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Note

Immunity for Vaccine Manufacturers: The Vaccine Act and Preemption of Design Defect Claims

*Eva B. Stensvad**

Stefan Ferrari was a normal toddler until the day he suddenly stopped talking.¹ The now eleven-year-old autistic boy's parents blame the booster shots he received when he was eighteen months old.² Hannah Bruesewitz was a healthy infant until she developed a seizure disorder following her third diphtheria-tetanus-pertussis (DTP) vaccine when she was six months old.³ She is now an eighteen-year-old with a residual seizure disorder and developmental delay who will require special medical care for the rest of her life.⁴ In Stefan's case, the Georgia Supreme Court ruled that the National Childhood Vaccine Injury Act (Vaccine Act) does not preempt all design defect claims if a safer alternative vaccine was known.⁵ In Pennsylvania, where Hannah resides, the Third Circuit interpreted the Vaccine Act to bar all such claims against vaccine manufacturers.⁶ In other words, Stefan is allowed to sue the vaccine manufacturer for his injuries; Hannah is not.

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1. Bill Rankin, *Allow Vaccine Suit, Parents Ask Justices*, ATLANTA J.-CONST., May 21, 2008, at B1, available at http://www.ajc.com/metro/content/metro/stories/2008/05/21/vaccine.html?cxntlid=inform_artr.

2. *Id.*

3. *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 236 (3d Cir. 2009), *cert. granted*, 130 S. Ct. 1734 (2010).

4. *Id.*

5. *Am. Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236, 237–38 (Ga. 2008).

6. *Bruesewitz*, 561 F.3d at 255.

Vaccines are one of medicine's greatest accomplishments.⁷ They prevent many potentially lethal and debilitating diseases.⁸ Even today, as fears of new influenza pandemics abound, there is a desperate rush to access vaccines to ward off these unknown dangers.⁹

Despite all the benefits vaccines afford, they also carry some risk of side effects, many of which are either unknown or unpredictable.¹⁰ Currently, there are over 5000 cases in Vaccine Court¹¹ in which families allege that vaccines containing thimerosal, a mercury derivative, caused their children to develop autism.¹² Increased vaccine litigation could potentially discourage manufacturers from remaining in the vaccine market, thus threatening the vaccine supply and the public health.¹³

The risk of vaccine shortages is a real possibility. Between 2001 and 2002 there were nationwide shortages of eight of the eleven recommended childhood vaccines.¹⁴ Only four manufacturers produce nearly all of the pediatric vaccines available in

7. See CDC, *Ten Great Public Health Achievements—United States, 1900–1999*, 48 MORBIDITY & MORTALITY WKLY. REP. 241, 241 (1999) (listing vaccination at the top of the list of the ten great public health achievements).

8. CDC, *Impact of Vaccines Universally Recommended for Children—United States, 1900–1998*, 48 MORBIDITY & MORTALITY WKLY. REP. 243, 245 (1999).

9. See Maura Lerner, *Flu Vaccine Shortage Shuttles Walk-In Clinics, For Now*, STAR TRIB. (Minneapolis, Minn.), Sept. 23, 2009, <http://www.startribune.com/lifestyle/health/60339972.html> (describing flu-shot clinic cancellations due to shortages).

10. See *Possible Side-Effects From Vaccines*, CDC, <http://www.cdc.gov/vaccines/vac-gen/side-effects.htm> (last modified June 3, 2010) (discussing the many possible side effects from various vaccines).

11. The Vaccine Act created a special court within the U.S. Court of Federal Claims, presided over by Special Masters that adjudicates all vaccine claims processed pursuant to the requirements of the Vaccine Act. See *Vaccine Program/Office of Special Masters*, U.S. CT. FED. CLAIMS, <http://www.uscfc.uscourts.gov/vaccine-programoffice-special-masters> (last visited Oct. 16, 2010).

12. See *About the Omnibus Autism Proceeding*, HEALTH RESOURCES & SERVICES ADMIN., <http://www.hrsa.gov/vaccinecompensation/omnibusproceeding.htm> (last updated Aug. 19, 2010) (explaining that as of August 2010, there were over 5000 cases involving claims of vaccine-related autism awaiting adjudication).

13. See H.R. REP. NO. 99-908, at 4 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6345 (explaining that due to an increase in vaccine litigation, the price of vaccines increased, the number of vaccine manufacturers decreased, and the level of immunization decreased).

14. *Losing Momentum: Are Childhood Vaccine Supplies Adequate?: Hearing Before the Subcomm. on Pub. Health of the S. Comm. on Health, Educ., Labor, and Pensions*, 107th Cong. 1 (2002) [hereinafter *Losing Momentum*] (statement of Sen. Jack Reed).

the United States.¹⁵ Five such vaccines are produced by only one manufacturer.¹⁶ The loss of *any* manufacturer from the market has the potential to cripple the vaccine supply. In 2004, one British manufacturer encountered production difficulties, resulting in a loss of half of the United States' supply of the flu vaccine.¹⁷ In 2009, there were national shortages of the seasonal flu vaccine as well as the novel H1N1 flu vaccine due to increased demand on an already strained supply.¹⁸ The burden of litigation may overwhelm an already struggling production system.

At the heart of this issue is the Vaccine Act,¹⁹ which sought to address the issues of vaccine safety, compensation for vaccine-related injuries, and liability protection for vaccine manufacturers.²⁰ The Act expressly prohibits litigation arising from "side effects that *were unavoidable* even though the vaccine was properly prepared and was accompanied by proper directions and warnings."²¹ This language has been interpreted in two different ways. In *Ferrari*, the court found that the statute only preempts defective design litigation after it has been determined, on a case-by-case basis, that the injury was, in fact, "unavoidable."²² In *Bruesewitz*, the court held that the statute preempts *all* vaccine design defect claims.²³ The *Ferrari* interpretation may affect vaccine manufacturers' continued participation in the market, and the *Bruesewitz* interpretation may affect public confidence in vaccination programs. The safety of vaccines, protection of public health, and security of the vaccine supply all depend on this critical distinction.

15. *Id.* at 2.

16. *Id.* at 4 (statement of Janet Heinrich, Director, Health Care—Public Health Issues, U.S. General Accounting Office).

17. Andrew Pollack, *U.S. Will Miss Half Its Supply of Flu Vaccine*, N.Y. TIMES, Oct. 6, 2004, at A1.

18. See, e.g., Delthia Ricks, *Seasonal Flu Vaccine Shortage Hits Long Island*, NEWSDAY, Oct. 16, 2009, at A8 (describing the suspension of flu clinics resulting from a shortage of the seasonal flu vaccine); Lerner, *supra* note 9 (reporting that vaccine demand is overwhelming the supply as manufacturers try to produce two different flu vaccines).

19. National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10 to -34 (2006).

20. See H.R. REP. NO. 99-908, at 5-7 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6346-48.

21. 42 U.S.C. § 300aa-22 (emphasis added).

22. *Am. Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236, 242 (Ga. 2008).

23. *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 255 (3d Cir. 2009), *cert. granted*, 130 S. Ct. 1734 (2010).

