



## Bruesewitz v. Wyeth's **Impact on the Vaccine Safety Debate**

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Childhood vaccines are extolled for effective prevention of dangerous diseases. However, a persistent anti-vaccine movement resists vaccination due to real and perceived links between vaccines and adverse health effects, including autism.<sup>3</sup> Closely related to the vaccine safety debate is the policy concern about balancing the need to compensate individuals who are harmed by vaccines and to prevent vaccine manufacturers from exiting the market due to the prospect of unmanageable tort liability. **The recent**

**Supreme Court decision in *Bruesewitz v. Wyeth* strikes a balance in favor of shielding vaccine manufacturers from design-defect liability and thus limits the options for claimants of certain vaccine-related injuries to recover compensation.**<sup>4</sup>

The *Bruesewitz* decision held that design-defect claims against vaccine manufacturers are preempted under the National Childhood Vaccine Injury Act (NCVIA).<sup>5</sup> Despite the Court's focus on statutory interpretation, the public health policy implications and vaccine safety debate lurked beneath the surface of the Court's reasoning. Although the Court's decision has largely been lauded as a win for public health, **some have criticized the decision as creating a dangerous regulatory vacuum for vaccine improvement and monitoring. This decision has significant ramifications for the vaccine compensation system, including the thousands of pending claims asserting a link between vaccines and autism.**

### **The Current Vaccine Injury Compensation Program**

In 1986, Congress enacted NCVIA and established the Vaccine Injury Compensation Program (VICP) in response to a destabilized vaccine market caused by manufacturer withdrawal due to increasing tort liability. The VICP is a no-fault program to compensate individuals who experience adverse reactions to vaccination and to protect vaccine manufacturers from certain types of liability to ensure a sufficient production of vaccine.<sup>6</sup> The VICP allows claimants to petition a vaccine court for an award paid from a fund created by excise taxes on vaccines. The vaccine court will issue an award if the adverse reaction is listed on the Vaccine Injury Table, which lists compensable injuries by vaccine type, without the petitioner needing to prove causation or fault. Alternatively, if the vaccine or injury is not included within the table, the vaccine court will issue an award if the claimant proves the vaccine caused the injury. The claimant may decide whether to accept the vaccine court's judgment or file a state tort claim against the manufacturer, unless the claim is preempted by NCVIA. Preempted claims may only be pursued in vaccine court and include claims relating to manufacturing defects, failures to warn and, after *Bruesewitz*, design-defects.

### **The Case: *Bruesewitz v. Wyeth***

**The *Bruesewitz* case was filed by Russell and Robalee Bruesewitz, who claimed that their daughter, Hannah, experienced seizures and suffered permanent disabilities following the administration of a diphtheria-tetanus-pertussis vaccine when she was six months old.<sup>7</sup> Hannah's parents petitioned the vaccine court on her behalf, but they were denied an award.<sup>8</sup> The Bruesewitzes rejected the vaccine court's ruling, and filed a state claim alleging, among other things, that the vaccine manufactured by Lederle Laboratories (later purchased by Wyeth) had a defective design that caused their daughter's disabilities.<sup>9</sup>**

The United States Supreme Court ruled that NCVIA preemptively bars all state-law design-defect claims against vaccine manufacturers.<sup>10</sup> Justice Scalia, writing for the majority, relied on a textual analysis of NCVIA's provision that no vaccine manufacturer is liable for a vaccine-related injury "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>11</sup> The Court

noted the policy concern of NCVIA to stabilize the market to entice manufacturers to remain in the vaccine business and avert the vaccine shortages seen in the 1980s due to the threat of tort liability.<sup>12</sup> The majority concluded that allowing design-defect tort claims, “the most speculative and difficult type of products liability claim to litigate,” would “hardly coax manufacturers back into the market.”<sup>13</sup>

In her dissent, Justice Sotomayor argued that the text of the statute did contemplate design-defect claims because it provided liability protection only for “unavoidable” side effects.<sup>14</sup> Accordingly, the adverse side effects could have been avoided if the vaccine in question had been designed differently. The dissent expressed concern that the majority’s decision creates a significant vacuum—the Food and Drug Administration’s approval process does not require vaccines to be optimally designed or continuously improved, and state tort liability for design defects has traditionally provided this incentive.<sup>15</sup> The dissent further pointed to the lack of post-approval regulatory oversight and the lack of competition in the vaccine market as exacerbating the regulatory vacuum.<sup>16</sup>

Whether the majority’s decision or the dissent’s concerns are correct will be determined as the effect of a bar on state design-defect claims against vaccine manufacturers plays out. Regardless, the decision adds a new component to the vaccine safety debate and could affect the large number of current claims asserting that vaccines have caused autism in children.

