

## BRUESEWITZ V. WYETH: The Return to Proper Preemption Analysis

**Introduction**

In February 2011, the United States Supreme Court in *Bruesewitz v. Wyeth LLC*<sup>1</sup> effectively abolished the use of the presumption against preemption in the analysis of express preemption provisions. *Bruesewitz* is the latest case dealing with whether the National Childhood Vaccine Injury Act<sup>2</sup> (hereinafter "NCVIA") blocks design-defect claims against vaccine manufacturers in state court.<sup>3</sup> Justice Scalia commanded a majority of six justices to two in holding that the NCVIA indeed blocks all design-defect claims in state courts.<sup>4</sup>

The Supreme Court's holding in *Bruesewitz* is in direct conflict with the recent trend in preemption jurisprudence, which utilizes a presumption against preemption in express preemption analysis.<sup>5</sup> This note argues that the Supreme Court correctly decided *Bruesewitz* by refusing to apply the presumption against preemption where Congress has expressly indicated its intent to preempt. No presumption against preemption is required by the Constitution, and it does not make sense for the Court to utilize a presumption against preemption in express preemption analysis. Furthermore, by correctly interpreting the preemption clause in the NCVIA, the Court helps accomplish Congress' goals of protecting America's children and efficiently compensating victims of vaccine-related injuries by

ensuring that vaccine manufacturers have effective incentives to stay in the market.

Part I will describe the NCVIA and its background. Part II will discuss the various precedent that has led to the issue in this case and argues that the decision in *Bruesewitz* marks a return to the traditional express preemption analysis. Part III describes the facts, significance, and arguments in *Bruesewitz* itself. Finally, Part IV argues that the Court correctly refused to use the presumption against preemption, and that the Court reached the most just conclusion in *Bruesewitz*.

### **Part I: The National Childhood Vaccine Injury Act**

Congress enacted the NCVIA in response to instability in the vaccine market during the early 1980s.<sup>6</sup> Between 1980 and 1984, injured plaintiffs sought \$3.5 billion in damages from vaccine manufacturers,<sup>7</sup> causing six manufacturers to pull out of the market.<sup>8</sup> To add to the instability, “[t]he majority of vaccine manufacturers left the market citing the unavailability of product liability insurance.”<sup>9</sup> The manufacturers’ withdrawal from the market left the nation with one manufacturer of the diphtheria pertussis and tetanus (hereinafter “DPT”) vaccine<sup>10</sup> and caused vaccine prices to greatly increase.<sup>11</sup> A tragic consequence of the rising vaccine prices and shortage was a “resurgence of [preventable] illnesses and deaths.”<sup>12</sup>

The NCVIA created a no-fault compensation system as an alternative to traditional tort claims against vaccine manufacturers.<sup>13</sup> A person who has been injured by a vaccine that is covered under the NCVIA may receive compensation via a fund under certain circumstances if he files a claim with a special "vaccine court."<sup>14</sup> A person may claim monetary compensation for any injury specified on the "Vaccine Injury Table" maintained by the Department of Human Health Services Secretary.<sup>15</sup> Although the Secretary has some discretion over potential modifications of the injury table, he must include any vaccine on the list that the Center for Disease Control recommends for "routine administration to children."<sup>16</sup> Once the vaccine court makes a judgment, the claimant may choose to either accept the vaccine court's judgment, or he may elect to proceed against the manufacturer in state court so long as his claim is not preempted by the NCVIA.<sup>17</sup>

The clause at issue in *Bruesewitz* 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 warning.<sup>18</sup>

There is a consensus among the courts that, by this provision, Congress meant to preempt at least *some* state law;<sup>19</sup> however, courts disagree over the extent that state law is preempted.<sup>20</sup>

## **Part II: Legal Background and Precedent**

The Supremacy Clause of the United States Constitution provides the basis for federal preemption of state law.<sup>21</sup> In determining whether a federal law preempts state law, the Supreme Court considers "the purpose of Congress [a]s the ultimate touchstone in every preemption case."<sup>22</sup> Congress can convey its purpose to preempt state law either expressly or the Court may imply that intent.<sup>23</sup> Congress may expressly communicate its intent to preempt state law by stating within the legislation that the law is meant to preempt state law.<sup>24</sup> When the text of an express preemption provision is ambiguous, the Supreme Court engages in standard statutory interpretation to determine the scope of the statute.<sup>25</sup>