This Note argues that both the *Bruesewitz* and *Ferrari* courts got it wrong. The text of the Vaccine Act requires some case-by-case analysis to determine whether a particular vaccine is unavoidably unsafe. Congress, however, has already conducted these analyses with respect to the federally encouraged pediatric vaccines. Therefore, the Vaccine Act preempts design defect claims with respect to these particular vaccines. Part I provides an overview of the role and regulation of vaccines, introduces the text and history of the Vaccine Act, and discusses the current controversy involving vaccine-related injuries and recent preemption jurisprudence. Part II critiques the arguments in favor of and against preemption, closely examining the plain text of the Vaccine Act and analyzing Congress's role in creating and regulating national vaccine policy. Part III argues that although the Act requires an analysis to determine whether a particular vaccine's benefits justify its risks, Congress is in a better position than judges or juries to conduct these inquiries. As the nation faces threats of global pandemics and vaccine shortages, it is essential that the Vaccine Act is interpreted to ensure the continued production, development, and safety of lifesaving vaccines, while adequately protecting those who are harmed as a result of such products.

I. VACCINE REGULATION, LEGISLATION, AND PREEMPTION

Vaccination is one of the greatest public health achievements in the United States.²⁴ It has greatly reduced the morbidity of diseases that once devastated the population, such as smallpox, measles, poliomyelitis, diphtheria, and pertussis.²⁵ Every state, and the District of Columbia, recognizes that vaccines are critical to maintain public health, and has instituted mandatory immunization requirements for children.²⁶ Despite the many benefits vaccines confer upon society, they also occasionally injure those whom they are supposed to protect.²⁷ This has led to rising fears of vaccines and some resistance to vac-

24. CDC, *supra* note 7, at 241.

25. CDC, *supra* note 8, at 245 tbl.2. Some diseases have nearly, if not completely, been eradicated through vaccination programs. *See id.*

26. CDC, CHILD CARE AND SCHOOL VACCINATION REQUIREMENTS: 2007–2008, at 4, available at <http://www2a.cdc.gov/nip/schoolsurv/combinedlaws2007.pdf> (last visited Oct. 10, 2010).

27. *Vaccine Safety and Adverse Events*, CDC, <http://www.cdc.gov/vaccines/vac-gen/safety/default.htm> (last modified Nov. 19, 2009) (explaining that all vaccines carry some risk).

ination programs.²⁸ Predictably, this has also led to civil litigation against vaccine manufacturers.²⁹

This Part provides a brief overview of the role of the federal government in vaccine regulation and sets forth the contents and history of the National Childhood Vaccine Injury Act of 1986.³⁰ This Part then introduces the current issues surrounding vaccination, including the two recent court decisions which have brought to the forefront the question of whether the Vaccine Act preempts certain civil claims against vaccine manufacturers.³¹

A. FEDERAL REGULATION OF VACCINES

The federal government has a long history of involvement in the effort to prevent childhood disease and regulate vaccine development and production, beginning with the Virus Serums and Toxins Act of 1902.³² Since then, it has taken an increasingly active role in promoting vaccine development and administration through numerous legislative acts, federal grants, and nationwide immunization initiatives.³³ The National Vaccine Program Office (NVPO), within the United States Department of Health and Human Services (HHS), is responsible for coordinating the activities of the many federal agencies involved in immunization efforts, including the Centers for Disease Control (CDC), Agency for International Development (USAID), Centers for Medicare and Medicaid Service (CMS), Health Resources and Services Administration (HRSA), National Institutes of Health (NIH), and the Food and Drug Administration

28. See, e.g., Alice Park, *How Safe Are Vaccines?*, TIME, June 2, 2008, at 36, 38 (explaining that “increasing numbers of parents are raising questions about whether vaccines . . . are actually harmful to children”).

29. See *About the Omnibus Autism Proceeding*, *supra* note 12 (noting that there are more than 5000 vaccine-related autism cases currently awaiting adjudication).

30. National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-1 to -34 (2006).

31. *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233 (3d Cir. 2009), *cert. granted*, 130 S. Ct. 1734 (2010); *Am. Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236 (Ga. 2008).

32. STAFF OF SUBCOMM. ON HEALTH & THE ENV'T OF THE H. COMM. ON ENERGY & COMMERCE, 99TH CONG., CHILDHOOD IMMUNIZATIONS 44 (Comm. Print 1986) [hereinafter CHILDHOOD IMMUNIZATIONS]; see also INST. OF MED., VACCINE SUPPLY AND INNOVATION 16–17 (1985) (describing the history of federal vaccine regulation and legislation).

33. See CHILDHOOD IMMUNIZATIONS, *supra* note 32, at 44–49 (describing congressional efforts to increase immunization levels throughout the nation).

(FDA), among others.³⁴ The CDC contracts for vaccine prices³⁵ and the federal government purchases over fifty percent of the childhood vaccines administered in the United States each year.³⁶ Federal encouragement of state vaccination programs has been highly successful, as all fifty states and the District of Columbia have enacted laws requiring childhood immunizations.³⁷

The two main programs through which the federal government directs vaccine policy are the Vaccines for Children (VFC) program, which provides free vaccines to children in need,³⁸ and the Section 317 Immunization Grant Program,³⁹ which provides grants to all fifty states, the District of Columbia, and other urban areas and territories, to provide vaccines to those not served by the VFC program.⁴⁰ The federal Advisory Committee on Immunization Practices (ACIP), representing eight different federal agencies and twenty-six nongovernment agencies,⁴¹ examines in detail the risks, benefits, costs, and public health need for each childhood vaccine.⁴² The ACIP draws upon a variety of sources of information, including “pub-

34. *National Vaccine Program Office*, U.S. DEPARTMENT HEALTH & HUM. SERVICES, <http://www.hhs.gov/nvpo/about.html> (last modified Sept. 27, 2006). The NVPO works to fulfill the goals of the National Vaccine Plan, which “provides a framework, including goals, objectives, and strategies, for pursuing the prevention of infectious diseases through immunizations.” *Id.*

35. See *CDC Vaccine Price List*, CDC, <http://www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm> (last updated Oct. 6, 2010) (listing current vaccine contract prices).

36. *Losing Momentum*, *supra* note 14, at 4 (statement of Janet Heinrich, Director, Health Care—Public Health Issues, U.S. General Accounting Office).

37. CDC, *supra* note 26, at 4.

38. *Vaccines for Children Program (VFC)*, CDC, <http://www.cdc.gov/vaccines/programs/vfc/default.htm> (last modified Oct. 7, 2010).

39. See Public Health Act, Pub. L. No. 87-868, § 317, 76 Stat. 1155, 1155–56 (1962) (codified as amended at 42 U.S.C. § 247b (2006)); *Centers for Disease Control and Prevention: Section 317 Immunization Program*, U.S. DEPARTMENT HEALTH & HUM. SERVICES, http://www.hhs.gov/recovery/reports/plans/section317immunization_cdc.pdf (last visited Oct. 16, 2010) (describing recent appropriations to the Section 317 Immunization Program).