### The Impact

**This case has significant ramifications for the approximately 5,000 pending claims in an omnibus proceeding before the vaccine court alleging that childhood vaccines caused autism. The Bruesewitz decision will likely restrict many of the claims to vaccine court and foreclose the possibility of a state tort law alternative for claims asserting that a defective design caused autism.**

Claims asserting a link between vaccines and autism have not generally been compensated in vaccine court under NCVIA because autism is not listed on the Vaccine Injury Table and due to the lack of credible medical evidence that vaccines cause autism.<sup>17</sup> A vocal anti-vaccine movement still believes that vaccines, particularly the thimerosal-containing measles-mumps-rubella (MMR) vaccine, cause autism despite the lack of medical evidence,<sup>18</sup> likely due to the co-occurrence of the timing of standard vaccine administration and the emergence of symptoms of autism.

Public health officials voice concern over threats to the health of the population as herd immunity to communicable diseases declines with lower rates of vaccination. Recent measles outbreaks demonstrate the potential public health dangers associated with decisions to not vaccinate. An example is the 2008 measles outbreak in San Diego, spreading primarily among unvaccinated schoolchildren and infants too young to be vaccinated.<sup>19</sup> Bruesewitz may strengthen liability protections of vaccine manufacturers necessary to maintain vaccine supply, but it does little to combat the problem of declining immunization rates among the anti-vaccine movement.

Generally, the Court’s decision has been hailed by public health commentators because it prevents the specter of a similar vaccine supply crisis that led to the passage of NCVIA. The position adopted by the Court was urged by the Department of Health and Human Services, the American Public Health Association, the American Academy of Pediatrics, and many other professional medical associations.<sup>20</sup> Nevertheless, like the dissent, some commentators have expressed concern that **vaccine manufacturers will have few incentives to improve their vaccine designs.** Both sides, and the Court, seem to recognize that the compensation scheme created by NCVIA was a significant and necessary public health achievement. In preempting state tort liability for design-defect claims, the Court may have been swayed by the success of the vaccine compensation program and the importance of the public health need for a stable vaccine supply.

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3 Donald G. McNeil Jr., A Multitude of Vaccine Benefits, Yet Controversy Persists, N. Y. Times,

Mar. 28, 2008, <http://www.nytimes.com/ref/health/healthguide/esn-vaccinations-ess.html> ;  
Inst. of Medicine, Immunization Safety Review: Vaccines and Autism (2004).

- 4 Bruesewitz v. Wyeth, Inc. , 131 S. Ct. 1068 (2011).
- 5 Id. at 1082; National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 et. seq.
- 6 National Vaccine Injury Program, Health Resources and Services Administration available at <http://www.hrsa.gov/vaccinecompensation/> (last accessed March 15, 2011).
- 7 Id.
- 8 Id. (The Bruesewitzs were awarded attorneys fees and costs by the vaccine court, but elected to pursue their claim in Pennsylvania state court).
- 9 Id.
- 10 Id. at 1082 (6-2 vote, with Justice Kagan sitting out).
- 11 42 U.S.C. § 300aa-22(b)(1) (2006).
- 12 Bruesewitz, 131 S. Ct. at 1072-73.
- 13 Id. at 1080.
- 14 Id., 131 S. Ct. at 1087 (Sotomayor, J., dissenting).
- 15 Id. at 1100-01 (Sotomayor, J., dissenting).
- 16 Id. at 1100-01 (Sotomayor, J., dissenting).
- 17 See, e.g. , *Cedillo v. Sec'y of Health and Human Services*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst v. Sec'y of Health and Human Services*, 604 F.3d 1343 (Fed. Cir. 2010).
- 18 Editorial, Autism Fraud, N.Y. Times, January 12, 2011 , at A28 (describing the British Medical Journal's finding that Dr. Andrew Wakefield's influential 1998 study finding a link between the MMR vaccine and autism was deliberately fraudulent. A report seven years after the Wakefield study indicated that the twelve original subjects' medical histories had been falsified in order to make vaccines culpable for injuries.)
- 19 CDC, 57 MMWR 203 (Feb. 29, 2008), <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5708a3.htm> .
- 20 Bruesewitz , 131 S. Ct. at 1085 (Breyer, J., concurring).

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