

# *BRUESEWITZ v. WYETH:* THE “UNAVOIDABLE” VACCINE PROBLEM

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## I. INTRODUCTION

With fear of vaccines on the rise<sup>1</sup> and the resurgence of Whooping Cough (Pertussis) nearing epidemic proportions in California,<sup>2</sup> now is a particularly apt time for the Supreme Court to assess the National Childhood Vaccine Injury Act (Vaccine Act).<sup>3</sup> *Bruesewitz v. Wyeth*<sup>4</sup> provides the Court with this opportunity. In *Bruesewitz*, the Court addresses whether federal law preempts state tort claims under the Vaccine Act.<sup>5</sup> How the statutory text is interpreted—specifically whether the Court will interpret “unavoidable” in the Vaccine Act to preempt design-defect claims—will determine whether a state jury, rather than a special master in Vaccine Court, may decide whether a differently designed vaccine could have prevented the resulting side effects.<sup>6</sup>

*Bruesewitz*’s outcome will affect more than just who will decide vaccine-design claims. According to the respondent Wyeth, a pharmaceutical company, permitting state juries to assess these claims will impair the vaccine market and injure the public as vaccine manufacturers withdraw from the market due to the rising cost of litigation.<sup>7</sup> Conversely, petitioner Bruesewitz, the family of a child

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1. Brian Deer, *How the Case Against the MMR Vaccine Was Fixed*, 342 BRITISH MED. J. 77 (2011); Jennifer Steinhauer, *Public Health Risk Seen As Parents Reject Vaccines*, N.Y. TIMES, Mar. 28, 2008, at 1.

2. Molly Hennessy-Fiske, *Whooping Cough Fight Broadens; Officials Urge More Vaccinations As Number of Cases Surges*, L.A. TIMES, July 20, 2010, at AA 1.

3. 42 U.S.C.A. §§ 300aa-1–300aa-34 (West 2010).

4. *Bruesewitz v. Wyeth*, No. 09-152 (U.S. argued Oct. 12, 2010).

5. Brief for Respondent at i, *Bruesewitz v. Wyeth*, No. 09-152 (U.S. July 23, 2010).

6. *Id.* at 4–5.

7. *See id.* at 55–57; Brief for American Academy of Pediatrics (AAP) et al. as Amici

injured by the Pertussis vaccine, views state-court liability as vital to compelling vaccine manufacturers to continue enhancing the safety and technology of vaccines.<sup>8</sup> Although *Bruesewitz* has garnered relatively little media attention,<sup>9</sup> the decision will have a direct and significant impact on the health and welfare of American children.<sup>10</sup>

## II. FACTS

Like millions of other infants in the 1990s, Hannah Bruesewitz received the DPT vaccine to protect her against Diphtheria, Pertussis, and Tetanus.<sup>11</sup> The Federal Advisory Committee on Immunization Practices recommended that children receive five doses of the DPT vaccine before they turn six years old.<sup>12</sup> On April 1, 1992, an apparently healthy six-month-old Hannah received her third dose of the Wyeth Tri-Immunol DPT vaccine and experienced seizures within hours.<sup>13</sup> Over the next eleven years, Hannah continued to have seizures; doctors diagnosed her with “pervasive developmental disorder and seizure disorder.”<sup>14</sup> To this day, Hannah suffers from residual seizure disorder and developmental impairment;<sup>15</sup> she requires “intensive high-quality one-on-one” occupational and speech therapy and will likely require medical care for the rest of her life.<sup>16</sup>

In 1995, the Bruesewitz family filed a claim in Vaccine Court for Hannah’s DPT-related injuries.<sup>17</sup> Established under the Vaccine Act, the Vaccine Court was created as part of the National Vaccine Injury Compensation Program (NVICP), which provides a compensation scheme for vaccine-related injury claims.<sup>18</sup> The Act requires a person

Curiae Supporting Respondents at 15–18, *Bruesewitz v. Wyeth*, No. 09-152 (U.S. July 23, 2010).

8. Brief for Petitioners at 51–57, *Bruesewitz v. Wyeth*, No. 09-152 (U.S. May 24, 2010); Brief for Mark Geistfeld as Amicus Curiae Supporting Petitioners at 3–4, *Bruesewitz v. Wyeth*, No. 09-152 (U.S. May 24, 2010); Brief for American Association for Justice (AAJ) as Amici Curiae Supporting Petitioners at 10–27, *Bruesewitz v. Wyeth*, No. 09-152 (U.S. May 24, 2010).

9. A LexisNexis search of “Schwarzenegger v. Entertainment Merchants’ Association” in the “News, Most Recent 2 Years” database yielded 110 results and “Snyder v. Phelps” yielded 327 articles while “*Bruesewitz v. Wyeth*” yielded only 81 results.

10. See Steinhauser, *supra* note 1 (citing cases in which parents have refused vaccinations for their children leading to deleterious health effects).

11. Brief for Petitioner, *supra* note 8, at 19.

12. *Bruesewitz v. Wyeth*, 561 F.3d 233, 236 (3d Cir. 2009).

13. *Id.*

14. *Id.*

15. *Id.* at 236.

16. *Id.*

17. *Id.* at 237.