However, Congress does not always expressly convey its intent to preempt state law. When this is the case, the courts employ one of two doctrines to imply that intent to preempt. The first category is referred to as "occupation of the field" or "field" preemption. Field preemption occurs where Congress has "legislated so comprehensively in a field that it must have

intended national uniformity of legislation, and, therefore, its legislation displaces all state regulation."<sup>26</sup> Historically, the Supreme Court has been reluctant to apply field preemption to state common-law tort claims<sup>27</sup> because Congress has not explicitly stated its intention to preempt.<sup>28</sup>

The second category is implied conflict preemption. When federal and state regulations conflict with each other to the point where it is impossible for someone to comply with both requirements, then Congress has intended federal law to preempt state law.<sup>29</sup> Also, implied conflict preemption can be found if state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."<sup>30</sup>

Throughout history, the Supreme Court has consistently used a presumption against preemption when performing implied preemption analysis.<sup>31</sup> A presumption against preemption makes sense in implied preemption analysis because, if Congress intended to preempt, then it would have included an express preemption provision in the legislation.<sup>32</sup> Congress has not traditionally employed a presumption against preemption in its express preemption analysis.<sup>33</sup>

However, *Cipollone v. Liggett Group, Inc.*<sup>34</sup> marks a turning point in express preemption analysis. There, the United States Supreme Court started the recent trend moving from the traditional approach to a modern approach, which utilizes the

presumption against preemption in express preemption analysis.<sup>35</sup> There, the son of a woman who died from lung cancer after smoking for forty years sued a cigarette manufacturer for failure to warn consumers about the ill health effects of smoking.<sup>36</sup> As a defense, the cigarette manufacturer contended that both the Federal Cigarette Labeling and Advertising Act (hereinafter "FCLA") and its successor protected the manufacturer from liability.<sup>37</sup> The FCLA and its successor expressly preempted state law in a preemption clause contained in the legislation.<sup>38</sup> The district court held that state regulations were preempted by federal regulations, but the court also held that state common-law actions were not preempted.<sup>39</sup> The appellate court reversed the district court's decision, ruling that the FCLA and its successor did not expressly preempt state common-law actions.<sup>40</sup> However, the appellate court also ruled that state common-law actions would conflict with federal law, and therefore state common-law actions were preempted by the FCLA.<sup>41</sup>

In his plurality opinion, Justice Stevens held that the FCLA did not preempt common law claims.<sup>42</sup> Justice Stevens noted that a narrow reading of the preemption provision in the FCLA is required because of the presumption against preemption.<sup>43</sup> However, because of changed language in the legislation subsequent to the FCLA, the Court found that state common-law

claims were ultimately preempted.<sup>44</sup> *Cipollone* dramatically extended the presumption of preemption to apply to express preemption cases, and thus began the modern trend of construing preemption provisions as narrowly as possible.<sup>45</sup>

After *Cippolone*, the Court began applying the presumption against preemption in express preemption cases.<sup>46</sup> In *American Products Corp. v. Ferrari*,<sup>47</sup> the Georgia Supreme Court continued the trend of applying the presumption against preemption in express preemption cases.<sup>48</sup> The Ferraris sued on behalf of their son, alleging that he suffered neurological damage caused by vaccine containing a small amount of mercury as a preservative.<sup>49</sup> They specifically alleged both strict liability and design-defect claims against the vaccine manufacturer.<sup>50</sup> The trial court ruled that the manufacturer's design defect claims were preempted by the NCVIA.<sup>51</sup> On appeal, the court reasoned that "despite clear legislative history favoring preemption, [*Bates v. Dow Agrosciences*<sup>52</sup>] imposes a 'duty to accept the reading . . . that disfavors pre-emption.'"<sup>53</sup> Furthermore, the appeals court held that *Bates* stood for the proposition that the presumption against preemption trumps legislative history when interpreting express preemption provisions.<sup>54</sup> Thus, the appellate court held that the Ferrari's common law design defect claims were not preempted by the NCVIA's preemption provision.<sup>55</sup>

The Georgia Supreme Court disapproved of the appellate court's assertion that *Bates* requires a court to ignore statutory interpretation in the analysis of an express preemption provision.<sup>56</sup> But, the court described *Bates* as "the most explicit statement yet of the presumption against preemption" that "fully demonstrate[s] its commitment to the presumption against preemption except in the narrowest of circumstances."<sup>57</sup> Thus, the court in *Ferrari* analyzed the text, structure, and legislative history of the statute in the shadow of a strong presumption against preemption. Ultimately, *Ferrari* affirmed the decision of the Court of Appeals that state common law design defect claims are not preempted by the NCVIA.<sup>58</sup>