40. See CDC, IMMUNIZATION GRANT PROGRAM (SECTION 317) (2007), available at <http://www.cdc.gov/NCIRD/progbriefs/downloads/grant-317.pdf>. A majority of the grants allocated under section 317 are for routine childhood vaccines. *Id.*

41. See *Advisory Committee on Immunization Practices (ACIP)*, CDC, <http://www.cdc.gov/vaccines/recs/acip/default.htm> (last modified Oct. 14, 2010).

42. See CDC, *General Recommendations on Immunization*, 55 MORBIDITY & MORTALITY WKLY. REP. 1, 1–2 (2006) (discussing the process by which the ACIP makes vaccine recommendations).

lished and unpublished studies . . . and expert opinion[s] of public health officials and specialists in clinical and preventive medicine,” in order to generate a list of recommended vaccines for children.⁴³ The Secretary of HHS then uses these recommendations in selecting vaccines for the various federal vaccine programs.⁴⁴

The Center for Biologics Evaluation and Research (CBER) within the FDA has primary responsibility for ensuring vaccine safety.⁴⁵ The FDA regulates vaccines as “biological products” pursuant to the Public Health Service Act (PHSA).⁴⁶ There are stringent regulations encompassing every aspect of vaccination, including licensing,⁴⁷ testing,⁴⁸ manufacturing,⁴⁹ and post-market reporting.⁵⁰ The Secretary of HHS has the authority to suspend or revoke licenses,⁵¹ and there are numerous provisions regarding post-market surveillance and risk evaluation.⁵² The FDA’s comprehensive and “rigorous” review of vaccines plays a crucial role in assuring the safety and efficacy of childhood vaccines.⁵³

The federal government is extensively involved in immunization in the United States. It plays a role in vaccine development, marketing, licensing, distribution, and regulation. Through its many agencies, vaccination programs, and advisory committees, it is a major force in shaping national vaccine policy.

43. *Id.* at 1.

44. See *ACIP Charter*, CDC, <http://www.cdc.gov/vaccines/recs/ACIP/charter.htm> (last updated Apr. 6, 2010) (describing ACIP’s provision of advice and guidance to the HHS, the CDC, and the states for the implementation of vaccination programs).

45. See *Vaccines*, FDA, <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/default.htm> (last updated Mar. 29, 2010).

46. 42 U.S.C. § 262 (2006).

47. 21 C.F.R. §§ 601.1–.29 (2010).

48. *Id.* § 601.25.

49. *Id.* §§ 600.10–.15.

50. *Id.* §§ 600.80, 601.70. For a detailed description of FDA regulation of vaccines, see Linda A. Willett, Note, *DPT Vaccine-Related Injury Actions: Federal Preemption Reconsidered*, 41 RUTGERS L. REV. 373 (1988) and Katherine Davenport, *Vaccines and the National Vaccine Injury Compensation Program* (Apr. 10, 2000) (unpublished student paper, Harvard Law School), available at http://leda.law.harvard.edu/leda/search/toc.php3?handle=HLS.Library.Leda/davenportk-vaccines_national_vaccine.

51. 42 U.S.C. § 262(a)(2)(A) (2006).

52. See, e.g., *id.* § 262(a)(2)(D), (d), (j).

53. See *Vaccines*, *supra* note 45.

B. VACCINE ACT LITIGATION

Despite all the safety mechanisms in place, injuries from vaccines still occur. These injuries sometimes give rise to litigation, which in turn prompts a flurry of legislative action. Such was the case when the Vaccine Act was enacted. In the early 1980s, a series of problems emerged that threatened the nation's immunization efforts. As immunization programs gained popularity and more children received vaccinations, there was also a concurrent increase in public awareness of vaccine-related injuries.⁵⁴ Those suffering from such injuries sought recompense through civil litigation, but the system was time-consuming, expensive, and often inadequate.⁵⁵ Rising litigation against vaccine manufacturers also resulted in difficulties procuring affordable product liability insurance, increased vaccine prices, and fewer vaccine manufacturers in the market.⁵⁶ By 1986, there was only one manufacturer of the polio vaccine, one manufacturer of the measles, mumps, and rubella vaccine, and two manufacturers of the DTP vaccine.⁵⁷ The "unstable and unpredictable childhood vaccine market [made] the threat of vaccine shortages a real possibility" and undermined the national goal of increasing the "availability and use of vaccines to prevent childhood diseases."⁵⁸ The country was dangerously close to vaccine shortages and a possible "resurgence of preventable diseases."⁵⁹

Congress sought a solution that would address both the inadequate approach to compensating those injured by recommended vaccines and the instability and unpredictability of the childhood vaccine market that threatened the nation's vaccine supply.⁶⁰ That solution was the Vaccine Act.⁶¹ Part A of the Act

54. See CHILDHOOD IMMUNIZATIONS, *supra* note 32, at 21.

55. See H.R. REP. NO. 99-908, at 6 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6347.

56. See *id.* at 4, 6. The price of one vaccine reportedly increased by as much as 2000 percent in only two years. CHILDHOOD IMMUNIZATIONS, *supra* note 32, at 60.

57. H.R. REP. NO. 99-908, at 7.

58. *Id.* at 5.

59. *Id.* at 7. Describing the threat of a nationwide vaccine shortage, one article states: "If there were [a] . . . clock marking the time remaining until vaccines become either unavailable or unacceptable . . . it would stand perilously close to midnight in the United States." Wendy K. Mariner & Mary E. Clark, *Confronting the Immunization Problem: Proposals for Compensation Reform*, 76 AM. J. PUB. HEALTH 703, 703 (1986), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1646786/pdf/amjph00269-0097.pdf>.

60. H.R. REP. NO. 99-908, at 7.

created a no-fault compensation program to ensure faster and easier recovery for those injured by vaccines.⁶² It also established a Vaccine Court to hear these claims,⁶³ in which injured parties are not required to prove causation or negligence⁶⁴ if their injuries are consistent with the Vaccine Injury Table created by the Act.⁶⁵ Congress hoped this program would provide better compensation for injured parties, while simultaneously diverting claims away from litigation against vaccine manufacturers.⁶⁶ Part B of the Act deals with the remedies available to an injured party should he or she reject the judgment of the Vaccine Court.⁶⁷ Finally, Part C provides for various mechanisms to ensure vaccine safety, including a recording and reporting system⁶⁸ and a mandate for safer childhood vaccines.⁶⁹

Under Part B, if an individual rejects the judgment of the Vaccine Court, he or she may pursue traditional litigation against the vaccine manufacturer according to state law, except as provided in various parts of section 22 of the Act.⁷⁰ Section 22(b)(1) states that a vaccine manufacturer shall not be liable for a “vaccine-related injury or death . . . [that] resulted from side effects that were unavoidable” if “the vaccine was properly prepared and was accompanied by proper directions and warnings.”⁷¹ This language was adopted from comment k of section 402A of the Restatement (Second) of Torts, which carves out an exception to strict liability of product manufacturers for products that are “unavoidably unsafe.”⁷² Under comment k, “ap-

61. See 42 U.S.C. §§ 300aa-10 to -34 (2006).

62. H.R. REP. NO. 99-908, at 3.

63. See 42 U.S.C. § 300aa-12 (1986).

64. H.R. REP. NO. 99-908, at 12.

65. 42 U.S.C. § 300aa-14 (2006). The Vaccine Injury Table contains known adverse events associated with particular vaccines and provides the basis for compensation if an individual suffers from one of the included events during the required time period. See *id.* For a detailed discussion of the compensation program procedure, see Victor E. Schwartz, *National Childhood Vaccine Injury Act of 1986: An Ad Hoc Remedy or a Window for the Future?*, 48 OHIO ST. L.J. 387, 389–92 (1987).