18. 42 U.S.C.A. § 300aa-10 (West 2010).

injured by a vaccine to bypass the civil-litigation system and pursue a claim in the Vaccine Court.<sup>19</sup> It allows claimants to overcome the burden of causation if the vaccine in question is covered under the Act, if the injury is included on the Vaccine Table (Table) of associated injuries, and if no evidence indicates that something other than the vaccine caused the injury.<sup>20</sup> If the injury is not included on the Table, but a claimant can prove that a vaccine caused the injury, the claimant may also recover in Vaccine Court.<sup>21</sup> The claimant is free to accept or reject the Vaccine Court’s decision, and may then pursue limited claims in state or federal court.<sup>22</sup>

The Bruesewitz family unsuccessfully pursued its claim in Vaccine Court. Because Hannah’s residual seizure disorder and encephalopathy were no longer considered “Table” injuries, the Vaccine Court dismissed the family’s claim without prejudice.<sup>23</sup> To proceed in Vaccine Court, Bruesewitz would need to prove causation-in-fact.<sup>24</sup> Bruesewitz, however, chose not to proceed in Vaccine Court and instead sued Wyeth directly alleging the vaccine was defectively designed by the company’s failure to produce a safer design.<sup>25</sup>

The district court granted summary judgment for Wyeth.<sup>26</sup> The court held that the Vaccine Act preempts all design-defect claims against FDA-approved vaccines from vaccine injures, both in negligence and strict liability.<sup>27</sup> The district court held that a case-by-case consideration would violate Congress’s intent to protect manufacturers from suit.<sup>28</sup> Bruesewitz appealed.<sup>29</sup>

Over the last century, the federal government has assumed control over the vaccine industry and has required approval of all manufacturing, licensing, and marketing of vaccines.<sup>30</sup> Since 1972, the Food and Drug Administration (FDA) has regulated all vaccines and biologics.<sup>31</sup> To market a vaccine in the United States, the vaccine

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19. *Id.*

20. *Id.*

21. *Id.*

22. 42 U.S.C.A. § 300aa-21(a) (West 2010).

23. *Bruesewitz v. Wyeth*, 561 F.3d 233, 237 (3d Cir. 2009).

24. *Id.*

25. *Id.*

26. *Id.*

27. *Id.*

28. *Id.* at 238.

29. Brief for Petitioner, *supra* note 8, at 2.

30. *Id.* at 4–6.

31. *Id.* at 6.

manufacturer must receive authorization to conduct clinical trials from the FDA.<sup>32</sup> After clinical trials have been conducted, the vaccine sponsor may apply for a biologics license and must prove that the vaccine is “safe, pure, potent, and effective.”<sup>33</sup> The vaccine is not required to be the safest feasible design, and the FDA does not ensure that drugs are optimally designed.<sup>34</sup> Manufacturers must follow strict regulations and may need subsequent FDA approval to change any aspect of the vaccine.<sup>35</sup> Much of the biomedical research on vaccine safety and innovation is performed by the federal government at the National Institutes of Health (NIH) and many vaccine recommendations and risk determinations are made by the Center for Disease (CDC) and other medical groups.<sup>36</sup> While the FDA relies on an adverse event reporting system and post-marketing studies to monitor any problems with approved vaccines, the FDA does not have the authority to order a manufacturer to adopt a safer alternative design for an already-licensed vaccine.<sup>37</sup>

Wyeth developed the Tri-Immunol vaccine to protect against Diphtheria, Pertussis, and Tetanus.<sup>38</sup> The vaccine received marketing approval in 1943.<sup>39</sup> It was incredibly successful in reducing the incidence of Pertussis in the United States.<sup>40</sup> Although the vaccine carried some risks (as all vaccines do), doctors and health officials agreed that the benefits of the vaccine to the community outweighed the risks to an individual.<sup>41</sup> Vaccination of large numbers of people causes “herd immunity”<sup>42</sup> and thereby halts the spread of disease

32. 21 C.F.R. §§ 312.2(a), 312.20–312.38 (West 2011).

33. Brief for Petitioner, *supra* note 8, at 6.

34. *Id.* at 6–7; *Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products*, FOOD & DRUG ADMIN., 4 (May 1998), <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM078749.pdf>.

35. 21 C.F.R. § 601.12(b) (West 2011).

36. Brief for United States as Amicus Curiae Supporting Respondents at 22–23, *Bruesewitz v. Wyeth*, No. 09-152 (U.S. July 23, 2010).

37. 21 C.F.R. § 601.12(b)(2)(i) (West 2011); Brief for Petitioner, *supra* note 8, at 9.

38. Brief for Respondent, *supra* note 5, at 18.

39. *Id.*

40. *Id.*

41. Brief for AAP, *supra* note 7, at 15; Brief for Buffler, et al. as Amici Curiae Supporting Respondents (11 Scientists) at 13, *Bruesewitz v. Wyeth*, No. 09-152 (U.S. July 30, 2010).

