no-fault compensation system, the majority

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123. *Id.*

124. *Id.*

125. *Id.*

126. *See Bruesewitz v. Wyeth, Inc.*, 508 F. Supp. 2d 430 (E.D. Pa. 2007).

127. *Bruesewitz*, 561 F.3d at 255-56. The Supreme Court granted certiorari, arguably as a result of the split that had occurred between the federal courts of appeals and the state courts. The Georgia Supreme Court previously upheld a finding of no preemption in a case involving alleged neurological damages caused by vaccines made with a mercury-laden preservative for which an alternative was available. *See American Home Products Corp. v. Ferrari*, 668 S.E.2d 236 (Ga. 2008). The Georgia Supreme Court affirmed a finding of no express preemption of the design defect claim, concluding that the statute required a case-by-case determination of unavoidability. *Id.* at 238-43. Interestingly, a Pennsylvania Superior Court has recently decided that the Vaccine Act preemption provision does not preempt such design defect claims. *See Wright v. Aventis Pasteur, Inc.*, 14 A.3d 850 (Pa. Super. Ct. 2011). That case was, of course, before the Supreme Court's decision in *Bruesewitz*.

128. Davis, *The "New" Presumption*, *supra* note 3, at 1251 ("*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. . . . 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."). I also predicted in my first article on preemption, *Unmasking the Presumption in Favor of Preemption*, 53 S.C. L. Rev. 967 (2002), that the Supreme Court would find express preemption in *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002). The Court unanimously found no preemption. I have learned my lesson.

129. *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068, 1075-79 (2011).

opinion strikes through the express preemption provision with the editing pen of an expert grammarian.<sup>130</sup> In the best sentence diagramming tradition, Justice Scalia finds that the “even though” clause clarifies the word “unavoidable” that precedes it: “It delineates the preventative measures that a vaccine manufacturer *must* have taken for a side-effect to be considered ‘unavoidable’ under the statute.”<sup>131</sup> The Court concludes that, “A side effect of a vaccine could *always* have been avoidable by use of a differently designed vaccine not containing the harmful element. The language of the provision thus suggests that the *design* of the vaccine is a given, not subject to question in the tort action.”<sup>132</sup> Thus, Justice Scalia resolves the ambiguity about unavoidability by concluding that it is unavoidable “*with respect to the particular design*” and not with respect to competing alternative designs that might be available.<sup>133</sup>

In design defect claims, the plaintiff must establish the condition that makes the design defective, and that typically includes establishing an alternative design that would have reduced the risk without impairing the functioning of the product. Consequently, it is also plausible that Congress intended that only vaccine formulations for which there was no feasible substitute, and for which there were, therefore, unavoidable side effects, were protected from liability. This is the dissent’s argument, and one based on comment *k* to Restatement (Second) of Torts section 402A, from which Congress constructed the Vaccine Act preemption provision.<sup>134</sup> That interpretation of section 22(b) also is a fair, but narrow interpretation which gives meaning to the presumption against preemption of state law, which Justice Scalia never mentions.

Justice Scalia supports his interpretation of the Act by noting that the statute mentions manufacturing defect claims and failure to warn claims but never mentions design defect claims.<sup>135</sup> He concludes that this failure must be a “deliberate choice, not inadvertence.”<sup>136</sup> “*Expressio unius, exclusio alterius.*”<sup>137</sup> Justice Scalia recognizes that the “if” clause makes sense un-

130. *Id.* at 1073-74.

131. *Id.* at 1075.

132. *Id.*

133. *Id.* at 1076. *See also id.* at n. 35 (the Court recognizes the problem when it responds to the dissent’s argument on the point in Footnote 35 by stating, “[i]he dissent makes no effort to ground that position in the text of [the Act]. We doubt that Congress would introduce such an amorphous test by implication when it otherwise micromanages vaccine manufacturers.” (alteration in original)).

134. *Id.* at 1089-1093 (Sotomayor, J., dissenting). *See generally*, Brief for Petitioners at 29, *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068 (2011) (No. 09-152); Brief of Mark A. Geistfeld, as Amicus Curiae in Support of Petitioners, *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068 (2011) (No. 09-152).

135. *Bruesewitz*, 131 S. Ct. at 1078-79.

136. *Id.* at 1076.