66. See H.R. REP. NO. 99-908, at 12–13.

67. *Id.* at 3.

68. See 42 U.S.C. § 300aa-25.

69. See *id.* § 300aa-27.

70. See *id.* § 300aa-22. Sections 22(b), (c) and (e) are the provisions that may affect state law. See *id.*

71. *Id.* § 300aa-22(b)(1).

72. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

parently useful and desirable product[s]” which have a known risk and are “quite incapable of being made safe for their intended and ordinary use” are considered “unavoidably unsafe.”⁷³ If “[s]uch a product [is] properly prepared, and accompanied by proper directions and warning, [then it] is not defective,” and the product’s manufacturer is not held strictly liable.⁷⁴

This section of the Vaccine Act has created enormous controversy. It shields manufacturers from some types of design defect liability,⁷⁵ but the limits of this preemption clause are not clearly defined. Because federal laws are “the supreme Law of the Land,”⁷⁶ and any “state laws that conflict with federal law are ‘without effect,’”⁷⁷ it is important to define the precise scope of this preemptive language. Courts generally agree that the clause encompasses design defect claims based in both strict liability and negligence.⁷⁸ They do not agree, however, as to whether all vaccines are, by definition, “unavoidably unsafe,” or instead, whether a vaccine can only be classified as “unavoidably unsafe” after a case-by-case analysis of the specifically challenged design element of the vaccine and its allegedly causal connection to a particular injury.⁷⁹ Even if a case-by-case assessment *is* required for each vaccine, it is not clear from the text *who* is supposed to make that determination—Congress, administrative agencies, or courts?

Two cases recently analyzed the express preemption clause in section 22(b)(1) of the Vaccine Act. In *American Home Products Corp. v. Ferrari*, the Georgia Supreme Court held that the Vaccine Act does not preempt all design defect claims against

73. *Id.*

74. *Id.* Comment k points to the rabies vaccine as “[a]n outstanding example” of an “[u]navoidably unsafe product.” *Id.*

75. The three categories of defective products which give rise to liability are manufacturing defects (“when the product departs from its intended design”), defective design (when the design itself carries unreasonable risks of harm), and defect due to inadequate instructions or warnings. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 (1998).

76. U.S. CONST. art. VI, § 1, cl. 2.

77. *Altria Grp., Inc. v. Good*, 129 S. Ct. 538, 543 (2008) (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)).

78. *See, e.g., Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 248 (3d Cir. 2009), *cert. granted*, 130 S. Ct. 1734 (2010); *Am. Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236, 242 (Ga. 2008).

79. *See, e.g., Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 835–36 (Neb. 2000) (noting that courts have disagreed as to comment k’s application).

vaccine manufacturers.⁸⁰ The parents of an autistic boy brought claims under strict liability and negligence, alleging that the manufacturers could have designed a safer children's vaccine.⁸¹ The *Ferrari* court relied heavily upon the conditional language of the statute,⁸² the desire to give meaning to the word "unavoidable,"⁸³ and subsequent legislative history stating that the Vaccine Act was not meant to "decide as a matter of law whether vaccines were unavoidably unsafe or not," but that "[t]his question is left to the courts."⁸⁴ Ultimately, the court found no "clear and manifest" congressional purpose to supplant state tort law,⁸⁵ and therefore concluded that section 22(b)(1) only preempted liability for defective designs "if it is determined, on a case-by-case basis, that the particular vaccine was unavoidably unsafe."⁸⁶

In *Bruesewitz v. Wyeth Inc.*,⁸⁷ the Third Circuit rejected the *Ferrari* court's reasoning and held that the Vaccine Act expressly preempted design defect claims.⁸⁸ The *Bruesewitz* court did not consider the presence of the word "unavoidable" to be dispositive, explaining that "it is always possible to construct through hindsight . . . alternate wording that would render it more clear."⁸⁹ The court rejected the legislative history upon which the *Ferrari* court relied, finding it to be unreliable subsequent history that said little about the intent of the earlier Congress that enacted the Vaccine Act.⁹⁰ Instead, the court reasoned that if a case-by-case analysis was needed for each vaccine to determine whether the side effects were unavoidable, then the preemption clause would effectively preempt nothing at all, since all claims would be subject to some judicial evaluation.⁹¹ Therefore, it found a "clear and manifest" expression of congressional intent to bar all design defect claims, without any

80. *Ferrari*, 668 S.E.2d at 242.

81. *Id.* at 237.

82. *See id.* at 240 ("The conditional nature of this clause contemplates the occurrence of side effects which are avoidable, and for which a vaccine manufacturer may be civilly liable.").

83. *See id.* at 240 (refusing to read out words from a statute).

84. *Id.* at 241 (quoting H.R. REP. NO. 100-391(I), at 691 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-364, 2313-365).

85. *Id.* at 242.

86. *Id.*

87. 561 F.3d 233 (3d Cir. 2009), *cert. granted*, 130 S. Ct. 1734 (2010).

88. *Id.* at 255.

89. *Id.* at 246.

90. *See id.* at 250.

91. *See id.* at 246.

“unavoidability” analysis. It concluded that at the very least, Congress intended to preclude design defect claims concerning the DTP vaccine at issue, since it was the design of the DTP vaccine and the resulting litigation which spawned the Vaccine Act.⁹²

In reaching their conclusions, both courts referred to a “presumption against preemption.”⁹³ The Supreme Court has repeatedly stated that there is a presumption against federal preemption, especially in areas traditionally regulated by the states.⁹⁴ When faced with equally plausible readings, the Court opts to accept the reading disfavoring preemption,⁹⁵ because it assumes that the “historic police powers of the States [are] not to be superseded . . . unless that [is] the clear and manifest purpose of Congress.”⁹⁶ Recently, the Court applied this presumption in holding that failure-to-warn claims against manufacturers of pharmaceuticals are not impliedly preempted by FDA approvals pursuant to the Food, Drug, and Cosmetic Act.⁹⁷ The Court has also used this presumption to find that the Medical Device Amendments do not expressly preempt negligent design claims regarding a product that has not been subjected to the FDA’s “rigorous” pre-market approval process.⁹⁸ The *Ferrari* and *Bruesewitz* courts, however, did not find it necessary to rely upon this doctrine, since both found a “clear and manifest” expression of congressional intent, albeit coming to opposite conclusions.⁹⁹

92. *Id.* at 250–51.

93. *Id.* at 240; *Am. Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236, 238–39 (Ga. 2008).

94. *See Bates v. Dow Agrosciences*, 544 U.S. 431, 449 (2005).

95. *See id.*

96. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

97. *See Wyeth v. Levine*, 129 S. Ct. 1187, 1191 (2009).

98. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477, 485 (1996).