42. “Herd immunity,” also known as “community immunity,” refers to the protection against certain diseases afforded to a given community by immunizing a high percentage of the community. Thus, if a few members of the community are not immunized, the community is still protected, as the disease will not be able to spread. If only a small percentage of the population is immunized, the disease could cause an outbreak. *CDC Vaccine Program Office: Glossary*,

throughout the community.<sup>43</sup> Because of the overwhelming benefits of herd immunity, state governments provide and require childhood vaccinations for all public school students.<sup>44</sup>

Tri-Immunol contained “whole cell” Pertussis vaccine, as well as Diphtheria and Tetanus toxoids, to stimulate an immune response.<sup>45</sup> Although some scientists suspected that whole-cell vaccines might cause some severe adverse reactions, several epidemiologic studies dismissed those concerns.<sup>46</sup> The vaccine did have some side effects,<sup>47</sup> but the Department of Health and Human Services (HHS) removed “residual seizure disorder” from the list of injuries associated with the DPT vaccine in 1995 due to insufficient medical evidence supporting a causal relationship.<sup>48</sup> Although alternative DPT vaccines existed, none were available for six-month-olds at the time of Hannah’s inoculation.<sup>49</sup>

### III. LEGAL BACKGROUND

#### A. *The Vaccine Act*

Congress established the NVICP under the Vaccine Act in 1986.<sup>50</sup> Congress conceived of the program to resolve two issues. First, Congress wanted to provide a more efficient, consistent, and cost-

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U.S. DEP’T OF HEALTH & HUMAN SERVS., <http://www.hhs.gov/nvpo/glossary1.htm> (last visited Jan. 15, 2011).

43. Brief for 11 Scientists, *supra* note 41, at 12.

44. *National Vaccine Program Office School Immunization Laws*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.hhs.gov/nvpo/law.htm#School%20immunization%20laws> (last visited Jan. 15, 2011).

45. Brief for Respondent, *supra* note 5, at 18. A “whole-cell” vaccine is prepared using the whole inactivated bacterial cells. A toxoid refers to that inactivated cell.

46. *Id.* at 18–19.

47. *Id.*

48. *Toner v. Lederle*, 779 F.2d 1429, 1431 (9th Cir. 1986); *Bruesewitz v. Wyeth*, 561 F.3d 233, 237 n.5. (3d Cir. 2009).

49. Though this is a point of contention for petitioners, everyone agrees that no other vaccine was actually on the market in the United States at the time. A “fractioned” cell vaccine existed in the 1970s, but the FDA refused to relicense it, so it was no longer on the market. In 1991, the FDA approved the “acellular vaccine” for children two years or older, but did not approve it for younger children until 1996. As of 1992, no alternative vaccines were available for infants in the U.S. *Toner*, 779 F.2d at 1431; *Bruesewitz*, 561 F.3d at 236–37. Japan had adopted the DTaP vaccine in the 1990s, but the Solicitor General stressed that the FDA and the CDC would never allow the risks that Japan took by using the vaccine without adequate clinical trials. Japan was battling an epidemic of 13,000 whooping cough cases after removing the DPT Vaccine from the market. Brief for Petitioner, *supra* note 8, at 18–19; Brief for United States, *supra* note 36, at 33.

50. See *supra* notes 18–22 and accompanying text.

effective system than civil litigation in response to concerns of vaccine-injury victims and their families.<sup>51</sup> Second, Congress sought to address the potential for massive liability that threatened the viability of the vaccine market—such liability reduced vaccine manufacturers’ ability to obtain insurance and substantially increased their legal costs.<sup>52</sup> In the ten years prior to the enactment of the NVICP, the number of vaccine manufacturers shrank from twenty-six to just four.<sup>53</sup> From 1980 to 1986, plaintiffs sued vaccine manufacturers for more than \$3.5 billion in damages.<sup>54</sup> Constant litigation threatened to jeopardize the supply of essential childhood vaccines in the country.<sup>55</sup> Congress passed the Vaccine Act in an effort to balance both the needs of the victims and vaccine providers.

The Vaccine Act contains an immunity provision, section 300aa-22, which protects manufacturers from civil liability claims for “unavoidable” injuries.<sup>56</sup> The statute, which is the source of controversy in this litigation, reads:

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 . . . 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>57</sup>

In section (e), the statute denies federal preemption of any state claims that it does not expressly preempt.<sup>58</sup> All parties agree that defective-manufacturing claims and failure-to-warn state claims are permitted under the Act,<sup>59</sup> but whether the Vaccine Act preempts design-defect state claims is unclear.

### *B. Federal Preemption in the FDA regulatory scheme*

*Bruesewitz* turns on the Court’s understanding of what in fact is preempted under the Vaccine Act. The federal government’s power to

51. H.R. REP. No. 99-908, at 4 (2006).

52. *Id.* at 4–5.

53. Brief for GSK, et al. as Amici Curiae Supporting Respondents at 7, *Bruesewitz v. Wyeth*, No. 09-152 (U.S. July 23, 2010).

54. *Id.* at 7.

55. *Id.* at 7–8.

56. 42 U.S.C.A. § 300aa-22(b)(1) (West 2010).

57. *Id.* (emphasis added).