137. *Id.*

der either the majority's or the dissent's assessment of it.<sup>138</sup> He rejects reference to comment *k* as unnecessary: "'Unavoidable' is hardly a rarely used word."<sup>139</sup>

Justice Scalia and Justice Sotomayor in dissent argue over whether the "even though" clause is a concessive subordinate clause or whether it is a coordinating conjunction.<sup>140</sup> Justice Scalia agrees that Congress could have written the clause more clearly, rendering the words after "unavoidable" superfluous.<sup>141</sup> He concludes that such superfluity is not a problem because the dissent's position "has superfluity problems of its own."<sup>142</sup> The grammar debate is resolved in Justice Scalia's favor by the six person majority.

The majority opinion also looks to the structure of the Vaccine Act to reinforce his reading of the preemption provision.<sup>143</sup> In this section of the opinion, he discusses the difficulty of "[s]triking the right balance between safety and efficacy" in the case of vaccines.<sup>144</sup> He comments that the Act, "which in every other respect micromanages manufacturers, is silent on how to evaluate competing designs."<sup>145</sup> He expresses concern over the lack of guidance in the Act regarding how to assess alternative designs, and concludes that such lack of guidance "strongly suggests that design defects were not mentioned because they are not a basis for liability."<sup>146</sup> Of course, the FDA does not evaluate competing designs, in the vaccine context or in the drug context. Consequently, such "lack of guidance" just as likely supports the conclusion that design defects are, indeed, intended to support a basis for liability. The regulatory structure at the time of the Vaccine Act defaulted to state tort law to make such assessments, as Justice Sotomayor points out.<sup>147</sup>

The key to Justice Scalia's opinion, seems to be, his perception that the Compensation Program, in combination with the reporting, monitoring and collaborative work of federal regulators, was a conscious choice by

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138. *Id.*

139. *Id.* at 1077.

140. *Id.* at 1077-78; *id.* at 1087 (Sotomayor, J., dissenting).

141. *Id.* at 1078.

142. *Id.* at 1078, n.48.

143. *Id.* at 1078-80.

144. *Id.* at 1079.

145. *Id.*

146. *Id.* ("Jurors, of course, often decide similar questions with little guidance, and we do not suggest that the absence of guidance alone suggests preemption.")

147. *Id.* at 1097 (Sotomayor, J., dissenting) ("Although the Vaccine Act charges the Secretary of Health and Human Services with the obligation to 'promote the development of childhood vaccines' and 'make or assure improvements in . . . vaccines, and research on vaccines,' neither the Act nor any other provision of federal law places a legal *duty* on vaccine manufacturers to improve the design of their vaccines to account for scientific and technological advances. Indeed, the FDA does not condition approval of a vaccine on it being the most optimally designed among reasonably available alternatives, nor does it (or any federal entity) ensure that licensed vaccines keep pace with technological and scientific advances." (internal citation omitted)).

Congress “to set priorities for federal vaccine research, and to coordinate federal vaccine safety and efficacy testing.”<sup>148</sup> The ostensible silence regarding design defect litigation “reflects a sensible choice to leave complex epidemiological judgments about vaccine design to the FDA and the National Vaccine Program rather than juries.”<sup>149</sup> The Vaccine Act’s structural quid quo pro, the fund for compensation, was at least in part in exchange for freedom from the costly tort litigation system.<sup>150</sup> In response to Justice Sotomayor’s concern that the FDA and the Vaccine Program are insufficient to spur adequate vaccine innovation and uncover information of risk, Justice Scalia considers this issue to be beside the point.<sup>151</sup> Not unsurprisingly, Justice Scalia finds no need to refer to the legislative history even though he recognizes that some of his colleagues would do so as a tool of statutory interpretation.<sup>152</sup>

What is to be made then, of the importance of *Bruesewitz* to express preemption analysis? It is a classic textual interpretation. Justice Scalia is not a fan of the “fair but narrow” interpretation of such provisions, as evidenced by his debates with Justice Stevens in cases like *Cipollone* and *Altria Group*. *Bruesewitz* is very much like *Riegel* in its approach to assessing congressional intent solely through the text of an express preemption provision.<sup>153</sup>

Justice Scalia is also not a fan of the presumption against preemption, which Justice Sotomayor refers to only in a footnote.<sup>154</sup> The presumption against preemption, had it been considered, supports the status quo of design defect liability whose operation was both known to Congress, understood by Congress, and the industry, based on longstanding practices. The Court continues to be erratic regarding the place of the presumption, signaling a return to its disfavor.