99. There is some debate as to whether the presumption against preemption applies at all when dealing with an express preemption clause rather than an issue of implied preemption. *See Bates*, 544 U.S. at 457 (Thomas, J., concurring in part and dissenting in part) (explaining that the “presumption does not apply . . . when Congress has included within a statute an express pre-emption provision”); Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 291–92 (2000) (arguing that the presumption against preemption makes little sense when used to interpret an express preemption clause); Michael X. Imbroscio, *Federal Preemption in the Non-Drug Context After Wyeth v. Levine* 15 (June 2009) (unpublished manuscript), available at <http://www.cov.com/mimbroscio/> (arguing that an “unrestrained ‘presumption against preemption’ doctrine could ‘emasculate’ an otherwise appropriate express preemption clause).

Thus, as it currently stands, individuals injured by vaccines in Georgia may sue vaccine manufacturers under any theory of liability, but individuals similarly injured in Pennsylvania cannot. This inconsistency has drawn the attention of the U.S. Supreme Court, which recently granted a writ of certiorari in *Bruesewitz v. Wyeth, Inc.*¹⁰⁰ The Supreme Court is now poised to rule on the preemptive scope of the Vaccine Act.

C. VACCINATION CONTROVERSY TODAY

The issues that confronted the nation in 1986—such as threats of vaccine shortages and demand for vaccines that exceeds the supply—are still in effect today.¹⁰¹ The loss of even one vaccine manufacturer has the potential to cripple the nation's vaccination programs.¹⁰² Meanwhile, an increasing number of parents are questioning the safety and necessity of childhood vaccines.¹⁰³ They have become particularly concerned with vaccines containing thimerosal, a mercury-containing compound that has been used as a preservative in vaccines since the 1930s.¹⁰⁴ Although preservatives are required to prevent contamination in multi-dose vials of vaccines,¹⁰⁵ a growing number of parents suspect thimerosal is a cause of their children's autism.¹⁰⁶ As of August 2010, over 5600 cases alleging a causal relationship between vaccinations and autism have been filed in the Vaccine Court.¹⁰⁷ So far, these claimants have not fared well.¹⁰⁸ If this trend continues, it is likely that they will

100. 130 S. Ct. 1734 (2010).

101. See, e.g., Lerner, *supra* note 9 (describing influenza vaccine shortages).

102. See Pollack, *supra* note 17, at A1 (discussing vaccine shortages resulting from the temporary suspension of one British manufacturer).

103. Park, *supra* note 28, at 38.

104. *Thimerosal in Vaccines*, FDA, <http://www.fda.gov/biologicsbloodvaccines/safetyavailability/vaccinesafety/ucm096228> (last updated Mar. 31, 2010).

105. See 21 C.F.R. § 610.15(a) (2010) ("Products in multiple-dose containers shall contain a preservative . . .").

106. Autism, or Autism Spectrum Disorders (ASDs), are developmental disabilities that cause communication, social, and behavioral challenges. *Autism Spectrum Disorders (ASDs): What Should You Know?*, CDC, <http://www.cdc.gov/ncbddd/autism/index.html> (last updated June 24, 2009). Approximately one in 110 children in the U.S. have an ASD. *Id.*

107. *About the Omnibus Autism Proceeding*, *supra* note 12.

108. Press Release, U.S. Dep't of Health & Human Servs., Statement from the Department of Health and Human Services Regarding the Decisions of the U.S. Court of Federal Claims in the Omnibus Autism Proceeding (Feb. 12, 2009), available at <http://www.hhs.gov/news/press/2009pres/02/20090212a.html> (explaining that after careful review, the Special Masters in the Vaccine Court have found no association between vaccines and autism).

next try to bring their injury claims to court.¹⁰⁹ An influx of thousands of product liability claims has an even greater potential to permanently shut down the vaccine supply than the litigation that led to the passage of the Vaccine Act in 1986. If these claims are preempted by the Vaccine Act, injured parties will only be able to recover for design-related claims in the Vaccine Court, and vaccine manufacturers will have the security they need to remain in the vaccine market. If these claims are not preempted, injured parties will have the ability to pursue recompense in any available venue, but manufacturers may fear their increased exposure to liability and abandon vaccine production in favor of more lucrative endeavors.

II. ARE ROUTINE CHILDHOOD VACCINES “UNAVOIDABLY UNSAFE” PRODUCTS?

The Vaccine Act’s express preemption clause¹¹⁰ exempts vaccine manufacturers from liability for injuries that “resulted from side effects *that were unavoidable* even though the vaccine was properly prepared and was accompanied by proper directions and warnings.”¹¹¹ In determining the scope of that language, courts have had difficulty defining the word “unavoidable.” One possibility is that vaccine injuries are, by definition, “unavoidable” whenever the vaccine is properly prepared and accompanied by proper directions and warnings.¹¹² This reading “essentially equate[s] FDA approval with a determination that side effects are ‘unavoidable.’”¹¹³ Another interpretation requires a preliminary case-by-case determination that the injuries could not have reasonably been avoided before those in-

109. See, e.g., Mary Holland, *Help Preserve the Right to Bring Vaccine Injury Claims to Civil Court*, AGE AUTISM (Aug. 26, 2009), <http://www.ageofautism.com/2009/08/help-preserve-the-right-to-bring-vaccine-injury-claims-to-civil-court.html>.

110. See *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 242 (3d Cir. 2009) (concluding that section 22(b)(1) of the Vaccine Act contains an express preemption clause), *cert. granted*, 130 S. Ct. 1734 (2010).

111. 42 U.S.C. § 300aa-22(b)(1) (2006) (emphasis added).

112. See *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 659, 664 (S.D. Tex. 2004) (explaining that because “[t]he drafters of § 22(b) were obviously aware of the different heads of products liability,” and only identified two of these as determinative of unavoidability, “[i]f the alleged defect . . . does not fall into one of these two enumerated categories, the defect is considered ‘unavoidable’”).

113. *Am. Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236, 237 (Ga. 2008) (quoting *Ferrari v. Am. Home Prods. Corp.*, 650 S.E.2d 585, 588 (Ga. Ct. App. 2007)).

juries are characterized as “unavoidable” for the purpose of preemption.¹¹⁴

This Part demonstrates that although the statute is facially ambiguous, examination of comment k¹¹⁵ reveals that some risk-benefit analysis is necessary before a vaccine’s side effects and injuries are characterized as “unavoidable.” The contents of the statute, along with Congress’s past and current behavior, demonstrate that Congress is the body responsible for conducting these analyses. This Part shows that Congress has already assumed this role as decisionmaker, and furthermore, that the Congress-as-decisionmaker interpretation of section 22(b)(1) is consistent with the Supreme Court’s preemption jurisprudence.

A. SECTION 22(B)(1) REQUIRES CASE-BY-CASE DETERMINATIONS OF UNAVOIDABILITY

The plain text of the statute does not clearly indicate its preemptive scope.¹¹⁶ If the statute preempts all claims for injuries arising where there is no manufacturing defect or failure to warn, then the word “unavoidable” is meaningless.¹¹⁷ The statute could have simply eliminated the words “that were unavoidable” and retained the same meaning.¹¹⁸ Yet giving full effect to the word “unavoidable” would make the entire clause pointless, because all side effects from vaccines are theoretically avoidable—a person can simply opt not to get vaccinated.