58. *Id.*

59. Brief for Respondent, *supra* note 5, at 46–47.

draft regulations that preempt state law is derived from the Supremacy Clause of the United States Constitution.<sup>60</sup> Courts recognize three types of preemption: express, implied, and field.<sup>61</sup> Express preemption refers to preemption explicitly mentioned in the statutory text.<sup>62</sup> Implied preemption is inferred if state law conflicts with federal law.<sup>63</sup> Field preemption, a form of implied preemption, occurs when federal law occupies an area of the law so much that there is no room for further state regulation.<sup>64</sup> All three forms of preemption require analysis of the statutory language and statutory scheme to determine whether Congress clearly and manifestly intended to preempt state law.<sup>65</sup> If the relevant language is unclear, courts presume that federal law does not preempt state law.<sup>66</sup>

Recently, the Supreme Court addressed express and implied federal preemption within the scope of the FDA-regulatory framework.<sup>67</sup> In *Riegel v. Medtronic*,<sup>68</sup> the Court held that the text of federal regulations preempted a New York negligence law that required a FDA-approved device to be safer than the FDA requires under the Medical Device Act (MDA).<sup>69</sup> Because the MDA expressly preempts state laws “different from, or in addition to, any requirement applicable . . . to the device under federal law,” the Court held that the FDA pre-market safety approval requirement written in the MDA expressly preempts New York’s tort law.<sup>70</sup> The majority emphasized that the text of the MDA only preempts state manufacturing defect and labeling rules, not design-defect claims, which were left unaddressed by the MDA.<sup>71</sup> In reaching its conclusion, the Court deferred significantly to the FDA’s interpretation and relied

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60. U.S. CONST. art. VI, cl. 2; *Hillsborough Cnty. v. Automated Med. Labs.*, 471 U.S. 707, 713 (1985).

61. *Hillsborough Cnty.*, 471 U.S. at 713.

62. *Id.*

63. *Id.*

64. *Id.*

65. *Bruesewitz v. Wyeth*, 561 F.3d 233, 243 (3d Cir. 2009).

66. *Medtronic v. Lohr*, 518 U.S. 470, 485 (1996).

67. *See generally* *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (holding that federal FDA regulations do not preempt state tort laws because FDA regulations do not prohibit stronger warning labels than approved); *Riegel v. Medtronic*, 555 U.S. 312 (2008) (finding that the Medical Device Act expressly preempted state tort law); *Medtronic*, 518 U.S. at 486–87 (denying that FDA regulations preempt state damages laws because they are not “different from” federal regulations under the Medical Device Act).

68. *Riegel v. Medtronic*, 555 U.S. 312 (2008).

69. *Id.* at 325.

70. *Id.*

71. *Id.* at 322–23.

heavily on statutory text of the MDA rather than its legislative history.<sup>72</sup>

Conversely, in *Wyeth v. Levine*,<sup>73</sup> the Court held that federal pharmaceutical labeling law does not implicitly preempt state law.<sup>74</sup> Because Wyeth could have substituted its label for a more stringent one without violating FDA regulations,<sup>75</sup> the *Wyeth* Court held that the federal and state laws did not conflict,<sup>76</sup> and thus the state law was not preempted.<sup>77</sup> Adherence to FDA-approved warning labels is not sufficient because these labels serve as the low standard of adequate warnings; state juries, the Court held, can decide whether labels appropriately warned of risks above the FDA standard.<sup>78</sup> The Court stressed that if the FDA intended to preempt state law, it could have included an express-preemption provision as it did in the MDA.<sup>79</sup>

#### IV. HOLDING

In *Bruesewitz*, the Third Circuit affirmed the lower court and concluded that section 22(b)(1) of the Vaccine Act expressly preempted design-defect claims given the legislative history and structure of the Act.<sup>80</sup> If courts were forced to engage in a case-by-case analysis to determine whether any vaccine's side effects were unavoidable, then *all* claims would go to a jury, and section (e)'s preemption provision would be rendered meaningless.<sup>81</sup> Additionally, the Third Circuit determined that the Act showed a “‘clear and manifest’ expression of congressional intent” to preempt design-defect claims based on the 1986 House Commerce Committee Report.<sup>82</sup> The court feared that allowing case-by-case evaluations of almost every vaccine-injury claim would defeat Congress's intent to ensure the viability of the vaccine market.<sup>83</sup>

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72. *Id.* at 326.

73. *Wyeth v. Levine*, 239 S. Ct. 1187 (2009).

74. *Id.*

75. *Id.* at 1196–97.

76. *Id.* at 1199.

77. *Id.*

78. *Id.* at 1230–31 (Alito, J., dissenting).

79. *Id.* at 1200 (majority opinion).

80. *Bruesewitz v. Wyeth*, 561 F.3d 233, 242, 255–56 (3d Cir. 2009).

81. *Id.* at 246.

82. *Id.* at 246–51.

83. *Id.* at 246.



## V. ARGUMENTS

The Supreme Court’s analysis of all statutes, even express preemption statutes, must begin with the statutory text.<sup>84</sup> Both parties agree that this case rests on the Court’s interpretation of the word “unavoidable” in section 22(b).<sup>85</sup> The Court likely will decide this issue by relying heavily on congressional intent and the policy implications of having state juries evaluate government public-health decisions.

### A. *Bruesewitz’s (Petitioner’s) Argument*

Bruesewitz argues that section 22(b) of the Vaccine Act holds vaccine manufacturers liable for vaccine-related injuries if the manufacturer could have designed a “safer alternative” to the vaccine.<sup>86</sup> According to Bruesewitz, within the context of the Act “unavoidable” means that a manufacturer is liable if “the side effect could have been avoided by a safer design.”<sup>87</sup> Citing the 1986 Committee Report, Bruesewitz argues that section 22(b) only codified an exemption for strict-liability design-defect claims carved out as a common law tort in the Restatement of Torts.<sup>88</sup> This clearly demonstrates that Congress had no intention of preempting vaccines from all design-related liability.<sup>89</sup> Additionally, Bruesewitz cites several state and federal cases that have defined “unavoidably unsafe” as a product design that eliminates unnecessary risks of harm that cannot be made safer.<sup>90</sup> By the time the Vaccine Act was adopted in 1986, “unavoidable” had adopted a specialized meaning in torts: safety risks that cannot be eliminated by a safer alternative design.<sup>91</sup>

Bruesewitz argues that the conditional structure of section 22 illustrates that the manufacturer must show “that the vaccine at issue

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84. *Id.* at 239.