### **Part III: Wyeth v. Bruesewitz**

Like any child in the United States, Hannah Bruesewitz received recommended doses of the DPT vaccine.<sup>59</sup> The vaccine Hannah received was made using whole bacterial cells.<sup>60</sup> There are other, non-FDA approved, DTP vaccines that are noncellular or acellular.<sup>61</sup> Noncellular and acellular vaccines are safer than the whole-cell vaccine; however, they are less effective.<sup>62</sup> Upon receiving her third vaccination, Hannah began suffering from seizures.<sup>63</sup> Doctors diagnosed Hannah with residual seizure disorder and developmental delay, and she will require medical care for the rest of her life.<sup>64</sup>

In April 1995, Hannah's parents filed a claim in the vaccine court set up by the NCVIA.<sup>65</sup> The vaccine court determined that Hannah could not recover compensation because her vaccines were not included on the vaccine table and her parents had failed to show cause.<sup>66</sup> Thereafter, Hannah's parents filed a claim in the Philadelphia Court of Common pleas alleging, *inter alia*, strict liability and negligence design-defect claims.<sup>67</sup> The suit was removed to the Eastern District of Pennsylvania, which granted summary judgment to the manufacturer on August 24, 2007.<sup>68</sup>

The Third Circuit Court of Appeals first provides an overview of the law dealing with express and implied preemption.<sup>69</sup> Then, the court begins its analysis by noting the presumption against preemption, for which the court cites *Bates v. Dow Agrosciences*<sup>70</sup> and *Cipollone v. Liggett Group, Inc.*<sup>71</sup> Thus, the Third Circuit Court of Appeals continues the modern trend of applying the presumption to express preemption analysis. The court correctly acknowledges that when dealing with express preemption provisions, it must determine the scope of that provision through standard statutory interpretation,<sup>72</sup> and the court ultimately finds that the NCVIA preempts state common law design defect-claims.<sup>73</sup> The Supreme Court of the United States subsequently granted writ of certiorari.

Writing for the majority, Justice Scalia makes no mention of a presumption against preemption.<sup>74</sup> He focuses his analysis of the preemption provision in the NCVIA purely on textualist and structuralist arguments, and then he spends the remainder of his opinion responding to Justice Sotomayor's dissent.<sup>75</sup> First, Justice Scalia argues that the "even though" clause within the statutory text "delineates the preventative measures that a vaccine manufacturer *must* have taken for a side-effect to be considered 'unavoidable' under the statute."<sup>76</sup> Thus, according to Justice Scalia, so long as there was adequate warning and proper manufacture, any remaining side-effects would be considered unavoidable under the statute.<sup>77</sup>

Scalia's structural argument proceeds as follows: (1) the statute states that a manufacturer's deviation from its vaccine's license provides evidence of a manufacturing defect or an inadequate warning.<sup>78</sup> (2) A vaccine's license meticulously lays out detailed manufacturing and warning requirements.<sup>79</sup> (3) The NCVIA, "which in every other respect micromanages manufacturers, is silent on how to evaluate competing designs."<sup>80</sup> (4) Therefore, the NCVIA leaves the design-defect judgment, which is one of balancing safety and efficacy, to the manufacturer, and Congress had only meant to allow inadequate warning and manufacturing defect claims.<sup>81</sup>

Scalia concludes that his interpretation of the NCVIA is the only interpretation supported by the text and structure of the Act.<sup>82</sup> Thus, he sees no reason to resort to legislative history, and he only offers his analysis of legislative history in order to show that the dissent is mistaken.<sup>83</sup>

Although Sotomayor offers her own textual and structural interpretations, she relies heavily on legislative history.<sup>84</sup> The most contentious issue between the majority and the dissent is whether the term “unavoidable” is used to denote that all vaccine design-defect claims are deemed unavoidable or if it is used to denote that not all vaccine designs are unavoidably unsafe. Justice Sotomayor opts for the latter interpretation,<sup>85</sup> and thus would hold that design-defect claims are allowed under the NCVIA.

#### **PART IV: Analysis**

In *Bruesewitz*, the Supreme Court returned express preemption analysis from the modern trend of applying the presumption against preemption to express preemption analysis to the traditional approach of using only ordinary statutory interpretation. In doing so, the Supreme Court correctly decided *Bruesewitz* because first, applying the presumption against preemption is not required by the Constitution, and second, applying the presumption against preemption makes sense for implied preemption analysis only.