Congress created a compensation alternative for most vaccine injury claims but clearly not for all. That Congress was able to accomplish enactment of such a scheme seems remarkable in light of the seemingly intractable legislative debates over most issues that come before Congress that we are witness to today. One could say, with regard to the compensa-

148. *Id.* at 1080.

149. *Id.*

150. *Id.*

151. *Id.*

152. *Id.* Justice Breyer, concurring, would look to the legislative history for support of the interpretation of the express preemption provision which he says is “a close” question. *Id.* at 1082-83 (Breyer, J., concurring).

153. *See* 552 U.S. 312 (2008).

154. *Bruesewitz*, 131 S. Ct. at 1096, n.15 (2011) (Sotomayor, J., dissenting) (“Given the long history of state regulation of vaccines, the presumption provides an additional reason not to read § 22(b)(1) as pre-empting all design defect claims, especially given Congress’ inclusion of an express saving clause in the same statutory section, and its use of the conditional “if” clause in defining the pre-emptive scope of the provision.” (internal citations omitted)).

tion scheme, that if Congress had wanted to create a different kind of scheme, say a truly exclusive compensation scheme, it could have said so much more clearly than it did. That criticism proves too much because it will, in hindsight, always be true of any legislative enactment. Tort litigation operating as a background to the Vaccine Act administrative scheme supports both the compensatory purpose of the Act and the incentive to create safer vaccines, but not as neatly as in cases in which there is no congressionally created compromise compensation scheme. The majority concluded that Congress need not create a compensation system that mirrors the tort litigation system to have intended to preempt that system.<sup>155</sup> That is fair. It also strikes me that *Bruesewitz* is unlikely to have broad impact on preemption of common law tort claims given the unique nature of the congressional compensation scheme in issue.

## VI. THE ROLE OF UNCERTAINTY

Vaccines have side effects, many of which are known, but not all. Information about the true nature of what such toxins do once introduced into the body, like what drugs do to the body, is produced over time—decades perhaps. Information about the risks known when a vaccine or other drug is approved immediately becomes out of date as soon as that vaccine or drug is widely used in the general population. The larger the population exposed to a drug or vaccine, the greater the potential of unanticipated side effects and the greater the need to acquire and respond to that knowledge to enhance public safety. I have always advocated that the tort litigation system provides the incentive for drug manufacturers to acquire and act on that knowledge of which only they are fully aware. The FDA, nor any regulatory agency, is simply incapable of acquiring and acting on that information as effectively as the manufacturer. Many have commented on the FDA's inability to track post-marketing adverse events of pharmaceuticals it approves.<sup>156</sup> The manufacturer is in command of that information.

“Science aims at the truth without ever being certain.”<sup>157</sup> The truth is illusory. The Vaccine Program that Congress created to respond to the known risks of childhood vaccines in 1986 was laudable. But time passes, and additional risks become realized. Who has the incentive to make the population aware of those risks? The well-intentioned federal regulators

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155. *Id.* at 1079-82.

156. *Id.* at 1099, n.20 (Sotomayor, J., dissenting) (“[W]e observed in *Levine* that the FDA is perpetually understaffed and underfunded, and the agency has been criticized in the past for its slow response in failing to withdraw or warn about potentially dangerous products. These practical shortcomings reinforce the conclusion that ‘state law offers an additional, and important, layer of consumer protection that complements FDA regulation.’” (internal citations omitted)).

157. DICTIONARY OF THE HISTORY OF IDEAS: CERTAINTY SINCE THE TWENTIETH CENTURY, 323 (Philip Wiener ed., 1973).

certainly do. But do they have the capacity? As with other drug regulation, the FDA has limited post-marketing authority regarding vaccines. The Centers for Disease Control gathers and tracks vaccine injury information and does comparative analyses of those already on the market, but it does not examine whether a safer alternative is available, and neither does any federal government agency.<sup>158</sup> As with research on the safety and effectiveness of other drugs, research on vaccine safety remains flawed and incomplete. The Vaccine Program provides for additional vaccines to be added to the Table and for injuries to be included. That has not worked as smoothly as some would have hoped.<sup>159</sup> Indeed, there is much criticism of the way Vaccine Court operates.<sup>160</sup>

The Vaccine Injury Compensation Program is a good model because it incorporates the opportunity to add vaccines and injuries to the Vaccine Table over time. Unfortunately, more injuries have been removed from the Table than have been added to it in the past decades,<sup>161</sup> and vaccines have been added with no corresponding injury side effect identified. That in itself may be the result of inadequate information. There continues to be a need to maximize avenues for acquiring information about vaccine risks. The ever present possibility of the operation of the tort system as a watchdog fulfills that role, but the tort system does not fit cleanly into the process, and is often an inefficient solution. Often, the system is used as a sledge hammer instead of the proverbial scalpel, but many safeguards of that system have been in place for decades; the burden of proof, the requirement of general and special causation, the expense of discovery and cost of litigation to all the parties to name a few. These are significant deterrents to widespread overuse of the civil action instead of the administrative scheme that Congress put in place.