85. Brief for Petitioner, *supra* note 8, at 25; Brief for Respondent, *supra* note 5, at 24.

86. Brief for Petitioner, *supra* note 8, at 30–31.

87. *Id.* at 29 (citing the dictionary definition of “unavoidable” and the Restatement of Torts).

88. Brief for Petitioner, *supra* note 8, at 39. Products liability experts agree that section 22(b) codifies comment K of the Restatement, which preempts only *strict liability* claims for manufacturers, not negligence claims. Brief for Ken Starr and Erwin Chemerinsky as Amici Curiae Supporting Petitioners at 18, *Bruesewitz v. Wyeth*, No. 09-152 (U.S. May 23, 2010); Brief of Mark Geistfeld, *supra* note 8, at 5–20.

89. Brief for Petitioner, *supra* note 8, at 50–51.

90. *Id.* at 30.

91. *Id.* at 30–31.

in the lawsuit was designed as safely as possible.”<sup>92</sup> Otherwise, Congress would have used clearer language to overcome the presumption against preemption.<sup>93</sup> For consistency with the plain text,<sup>94</sup> Bruesewitz urges the Court to read the “even though” clause of the statute as preempting tort liability only if manufacturers have properly labeled and manufactured the vaccine and endured a case-by-case analysis of the vaccine’s side effects.<sup>95</sup>

Relying on committee reports and media statements by members of Congress at the time of and after the Act was passed, Bruesewitz contends that legislative history clearly shows that Congress did not intend to preempt state law.<sup>96</sup> Bruesewitz points to the Energy and Commerce Committee’s rejection of a proposed amendment to immunize vaccine manufacturers from liability for failing to develop safer designs.<sup>97</sup> Furthermore, the 1986 Committee Report stresses that the Vaccine Court should serve as an alternative to the tort system, not a replacement.<sup>98</sup>

Bruesewitz contends that permitting drug-manufacturer liability is consistent with both Congress’s intent in enacting the Vaccine Act and its policy goals.<sup>99</sup> According to Bruesewitz, Congress intended to promote vaccine safety and ensure fair compensation to victims.<sup>100</sup> If the law held manufacturers civilly liable, then manufacturers would be encouraged to improve their designs and injured patients would be properly compensated.<sup>101</sup> Bruesewitz denies vaccine manufacturers’ contentions that increased liability would threaten the stability of the vaccine market, alluding to undefined and unsubstantiated profits that vaccines generate for manufacturers.<sup>102</sup>

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92. *Id.*

93. *Id.* at 39.

94. *Id.* at 41.

95. *Id.* at 35.

96. *Id.* at 44–51.

97. *Id.* at 45–46.

98. *Id.* at 47.

99. *Id.* at 51–57.

100. *Id.*

101. *Id.* at 54–55.

102. Reply Brief for Petitioners at 19, *Bruesewitz v. Wyeth*, No. 09-152 (U.S. Aug. 23, 2010).

### B. Wyeth’s (Respondent’s) Arguments

Wyeth argues that the Vaccine Act clearly preempts design-defect claims.<sup>103</sup> The company contends that the relevant statutory language (“even though the vaccine was properly prepared”) modifies the definition of what it means for a vaccine’s side effect to be “unavoidable.” Bruesewitz, in contrast, argues that this language creates additional requirements the drug manufacturer must meet.<sup>104</sup> Wyeth asserts that Bruesewitz’s interpretation of the statutory text is a result of an alteration of Congress’s specific word choices—an alteration that misstates congressional intent. Wyeth notes that the Act says “side effects that were unavoidable even though . . . ,” not “unavoidable side effects even though . . . ,” as Bruesewitz interprets the language. This inversion of the statutory language, Wyeth contends, changes the Act’s meaning, which was intended to shield manufacturers from liability if they met their statutory obligations.<sup>105</sup> Bruesewitz, in contrast, interprets the Act to indemnify manufacturers from liability only if the vaccine’s side effects are unavoidable *and* the manufacturer fulfilled its additional legal obligations.<sup>106</sup>

Wyeth stresses that the Vaccine Act provides mechanisms other than liability to ensure that the industry continues to work on producing safer vaccines—like making HHS responsible for promoting and ensuring vaccine-safety development.<sup>107</sup> Allowing case-by-case analyses would put that responsibility back into the hands of juries, which tend to overlook the social benefits of vaccines and focus only on the relatively small number of vaccine-related injuries.<sup>108</sup> Thus, the Vaccine Act relies on HHS to determine the most effective and necessary vaccines rather than on an amalgam of state laws and jury verdicts.<sup>109</sup> Recognizing that vaccines necessarily have side effects, Congress chose to compensate vaccine-injury victims through the Vaccine Court, rather than state court.<sup>110</sup> Wyeth argues that a jury’s responsibilities should be limited to deciding manufacturing-defect claims, so as to not interfere with HHS and FDA responsibilities.