Nowhere in the Supremacy Clause<sup>86</sup> of the Constitution is a presumption against preemption mentioned. Because the presumption is not present in the Constitution, the Court is not required to apply it in any sort of preemption analysis. Critics may argue that the presumption against preemption is required in an effort to protect the principles of federalism that underlie the Constitution.<sup>87</sup> Although the structure of the Constitution gives each state clear police power, the Constitution explicitly gives Congress the power to create the supreme law of the land.<sup>88</sup> Thus, whatever power Congress exercises that is enumerated in the Constitution takes precedent over any state powers. Where Congress has already expressed its intention to preempt state law, the only thing left for the Court to do is determine the scope of that preemption.<sup>89</sup> It makes no sense to assume that Congress did not intend to preempt state law where it has expressly made that intention clear. Rather than be afraid to find preemption, in order to remain true to the Constitution, the Court has a duty to use the traditional tools of statutory interpretation in order to figure out what Congress actually meant.<sup>90</sup> Using a presumption against preemption in this context would be a disservice to Congress' true intention.

Furthermore, the Court reached the correct conclusion because allowing state common law design-defect claims would frustrate the twin purposes of the NCVIA.<sup>91</sup> The very purpose

behind the NCVIA was to prevent manufacturers from pulling out of the vaccine market by limiting their exposure to liability.<sup>92</sup> The other purpose behind the NCVIA was to grant America's children access to vaccines. Allowing common law design-defect suits would put vaccine manufacturers in the same exact place they were before Congress passed the NCVIA, and Congress surely did not intend their legislation to maintain the status quo.

Critics of my position may argue that recent case law surrounding the presumption against preemption is binding precedent that the court needs to follow.<sup>93</sup> However, before the modern trend following *Cipollone* and *Bates* there was extensive case law to support the proposition that a presumption against preemption is not required when interpreting an express preemption provision.<sup>94</sup> Because this proposition is not required by the Constitution and it makes more sense than the modern approach, the Court was correct when it did not utilize the presumption in its analysis.

## **V. Conclusion**

*Bruesewitz v. Wyeth* marks an incredibly important point in preemption jurisprudence. By returning to the traditional approach of analyzing express preemption provisions, the United States Supreme Court's analysis holds true to the text, structure, and principles of the Constitution. In addition, the case was correctly decided because to interpret the NCVIA to

allow design defect claims would return the vaccine market back to the state it was in before the Congress enacted it. The decision in *Bruesewitz* is vital not only to protecting the Constitution and congressional intent, but also to protecting America's children by providing vaccine manufacturers adequate incentive to stay in the market.

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<sup>1</sup> *Bruesewitz v. Wyeth LLC*, 562 U.S. \_\_\_\_, No. 09-152 (Feb. 22, 2011).

<sup>2</sup> 42 U.S.C. § 300aa-22(a)(1) (2008).

<sup>3</sup> *Bruesewitz*, No. 09-152, slip op. at 1 (Scalia, J.).

<sup>4</sup> *Id.* at 19.

<sup>5</sup> See generally Mary J. Davis, *The "New" Presumption Against Preemption*, 61 HASTINGS L. J. 1217 passim (2010) (discussing the modern trend of preemption case-law, which has generally moved toward interpreting express and implied preemption narrowly).

<sup>6</sup> See *Bruesewitz*, No. 09-152, slip op. at 3 (Scalia, J.) ("To stabilize the vaccine market and facilitate compensation, Congress enacted the NCVIA in 1986."); Daniel A. Cantor, *Striking a Balance Between Product Availability and Product Safety: Lessons from the Vaccine Act*, 44 AM. U. L. REV. 1853, 1858 (date unavailable).

<sup>7</sup> Cantor, *supra* note 6, at 1858 (citing Subcomm. on Health and the Env't of the House Comm. on Energy and Commerce, 99th Cong., 2d Sess, *Childhood Immunizations* 72 (Comm. Print 1986) (presenting results of vaccine manufacturer survey)).

<sup>8</sup> *Id.*

<sup>9</sup> *Id.* at 1859.

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<sup>10</sup> 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, 789 (2006-2007).

<sup>11</sup> Cantor, *supra* note 6, at 1859.

<sup>12</sup> Theodore Ruger, *Preemption of Vaccine Injury Lawsuits Upheld*, REG BLOG (Apr. 5, 2011), <http://www.law.upenn.edu/blogs/regblog/2011/04/us-supreme-court-rules-in-favor-of-preemption-for-vaccine-injury-lawsuits.html>.