An examination of comment k of section 402A of the Restatement (Second) of Torts, from which this language was borrowed,¹¹⁹ sheds some light on this matter. Comment k creates

114. *See id.*

115. *See* RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

116. *See* CSX Transp., Inc. v. Easterwood, 507 U.S. 658, 664 (1993) (explaining that the first step of statutory construction of an express preemption clause is to “focus on the plain wording”).

117. Courts strive to give meaning to every word in a statute, and would disfavor such a reading. *See Ferrari*, 668 S.E.2d at 240 (refusing to read out words from the statute); HENRY CAMPBELL BLACK, HANDBOOK ON THE CONSTRUCTION AND INTERPRETATION OF THE LAWS 83 (2008).

118. On the other hand, Congress could easily have drafted the statute to explicitly preserve design defect claims, just as it did with manufacturing and failure to warn claims. Section 22(b) could have read: “even though the vaccine was properly designed, properly prepared, and was accompanied by proper directions and warnings.” Either way, this statute is “inartfully drafted.” Nitin Shah, Note, *When Injury Is Unavoidable: The Vaccine Act’s Limited Preemption of Design Defect Claims*, 96 VA. L. REV. 199, 203, 219 (2010).

119. H.R. REP. NO. 99-908, at 25–26 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6366–67.

an exception from strict liability design defect claims¹²⁰ for “[u]navoidably unsafe products.”¹²¹ These are “products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use,” yet are “apparently useful and desirable.”¹²² The comment sets forth the rabies vaccine as an example of such a product, because although the vaccine can cause serious injuries, rabies itself is fatal, and so “the use of the vaccine [is] fully justified.”¹²³ The comment, however, does not state that *all* vaccines are “unavoidably unsafe,” but rather “many other . . . vaccines” may qualify for this exception.¹²⁴ States that have adopted comment k have interpreted it differently,¹²⁵ but most require a case-by-case analysis of the risks and benefits of the specific product at issue.¹²⁶ Although there was no general agreement on the meaning of comment k in 1986 when the Vaccine Act was enacted,¹²⁷ the language of the comment itself seems fairly straightforward. The comment conducts a risk-benefit analysis of the rabies vaccine, and in referring to “an apparently useful and desirable product,” it is clear that *some* entity must make this determination.¹²⁸ In fact, one court acknowledged that it was “expanding the literal interpretation of comment k” by creating a per se rule that all FDA-approved prescription medications are “unavoidably unsafe.”¹²⁹

120. Victor E. Schwartz, *Unavoidably Unsafe Products: Clarifying the Meaning and Policy Behind Comment K*, 42 WASH. & LEE L. REV. 1139, 1146 (1985) (“[C]omment k deals with liability for *design* of . . . products.”).

121. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

122. *Id.*

123. *Id.*

124. *Id.*

125. See *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 835 (Neb. 2000) (explaining that comment k “has been interpreted in a variety of ways in other jurisdictions”).

126. See *Bryant v. Hoffman-La Roche, Inc.*, 585 S.E.2d 723, 726 (Ga. Ct. App. 2003) (“Most of the states that have adopted Comment k have applied it in a more limited fashion and on a case-by-case basis.”); *Toner v. Lederle Labs.*, 732 P.2d 297, 308 (Idaho 1987) (finding that the comment only applies “when the situation calls for it”). A minority of states do not require a case-by-case determination for FDA-approved pharmaceuticals. See, e.g., *Young v. Key Pharm., Inc.*, 922 P.2d 59, 64 (Wash. 1996) (“[A] separate determination of whether a product is unavoidably unsafe need not be made on a case-by-case basis if that product is a prescription drug.”).

127. See *Militrano v. Lederle Labs.*, 769 N.Y.S.2d 839, 844–45 (N.Y. Sup. Ct. 2003) (explaining that by 1986 courts had come to different conclusions as to whether a case-by-case determination was required for prescription drugs).

128. See RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

129. *Grundberg v. Upjohn Co.*, 813 P.2d 89, 90 (Utah 1991).

The language of comment k and its adoption in the Vaccine Act suggests that some case-by-case analysis is required to determine if a vaccine is “apparently useful and desirable,” despite its inherent risks, so as to justify its use. However, the question remains as to *whom* this should be apparent.

B. CONGRESS DECIDES WHETHER A VACCINE IS UNAVOIDABLY UNSAFE

The *Bruesewitz*¹³⁰ and *Ferrari*¹³¹ courts grappled with the question of whether section 22(b)(1) requires a case-by-case examination, but neither court considered who Congress intended to conduct this inquiry or whether it had already been performed with respect to childhood vaccines.¹³² The text of the Vaccine Act does not clearly express who should make these case-by-case determinations, but the contents of the Act strongly suggest that Congress intended to assume this decision-making role. Although the legislative history of the Act is not clear on this point, Congress has demonstrated through action that it is the body responsible for making these decisions—it did so long before the Vaccine Act and has continued to do so since.

1. The Structure and Contents of the Vaccine Act: Congress’s Role as Gatekeeper

Despite the lack of any clear statement in the text indicating that Congress intended to assume the task of conducting risk-benefit analyses of childhood vaccines, the contents of the Vaccine Act itself show that Congress contemplated a large role for the federal government in making these determinations. The Act authorizes the Secretary of HHS to establish a “National Vaccine Program to oversee and carry out Federal vaccine-related research, testing, licensing, production, and distribution activities concerning all vaccines.”¹³³ It created a National Vaccine Advisory Committee (NVAC) to make recom-

130. *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 240 (3d Cir. 2009), *cert. granted*, 130 S. Ct. 1734 (2010).

131. *Am. Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236, 242 (Ga. 2008).

132. “[T]he purpose of Congress is the ultimate touchstone’ in every pre-emption case.” *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963)).

133. H.R. REP. NO. 99-908, at 4 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6345; *see also* 42 U.S.C. §§ 300aa-1 to -2 (2006).

mentations based on safety and efficacy.¹³⁴ Subpart C of the Vaccine Act¹³⁵ is replete with provisions providing for the recording and reporting of adverse events,¹³⁶ dissemination of vaccine information,¹³⁷ and promotion of research and development of safer childhood vaccines.¹³⁸ Specifically, Congress delegated to the Secretary of HHS the responsibility of establishing a “task force on safer childhood vaccines” and “mak[ing] or assur[ing] improvements in . . . the licensing, manufacturing, processing, testing, labeling, warning, . . . administration, . . . [and] surveillance” of vaccines “in order to reduce the risks of adverse reactions.”¹³⁹ Furthermore, the Act provides for the involvement of multiple federal agencies in making such policy and safety assessments.¹⁴⁰

It is evident from these provisions that Congress sought to take over the leadership role in making vaccine-related decisions. It delegated much of this responsibility to other agencies and decisionmaking bodies, but ultimately assumed the responsibility for nationwide policies regarding the safety and efficacy of various childhood vaccines.