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103. Brief for Respondent, *supra* note 5, at 29.

104. *Id.*

105. *Id.* at 32–33.

106. *Id.*

107. Brief for United States, *supra* note 36, at 31; Brief for Respondent, *supra* note 5, at 36.

108. Brief for Respondent, *supra* note 5, at 36–37.

109. *Id.*

110. *Id.* at 37.

Although Wyeth acknowledges that the Restatement of Torts may help elucidate whether Congress intended the Vaccine Act to preempt design-defect claims, it is not clear that the Restatement preempted only strict liability.<sup>111</sup> Before Congress passed the Vaccine Act, some state courts had interpreted the relevant section of the Restatement of Torts to preempt both strict *and* negligence liability.<sup>112</sup> Because both parties are calling for the preemption of some state common law, the presumption against preemption is moot.<sup>113</sup> And it is also not clear that section 22(b) actually codified the exact restrictions in the Restatement rather than the principles it provides of manufacturer protection.<sup>114</sup>

Finally, Wyeth refutes Bruesewitz's main policy argument that manufacturer liability is essential to protect public health and ensure new vaccine developments.<sup>115</sup> Since the 1986 enactment of the Vaccine Act, manufacturers have brought over twenty new vaccines to market even without liability for design-defect claims.<sup>116</sup> Wyeth argues that design-defect claims do not inherently encourage more disclosure from manufacturers than a manufacturing-defect claim would (if there is any additional information to disclose).<sup>117</sup> In assessing the vaccine market and enacting the Vaccine Act, Wyeth argues that Congress sought to improve and protect public health not through litigation, but by ensuring a ready supply of vaccines and preventing manufacturers from leaving the market.<sup>118</sup> With design-defect liability, there would be an inevitable onslaught of litigation, which could have a devastating effect on public health.<sup>119</sup> The Solicitor General also views the addition of tort claims as detrimental to the vaccine industry, and ultimately public health.<sup>120</sup>

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111. *Id.* at 42.

112. *Id.* at 42–44.

113. Both parties are trying to preempt some state court decision with federal law interpretation. Bruesewitz wants to preempt state court decisions that interpret comment K in the Restatement of Torts as only preempting strict liability while Wyeth wants to preempt any state decision interpreting comment K as preempting strict and negligence liability. If there is a presumption against preemption, it should impact both parties equally. Therefore the presumption should not hurt or help either party. *Id.* at 45.

114. *Id.* at 42 n.24.

115. *Id.* at 53–57.

116. *Id.* at 28.

117. *Id.*

118. *Id.* at 53–57.

119. *Id.* at 57.

120. *Id.* at 24–25.

## V. ANALYSIS

Although Hannah Bruesewitz’s case is emotionally moving, the Court likely will find for Wyeth based on Wyeth’s policy rationale. Because the statutory text and congressional intent are unclear, the Court’s public policy preferences likely will determine the outcome of this case.

Even though Wyeth’s public health argument is persuasive, Wyeth must first overcome the presumption against preemption. Notable law professors, including Ken Starr and Erwin Chemerinsky, argue that the Third Circuit disregarded this presumption, and thus the Court should reverse.<sup>121</sup> Because the Vaccine Act does not contain a clear and manifest purpose to preempt categorically, and because Bruesewitz’s interpretation is equally plausible, Starr and Chemerinsky advocate the preservation of state law.<sup>122</sup> If Congress intended to preempt design-defect claims, they argue, it would have used clearer language.<sup>123</sup> Another distinguished law professor, Mark Geistfeld, also supports Bruesewitz’s interpretation based on the Restatement of Torts.<sup>124</sup> Like Bruesewitz, Geistfeld argues that the Restatement’s liability exemption applies only to strict liability; negligence liability must remain to incentivize producers to eliminate unreasonably dangerous products from the market.<sup>125</sup> That this scheme might threaten the vaccine market is a necessary consequence of tort law’s intent to promote product safety.<sup>126</sup> Stressing the legislative history of the Act, Geistfeld argues that the Vaccine Act adopts the Restatement’s immunity for strict liability.<sup>127</sup>

These arguments highlight Wyeth’s primary obstacle: where the text and legislative history are ambiguous, preemption should be avoided.<sup>128</sup> Although the presumption against preemption is well-

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121. *See generally* Brief for Starr and Chemerinsky, *supra* note 88 (arguing that the principles of federalism require the presumption against preemption in this case).

122. *Id.* at 14–18.

123. *Id.* at 15.

124. *See generally* Brief for Mark Geistfeld, *supra* note 8 (explaining and applying the principles of comment K to the Vaccine Act).

125. *Id.*

126. *Id.*

127. *Id.* at 6–7.