<sup>13</sup> Rutkow, *supra* note 10, at 684 (citing National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3756).

<sup>14</sup> *Id.* at 686 (explaining that a person may receive compensation if the person shows an injury listed on a vaccine injury table that provides for automatic compensation, the person proves that the vaccine caused his condition, or the person shows that a vaccine aggravated a pre-existing condition).

<sup>15</sup> *Id.* at 686-87.

<sup>16</sup> *Id.* at 87 (citing 42 U.S.C. § 300aa-14(e) (2006)).

<sup>17</sup> *Id.* at 688.

<sup>18</sup> 42 U.S.C. § 300aa-22(b) (1) (2008).

<sup>19</sup> Courts dealing with this issue recognize that Congress would not have included 42 U.S.C. 300aa-22(b) (1) in the statute if it had not intended NCVIA to preempt at least *some* state law.

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Clearly, courts that hold design defect claims are preempted agree. However, even courts that hold design defect claims are not preempted agree as well. See *infra* note 20.

<sup>20</sup> Compare *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 301-02 (E.D. Pa. 2004) (holding that all design-defect claims are barred) with *Am. Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236, 238 (2008) (noting that NCVIA preempts state law to a certain extent, although it does not preempt all design-defect claims).

<sup>21</sup> U.S. Const. art. VI, cl. 2 ("This Constitution, and the laws of the United States . . . shall be the supreme law of the land; and the judges in every state shall be bound thereby, anything in the Constitution or laws of any State to the contrary notwithstanding.").

<sup>22</sup> *Wyeth v. Levine*, 129 S. Ct. 1187, 1194 (2009) (citation omitted).

<sup>23</sup> Mary J. Davis, *The "New" Presumption Against Preemption*, 61 HASTINGS L. J. 1217, 1221 (2010).

<sup>24</sup> *Id.*

<sup>25</sup> *Id.* (citing *Altria Group, Inc. v. Good*, 129 S. Ct. 538, 543 (2008)); see also *Cipollone v. Liggett Group, Inc.* 505 U.S. 504, 516 (1992).

<sup>26</sup> Davis, *supra* note 23.

<sup>27</sup> *Id.*

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<sup>28</sup> *Wyeth v. Levine*, 129 S. Ct. 1187, 1194-95 (2009).

<sup>29</sup> Mary J. Davis, *The "New" Presumption Against Preemption*, 61 HASTINGS L. J. 1217, 1221 (2010).

<sup>30</sup> *Id.* (quoting David G. Owen, PRODUCTS LIABILITY LAW § 14.4 at 942 (2d rev. ed. 2008)).

<sup>31</sup> Daniel A. Cantor, *Striking a Balance Between Product Availability and Product Safety: Lessons from the Vaccine Act*, 44 AM. U. L. REV. 1853, 1858 n. 179 (date unavailable).

<sup>32</sup> See *Cipollone v. Liggett Group Inc.*, 505 U.S. 504, 545-46 (1992) (Scalia, J., concurring) (discussing past Supreme Court cases where the court has not traditionally used a presumption against preemption in express preemption analysis but not in implied preemption analysis).

<sup>33</sup> *Id.*

<sup>34</sup> 505 U.S. 504 (1992).

<sup>35</sup> *Id.* at 516 (Stevens, J.) (plurality opinion).

<sup>36</sup> *Id.* at 508.

<sup>37</sup> *Id.* at 510.

<sup>38</sup> *Id.* at 514.

<sup>39</sup> *Id.* at 510.

<sup>40</sup> *Id.*

<sup>41</sup> *Id.*

<sup>42</sup> *Id.* at 518.

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<sup>43</sup> *Id.*

<sup>44</sup> *Id.*

<sup>45</sup> See Mary J. Davis, *The "New" Presumption Against Preemption*, 61 HASTINGS L. J. 1217, 1239 (2010); Cipollone, 505 U.S. at 545 (Scalia, J., dissenting) (noting that the court has announced two completely new principles that cause a narrow construction of express preemption provisions).

<sup>46</sup> Davis, *supra* note 45 (noting that in *Medtronic v. Lohr*, 518 U.S. 280 (1995), the Court applied the presumption to express preemption).

<sup>47</sup> 668 S.E.2d 236 (Ga. 2008).

<sup>48</sup> Sean W. Shirley and Jeremy W. Gregory, *Contagious Trend or Isolated Outbreak? Manufacturers No Longer Immunized in Georgia*, 51 No. 2 DRI FOR DEF. 24, 1 (Feb. 2009).