2. Legislative History of the Vaccine Act Is Unclear

The “regulatory context,” which served as the “catalyst for passage” of the Act, can help illuminate Congress’s purpose.¹⁴¹ Prior to 1986, courts decided on a case-by-case basis whether a vaccine was unavoidably unsafe¹⁴² and came to different conclusions.¹⁴³ Vaccine manufacturers became concerned with

134. 42 U.S.C. § 300aa-5 (2006). One of the functions of NVAC is to “[r]ecommend research priorities” to improve vaccine safety and efficacy. *National Vaccine Advisory Committee (NVAC)*, U.S. DEPARTMENT OF HEALTH & HUM. SERVICES, <http://www.hhs.gov/nvpo/nvac/> (last visited Oct. 17, 2010).

135. 42 U.S.C. §§ 300aa-25 to -28.

136. *Id.* § 300aa-25.

137. *Id.* § 300aa-26.

138. *Id.* § 300aa-27.

139. *Id.*

140. *See, e.g., id.* § 300aa-2(a)(7), (8) (mandating that the Director of the Vaccine Program coordinate with federal agencies and nongovernmental entities to monitor vaccine safety, efficacy, and demand).

141. *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 519 (1992).

142. *See, e.g., Johnson v. Am. Cyanamid Co.*, 718 P.2d 1318, 1323 (Kan. 1986) (finding the Sabin Polio vaccine “unavoidably unsafe”).

143. *Compare Graham v. Wyeth Labs.*, 666 F. Supp. 1483, 1497 (D. Kan. 1987) (refusing to find as a matter of law that the whole cell DTP vaccine is unavoidably unsafe), *with White v. Wyeth Labs., Inc.*, 533 N.E.2d 748, 754 (Ohio 1988) (holding that the DTP vaccine containing whole cell pertussis is unavoidably unsafe).

their potential exposure to large damages awards and product liability insurers became hesitant to provide insurance coverage to these manufacturers.¹⁴⁴ For these reasons, vaccine manufacturers started to withdraw from the market, jeopardizing the supply of childhood vaccines.¹⁴⁵ Through the Vaccine Act, Congress sought to provide more predictability with respect to manufacturers' liability.¹⁴⁶ There was also a competing purpose of the Vaccine Act—to ensure that those who suffered from vaccine-related injuries were able to secure adequate compensation.¹⁴⁷ It is difficult to determine from these dueling legislative purposes whether Congress intended to foreclose design defect claims against manufacturers of childhood vaccines, since under either interpretation, one legislative purpose is promoted at the expense of the other.

The legislative history of the Vaccine Act does little to clarify Congress's intent.¹⁴⁸ A House Report by the Committee on Energy and Commerce (1986 Report) made it clear that Congress intended to make civil tort claims more difficult for plaintiffs, in exchange for providing them with “a comprehensive and fair compensation system” in the Vaccine Court.¹⁴⁹ The concept of “unavoidably unsafe” “appl[ies] to the vaccines covered in the bill . . . [and] such products [are] not [to] be the subject of liability in the tort system.”¹⁵⁰ Furthermore, unless there is a manufacturing defect or failure-to-warn claim, people injured by vaccines covered by the Act “should pursue recompense in the compensation system, not the tort system.”¹⁵¹ The 1986 Report casts doubt on whether a court or jury could fairly decide these cases in which a blameless child is pitted against an impersonal manufacturer.¹⁵² Together, these statements indicate that Congress intended to take these decisions away

144. See H.R. REP. NO. 99-908, at 6 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6347.

145. *Id.* at 6–7.

146. See *id.* at 7 (explaining that the Act was intended to give “manufacturers . . . a better sense of their potential litigation obligations”).

147. *Id.* at 6.

148. This is not uncommon, as “legislative history is itself often murky, ambiguous, and contradictory.” *Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546, 568 (2005).

149. H.R. REP. NO. 99-908, at 25.

150. *Id.* at 26.

151. *Id.*

152. See *id.*

from trial courts and to make the risk-benefit decisions for the particular vaccines covered by the Act.

The 1986 report, however, also states that “[v]accine injured persons will now have an appealing *alternative* to the tort system,”¹⁵³ which seems to indicate that Congress did not completely remove any particular cause of action from civil litigation. Furthermore, when enacting legislation to fund the Vaccine Act’s compensation program in 1987, the same committee that wrote the 1986 report stated that “[i]t is not the Committee’s intention to preclude court actions under applicable law,” and that the Act did not purport to “decide as a matter of law the circumstances in which a vaccine should be deemed unavoidably unsafe.”¹⁵⁴ While this is technically subsequent legislative history, it may still be entitled to some weight.¹⁵⁵

The legislative history reveals a plethora of statements that can be construed to support either argument.¹⁵⁶ While it is apparent that there is no clear statement of legislative intent with respect to who decides whether a vaccine is beneficial enough to warrant its risks, Congress has made it clear through its behavior with respect to vaccination programs in the United States that it intended to assume the role as decisionmaker.

3. Congress Acts as Decisionmaker

Reading the Act “against the backdrop of regulatory activity”¹⁵⁷ elucidates Congress’s intent to decide vaccine policy. Congress has a lengthy history of enacting vaccine-specific legislation to promote particular vaccines. Examples include the Poliomyelitis Vaccination Assistance Act of 1955,¹⁵⁸ the Vaccination Assistance Act of 1962,¹⁵⁹ the National Swine Flu Immunization Program of 1976,¹⁶⁰ and most recently, the Public

153. *Id.* (emphasis added).

154. H.R. REP. NO. 100-391(I), at 691 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-364, 2313-365.

155. Shah, *supra* note 118, at 232.

156. *See, e.g.*, 132 CONG. REC. H9943-02, at 29 (1986) (statement of Rep. Henry Waxman) (stating that an individual may bring a civil claim if an “inadequately researched” vaccine causes an injury).

157. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 519 (1992).

158. Pub. L. No. 84-377, 69 Stat. 704 (1955).

159. Pub. L. No. 87-868, 76 Stat. 1155 (1962).

160. Pub. L. No. 94-380, 90 Stat. 1113 (1976).

Readiness and Emergency Preparedness (PREP) Act.¹⁶¹ Moreover, when Congress chose to encourage certain pediatric vaccines, it knew not only that these vaccines were not entirely safe,¹⁶² but that some of them even had safer alternatives. For example, the federal government chose for its public immunization program the Sabin Polio vaccine over the safer, but arguably less effective, Salk vaccine.¹⁶³ When the Vaccine Act was passed, Congress continued to promote the usefulness of the DTP vaccine containing whole-cell pertussis, despite the knowledge that an acellular design was already being used abroad.¹⁶⁴ Even though some children would suffer adverse reactions from this vaccine, the federal government continued to support mandated vaccination for all school-aged children because it considered the benefits of the imperfect vaccine to outweigh the risks of going unvaccinated.¹⁶⁵

Notably, these decisions to promote less safe vaccine designs are consistent with the Vaccine Act's adoption of comment k, which justifies the use of beneficial products that cannot be made safe.¹⁶⁶ A vaccine that cannot be made safe may be "unavoidably unsafe" even if it *could* be made safer, where use of the less safe product is best for public policy. Congress has already made such public policy decisions with respect to certain vaccines.¹⁶⁷

161. 42 U.S.C. § 247d-6d (2005). The PREP Act provides tort immunity for manufacturers of vaccines deemed necessary to prevent a public health crisis. *Public Readiness and Emergency Preparedness Act Questions and Answers*, U.S. DEPARTMENT HEALTH & HUM. SERVICES, <http://www.phe.gov/preparedness/legal/prepact/pages/prepqa.aspx> (last visited Sept. 29, 2010). Recently, this has been extended to include protection for manufacturers of the H1N1 Influenza vaccine. Pandemic Influenza Vaccines—Amendment, 74 Fed. Reg. 30,294 (June 25, 2009).