128. *See supra* notes 88 (contending that, despite Wyeth’s well-demonstrated arguments stating otherwise, the Vaccine Act’s legislative history clearly adopts the Restatement of Torts) and 121 (arguing that the Court should necessarily presume against preemption due to the lack of clarity in the Vaccine Act) and accompanying text.

established and generally followed,<sup>129</sup> Congress stated that certain sections of the Act are not preempted.<sup>130</sup> This suggests that Congress did intend for *some* parts to be preempted.<sup>131</sup> Both parties provide plausible interpretations of the statutory language. But, as the Third Circuit points out, it would be unreasonable to find that *nothing* is preempted when section (e) clearly indicates that the Act preempts *some* state law.<sup>132</sup> Though both liberal and conservative professors argue that any preemption in the Vaccine Act is too subtle to overcome the presumption against preemption, Wyeth could win the support of both liberal and conservative justices on this point. Conservative justices, like Justices Scalia and Alito, and Chief Justice Roberts, recently have found preemption in even less clear cases.<sup>133</sup> More liberal justices, like Justice Breyer, may find design-defect claims preempted based on the legislative history of the Act or based on the threat to public health.

Despite Geistfeld's arguments, the Vaccine Act's legislative history does not mention an explicit adoption of the Restatement of Torts. Instead, a 1986 Committee Report expresses Congress's intent to embrace the "principles" of the Restatement of Torts and does not distinguish between the Act's preemption of strict and negligence liability.<sup>134</sup> Congress could have extended the Restatement's immunity from strict liability to negligence liability in an effort to safeguard the vaccine market, but the Committee Report and the Act are unclear.

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129. See *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005) ("In areas of traditional state regulation, [the Supreme Court] assume[s] that a federal statute has not supplanted state law unless Congress has made such an intention 'clear and manifest.'"); see also *City of Milwaukee v. Illinois*, 451 U.S. 304, 317 (1981) (stating that presumption requires "evidence of a clear and manifest purpose"); *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 146-47 (1963) ("[W]e are not to conclude that Congress legislated [this] . . . in the absence of an unambiguous congressional mandate to that effect . . .").

130. See 42 U.S.C.A. § 300aa-22(e) (West 2010) ("No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part.").

131. *Id.*

132. *Bruesewitz v. Wyeth*, 561 F.3d 233, 246 (3d Cir. 2009).

133. *Riegel v. Medtronic*, 555 U.S. 312, 312 (2008) (Scalia, J., majority opinion); *Wyeth v. Levine*, 129 S. Ct. 1187, 1217 (2009) (Alito, J., dissenting).

134. H. REP. NO. 99-908, at 26 (1986) ("The Committee has set forth [c]omment K in this bill because it intends that the principle in [c]omment K regarding 'unavoidably unsafe' products, i.e., those products which in the present state of human skill and knowledge cannot be made safe, apply to the vaccines covered in the bill and that such products not be the subject of liability in the tort system.").

As Wyeth demonstrates, the Restatement of Torts is not dispositive, as it does not directly discuss the Vaccine Act.<sup>135</sup>

Although both parties have equally plausible readings of the statute, Bruesewitz’s definition of “unavoidable” renders its interpretation unreasonable. Under *United States v. Kirby*,<sup>136</sup> the Court held that it avoids literal interpretations of statutes that lead to absurd consequences.<sup>137</sup> Bruesewitz asks the Court to recognize that “unavoidable” had a special meaning as of 1986: “a product’s safety risks are ‘unavoidable’ only when they cannot be eliminated by a safer alternative design.”<sup>138</sup> But any alternative design is inherently a different product than that approved by the FDA, as any modification to a design yields a new vaccine.<sup>139</sup> Bruesewitz’s definition would lead to an absurd consequence: it would hold manufacturers liable for injuries if an alternative product *could* exist and manufacturers did not implement it, even if the manufacturer does not have the licenses or the ability to produce the alternative product. During oral arguments, Justice Kennedy noted that Bruesewitz’s interpretation would afford drug manufacturers even less protection than before Congress passed the Vaccine Act.<sup>140</sup> Moreover, Bruesewitz demands “safer” vaccines, but ignores the real consequence that fewer side effects may result in less effective vaccines.<sup>141</sup> Bruesewitz essentially asks the Court to regulate the choice of products a manufacturer produces—a task that the government agrees should only be performed by experts, doctors, and the FDA.<sup>142</sup>

Contrary to Bruesewitz’s claims, imposing tort liability likely would do little to improve safety, as manufacturers control very little of the process involved in researching and developing vaccines.<sup>143</sup> HHS tightly regulates the vaccine development process and the NIH

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135. Brief for Respondent, *supra* note 5, 40–41.

136. *United States v. Kirby*, 74 U.S. 482 (1866).

137. *Id.* at 486 (“All laws should receive a sensible construction. General terms should be so limited in their application as not to lead to injustice, oppression, or an absurd consequence . . .”).

138. Brief for Petitioner, *supra* note 8, at 30–31.

139. Brief for United States, *supra* note 36, at 32–33.

140. Transcript of Oral Argument at 14, 16–17, *Bruesewitz v. Wyeth*, No. 09-152 (2010).

141. Brief for United States, *supra* note 36, at 31 (“Guaranteeing that a vaccine is potent enough to ensure that a disease is contained or eradicated in this way entails trade-offs between safety and potency.”).

142. *Id.* at 19–23.

143. *Id.*

actually performs much of the research.<sup>144</sup> The federal government weighs the risks and benefits of all of the available vaccines and recommends a specific vaccine for routine administration based on societal benefit.<sup>145</sup> In 1992 it recommended only Wyeth's DPT vaccine.<sup>146</sup> Furthermore, most of the amici advocating tort law to improve vaccine safety express great dissatisfaction with the Vaccine Court and updates to the Table.<sup>147</sup> This is not an issue that should be addressed in this case; though the Vaccine Act and its injury table may be significantly out of date, failures on the part of Congress and HHS are not adequate reasons to impose additional liability on manufacturers.