<sup>49</sup> Ferrari, 668 S.E.2d at 237.

<sup>50</sup> *Id.*

<sup>51</sup> *Id.*

<sup>52</sup> 544 U.S. 431 (2005).

<sup>53</sup> Ferrari, 668 S.E.2d at 237 (quoting *Ferrari v. American Home Products Corp.*, 286 Ga.App. 305, 311 (2007)).

<sup>54</sup> Beck/Herrmann, *Vaccine Preemption - A Murder at the Bates Motel?*, DRUG AND DEVICE LAW (July 26, 2007)

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<http://druganddevicelaw.blogspot.com/2007/07/vaccine-preemption-murder-at-bates.html>.

<sup>55</sup> *Id.*

<sup>56</sup> Ferrari, 668 S.E.2d at 239.

<sup>57</sup> *Id.* (citing J. Edgen, *The Normalization of Product Preemption Doctrine*, 57 ALA. L. REV. 725, 762-763 (III) (B) (2006)).

<sup>58</sup> *Id.* at 243.

<sup>59</sup> *Bruesewitz v. Wyeth*, 561 F.3d 233, 236 (3d Cir. 2009).

<sup>60</sup> *Id.*

<sup>61</sup> Daniel A. Cantor, *Striking a Balance Between Product Availability and Product Safety: Lessons from the Vaccine Act*, 44 AM. U. L. REV. 1853, 1892 (date unavailable).

<sup>62</sup> *Id.*

<sup>63</sup> *Id.*

<sup>64</sup> *Bruesewitz*, 561 F.3d at 236.

<sup>65</sup> *Id.* at 237.

<sup>66</sup> *Id.*

<sup>67</sup> *Id.*

<sup>68</sup> *Id.*

<sup>69</sup> *Id.* at 238-40.

<sup>70</sup> *Id.* at 240 (quoting *Bates v. Dow Agrosciences*, 544 U.S. 431, 449 (2005)).

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<sup>71</sup> *Id.* (citing *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992)).

<sup>72</sup> *Id.* at 245.

<sup>73</sup> *Id.* at 255.

<sup>74</sup> *Bruesewitz v. Wyeth LLC*, 562 U.S. \_\_\_\_, No. 09-152, slip op. passim (Feb. 22, 2011) (Scalia, J.).

<sup>75</sup> *Bruesewitz*, No. 09-152, slip op. at 7-19. (Scalia, J.).

<sup>76</sup> *Id.* at 7 (emphasis in original).

<sup>77</sup> *Id.*

<sup>78</sup> *Id.* at 13.

<sup>79</sup> *Id.*

<sup>80</sup> *Id.*

<sup>81</sup> *Id.* at 13-14.

<sup>82</sup> *Id.* at 16.

<sup>83</sup> *Id.*

<sup>84</sup> *Bruesewitz*, No. 09-152, slip op. at 1-28. (Sotomayor, J.).

<sup>85</sup> *Id.* at 8.

<sup>86</sup> U.S. Const. art. VI, cl. 2 ("This Constitution, and the laws of the United States . . . shall be the supreme law of the land; and the judges in every state shall be bound thereby, anything in the Constitution or laws of any State to the contrary notwithstanding.").

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<sup>87</sup> Am. Home Prods. Corp v. Ferrari, 668 S.E.2d 236, 238 (2008) (“[B]ecause the states are independent sovereigns in our federal system . . . we `start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act . . . .’”) (citation omitted).

<sup>88</sup> U.S. Const. art. VI, cl. 2.

<sup>89</sup> Bruesewitz v. Wyeth Inc., 561 F.3d 233, 243 (3d Cir. 2009) (citing Lorillard Tobacco Co., 533 U.S. 525, 541 (2001)).

<sup>90</sup> Cipollone v. Liggett Group Inc., 505 U.S. 504, 546 (1992) (Scalia, J., dissenting).

<sup>91</sup> The twin purposes of the NCVIA are: (1) to keep manufacturers in the market and (2) to fairly compensate victims of vaccine-related injuries. See Lainie Rutkow et. al., *Balancing Consumer and Industry Interests in Public Health: The National Vaccine Injury Compensation Program and its Influence During the Last Two Decades*, 111 PENN ST. L. REV. 681, 709 (2006-2007).

<sup>92</sup> *Id.*

<sup>93</sup> See e.g., Cipollone, 505 U.S. at 530-31.

<sup>94</sup> *Id.* at 545-46 (Scalia, J., dissenting).