It is such cases in which the presumption against preemption should operate to preserve longstanding traditional tort laws of responsibility. Product manufacturers, including vaccine manufacturers, have regulatory and market incentives to improve their products performance, but the ever-present possibility of the tort system operating to uncover the risks of which only the manufacturer realistically will be aware is a powerful one. Yes,

158. *Bruesewitz*, 131 S. Ct. at 1099, n.19 (Sotomayor, J., dissenting).

159. See Brief of Amici Curiae National Vaccine Information Center, Its Co-Founders and 24 Other Organizations in Support of Petitioners at 13-14, *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068 (2011) (No. 09-152); Brief of Amicus Curiae Marguerite Willner in Support of Petitioners at 21-23, *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068 (2011) (No. 09-152).

160. See *National Vaccine Injury Compensation Program*, HRSA.GOV, [http://www.hrsa.gov/vaccinecompensation/statistics\\_report.htm#claims\\_filed](http://www.hrsa.gov/vaccinecompensation/statistics_report.htm#claims_filed) (last visited May 19, 2011) (showing approximately twenty percent of petitions that have been compensated).

161. See, e.g., Brief of Vaccine Injured Petitioners Bar Association, the George Washington University Law School Vaccine Injury Clinic, and Zenoria Phillips Deloatch, as Personal Representative of the Estate of Moshella F. Roberts, as Amici Curiae in Support of Petitioners passim, *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068 (2011) (No. 09-152).

the need for a healthy vaccine supply is great. The burden to establish congressional intent to immunize the entire industry for its design choices should also be great and the presumption against preemption represents that burden. The majority in *Bruesewitz* did not see it that way.

The Court may be determined to simply resolve preemption matters on a statute by statute basis, which will have the effect of creating administrative agency preemption for some agencies and for some tort claims but not for others. That result would be unfortunate and unfair. It would increase the uncertainty that currently exists about the preemptive scope of regulatory schemes. It would attach a preemption analysis to statutory language that the authoring Congresses could not have imagined.

It may be, however, that the agency-by-agency approach the Supreme Court is implementing through its preemption doctrine will have the effect of spurring society to have the kind of society wide conversation that Judge Calabresi envisions.<sup>162</sup> It may force our legislators, regulators, judges, lawyers and policy experts to engage in a meaningful way about the kind of regulatory system that may be needed to respond to excessive risks in our increasingly complex society, to compensate fairly for those risks, and to reduce them appropriately in the balanced way that the majority opinion in *Bruesewitz* thought Congress did in the case of vaccines.

Uncertainty is inevitable. Systems must respond to inevitable uncertainty and inadequacy of information. Having a mechanism by which the uncertainty inherent in one system is evaluated through the lens of another, even if only occasionally, enhances the opportunity to reduce the uncertainty. We should not so quickly dismiss the tort litigation system as an important, longstanding complement to more formal regulatory action for responding to uncertainty in risk information.

In the light of the past twenty years, the Vaccine Program has been moderately successful. Moderately, because there are many who complain the Program is slow, unfriendly to victims, and more restrictive in operation than was originally intended.<sup>163</sup> The operation of the Program was not at issue in *Bruesewitz*. One might hope that, now that design defect litigation is no longer available as a complement to the compensation system, the Program will increasingly come under scrutiny to defend its effectiveness in carrying out its mandate to compensate and increase vaccine safety.

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162. See Calabresi, *supra* note 15.

163. See Brief of Amicus Curiae Marguerite Willner, *supra* note 159, at 3. (“The compensation system has not lived up to Congress’s expectations. HHS, which administers the Program, has wrought administrative changes that make it difficult for petitioners to recover for their injuries. . . . These difficulties, coupled with the dearth of information about vaccine safety, render state tort actions a critical safety-valve in the regulatory system.”).