As most of the medical professional amici agree, Wyeth's policy argument that immunity avoids market collapse and more effectively prevents outbreaks is more persuasive than Bruesewitz's argument that tort liability strengthens the vaccine market.<sup>148</sup> While Bruesewitz denies that this is a serious problem, vaccine manufacturing is inherently costly and yields very little financial rewards for companies—their biggest customer is the government which receives vaccines at reduced costs.<sup>149</sup> When the Vaccine Act was created, vaccine manufacturers faced lawsuits for DPT-related injuries from plaintiffs seeking more than thirty times the market value of the DPT vaccine.<sup>150</sup> Expert scientists and doctors agree that immunizing vaccines from liability is the best way to prevent the vaccine market from collapsing.<sup>151</sup> And due to the reputation of these amici, most notably the American Academy of Pediatrics, their arguments probably will weigh heavily in the justices' minds when they make their decision.<sup>152</sup>

144. *Id.*

145. Transcript of Oral Argument, *supra* note 140, at 41, 48–51.

146. *Id.* at 48–53.

147. *See e.g.*, Brief for Marguerite Willner as Amicus Curiae Supporting Petitioners, at 20–31, *Bruesewitz v. Wyeth*, No. 09-152 (May 24, 2010) (arguing that the Table injuries are incomplete); Brief of Vaccine Injured Petitioners Bar Association, et al. as Amici Curiae Supporting Petitioners, at 9–18, *Bruesewitz v. Wyeth*, No. 09-152 (May 24, 2010) (arguing that the vaccine compensation system is not working.).

148. *See* Brief of AAP, *supra* note 7, at 23–27; Brief of 11 Scientists, *supra* note 41, at 20.

149. *Id.* at 11–12.

150. *Id.* at 13.

151. *See* Brief of AAP, *supra* note 7, at 9–10; *see also* Brief for 11 Scientists, *supra* note 41, at 15.

152. Justice Breyer expressed his trust in the American Academy of Pediatrics' policy evaluation in contrast to statements he has made in prior opinions. Transcript of Oral Argument, *supra* note 140, at 16.



Based on the dissents in other preemption cases it is likely this case will split 5-3 for Wyeth.<sup>153</sup> Wyeth likely has the support of at least Justices Alito and Scalia and Chief Justice Roberts based on the tenor of their dissent in *Wyeth v. Levine* and the nature of their questioning and comments during *Bruesewitz*'s oral arguments.<sup>154</sup> Justices Ginsburg and Thomas have made their views of policy and statutory interpretation apparent. Justice Ginsburg voted against preemption in a much more straightforward express-preemption case,<sup>155</sup> and Justice Thomas consistently votes in favor of strict adherence to the presumption against preemption when clear language does not indicate otherwise.<sup>156</sup> Justice Breyer's concern for the vaccine market and Justice Kennedy's apprehension about the expense of litigation<sup>157</sup> both lean in favor of Wyeth. Justice Sotomayor's position remains unclear, but during oral arguments she indicated a distrust of government oversight of the vaccine industry.<sup>158</sup>

Given the evidence indicating Congress's intent to protect the vaccine market and the support of medical professionals for vaccine companies in this case, Wyeth ultimately seems poised to win. While scientists and doctors understand that no vaccine is completely safe, most agree that it is still safer to take one than not.<sup>159</sup> And even those who do not take the vaccine benefit from them: herd immunity prevents epidemics and widespread disease.<sup>160</sup> Therefore, there is a strong societal and public welfare interest in preserving the vaccine market. Too often juries overlook the public welfare arguments and see only the tragic story before them. As Justice Scalia wrote, “[a] jury . . . sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court.”<sup>161</sup> This thought concerned even Justice Ginsburg, the lone dissent in *Riegel v. Medtronic*,<sup>162</sup> who asked *Bruesewitz* “if there's a safer alternative, it must be pursued

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153. Justice Kagan will take no part in this decision due to her previous role as Solicitor General.

154. *Wyeth v. Levine*, 129 S. Ct. 1187, 1217 (2009) (Alito, J., joined by Scalia, J., and Roberts, C.J., dissenting). See also Transcript of Oral Argument, *supra* note 140, at 5–11.

155. *Riegel v. Medtronic*, 552 U.S. 312, 333 (2008) (Ginsburg, J., dissenting).

156. *Wyeth*, 129 S. Ct. at 1205 (Thomas, J., concurring).

157. Transcript of Oral Argument, *supra* note 140, at 24.

158. *Id.* at 30–32.

159. Brief for AAP, *supra* note 7, at 15.

160. Brief for 11 Scientists, *supra* note 41, at 11–12.

161. *Riegel v. Medtronic*, 552 U.S. 312, 325 (2008).

162. *Id.* at 333 (Ginsburg, J., dissenting).

regardless of costs?”<sup>163</sup> While the decision in this case should turn only on the Court’s interpretation of the Vaccine Act, the Court cannot and likely will not overlook the policy implications when it votes in Wyeth’s favor.

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163. Transcript of Oral Argument, *supra* note 140, at 14.