162. No vaccine is entirely safe. CDC, *supra* note 42, at 1.

163. See *Johnson v. Am. Cyanamid Co.*, 718 P.2d 1318, 1320–22 (Kan. 1986) (discussing the history of polio vaccines).

164. See CHILDHOOD IMMUNIZATIONS, *supra* note 32, at 18 tbl.1 (recommending the DTP vaccine for infants and children); *id.* at 38 (describing efforts to develop an acellular pertussis vaccine and the Japanese success with such a vaccine). The whole-cell vaccine is associated with adverse events such as local inflammatory reactions, vomiting, protracted crying, convulsions, and severe neurological disease. INST. OF MED., *supra* note 32, at 69–71. Unlike the "undesirably crude and reactive" whole-cell vaccine, the acellular vaccine contains only two protein antigens from the pertussis bacterium and causes fewer side effects. CHILDHOOD IMMUNIZATIONS, *supra* note 32, at 38.

165. Willett, *supra* note 50, at 396.

166. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

167. See *supra* note 163 and accompanying text.

Congress has also directly and indirectly authorized various agencies and groups to conduct investigations of each vaccine and its related injuries. For example, the ACIP¹⁶⁸ evaluates each recommended vaccine, utilizing data from a multitude of sources, and uses this information to guide the other federal vaccine programs.¹⁶⁹ ACIP's guidance extends to the selection of appropriate vaccines, proper use of each vaccine, and creation of a list of vaccines to administer to children through the VFC program.¹⁷⁰ ACIP's deliberations "include consideration of population based studies such as efficacy, cost benefit, and risk benefit analyses."¹⁷¹ NVAC¹⁷² also plays a role in vaccine development, research, and administration.¹⁷³ NVAC advises the Assistant Secretary for Health with respect to vaccination safety and supply for both pediatric and adult populations, as well as with respect to specific vaccine issues.¹⁷⁴

The recent preemption cases in the realm of pharmaceuticals and medical devices place a great deal of weight on the presumption against preemption.¹⁷⁵ This presumption predominantly applies "in areas of traditional state regulation," where out of respect for state sovereignty, the Court presumes that "Congress does not cavalierly pre-empt state-law causes of action."¹⁷⁶ Traditionally, issues of safety and health fall within the ambit of State regulation.¹⁷⁷ The states, however, have a

168. See *ACIP Charter*, *supra* note 44 (setting forth the statutory authority for the ACIP).

169. See *CDC*, *supra* note 42, at 1.

170. See *ACIP Charter*, *supra* note 44.

171. *Id.* The ACIP's "recommendations for vaccination practices balance scientific evidence of benefits for each person and to society against the potential costs and risks for vaccination for the individual and programs." *CDC*, *supra* note 42.

172. See *National Vaccine Advisory Committee (NVAC)*, *supra* note 134.

173. *Id.*

174. For a list of many of NVAC's reports and recommendations, see *Reports, Recommendations, and Resolutions*, U.S. DEPARTMENT HEALTH & HUM. SERVICES, <http://www.hhs.gov/nvpo/nvac/reports/index.html> (last visited Oct. 17, 2010).

175. See, e.g., *Wyeth v. Levine*, 129 S. Ct. 1187, 1194–95 (2009) (relying upon the presumption to find that there is no implied preemption for failure-to-warn claims); *Medtronic v. Lohr*, 518 U.S. 470, 485 (1996) (applying the presumption to find that design defect claims for medical devices that have not undergone pre-market approval are not preempted).

176. *Lohr*, 518 U.S. at 485.

177. See *id.* (noting "the historic primacy of state regulation of matters of health and safety"); *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985) (citing *Slaughter-House Cases*, 83 U.S. 36, 62 (1873) (explaining that the States traditionally "legislate as to the protection of the lives, limbs,

minimal role in vaccination policy compared to that of the federal government.¹⁷⁸ Although the states have discretion in administering vaccination programs and creating state-specific vaccination mandates,¹⁷⁹ the federal government is the predominant funding source for these programs¹⁸⁰ and the states' vaccination policies derive from the ACIP's recommendations.¹⁸¹ In practice, therefore, the federal government makes all major vaccine-related policy decisions and the states merely choose how to implement those policies.

The federal government recognizes that *it* has the obligation to provide the states with vaccines¹⁸² and that states are only an "adjunct in carrying out the Federal government's responsibility to prevent the spread of infectious diseases."¹⁸³ Through the various vaccine programs, such as the VFC and Section 317 Immunization Grant programs, the federal government has expended tremendous amounts of resources to supply vaccines to the states.¹⁸⁴ The federal government is more than a mere financier of vaccination programs—it also mandates pediatric vaccination programs as a condition of re-

health, comfort, and quiet" of their residents)); *see also* *Whalen v. Roe*, 429 U.S. 589, 603 n.30 (1977) ("[T]he State has broad police powers in regulating the administration of drugs by health professionals.").

178. For a discussion of the expansive role of the federal government in vaccination policy, see *supra* notes 32–53 and accompanying text.

179. *See, e.g.*, CDC, *supra* note 26, at 2 (discussing a report of "state laws, regulations, or rules that impose vaccination requirements" for children). The vaccine requirements are categorized by state. *Id.*

180. Most states depend primarily upon federal programs, such as the VFC and Section 317 Immunization Grant programs, to provide vaccines for their residents. INST. OF MED., CALLING THE SHOTS: IMMUNIZATION FINANCE POLICIES AND PRACTICES 8 (2000).

181. States' immunization schedules are often derived directly from the ACIP's recommendations. *See, e.g.*, MINN. DEPT OF HEALTH, HISTORY OF THE MINNESOTA SCHOOL IMMUNIZATION LAW (2004), available at <http://www.health.state.mn.us/divs/idepc/immunize/laws/history.pdf> (explaining that Minnesota's immunization laws have been amended so as to be consistent with the ACIP's recommendations); TEX. DEPT OF STATE HEALTH SERVS., RECOMMENDED IMMUNIZATION SCHEDULE FOR PERSONS AGED 0 THROUGH 6 YEARS (2010), available at <http://www.dshs.state.tx.us/immunize/docs/6-105.pdf> (reprinting CDC's immunization schedule for Texas pediatric population).

182. 42 U.S.C. § 1396s(a)(2)(A) (2006).

183. H.R. REP. NO. 99-908, at 5 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6346.

184. *See* INST. OF MED., *supra* note 180, at 8 (explaining that in fiscal year 1999 alone, the federal government spent more than \$600 million in vaccine supplies through the VFC and section 317 programs). For specific amounts awarded to each state between 1995 and 1999, see *id.* at 272–81.

ceiving other federal assistance.¹⁸⁵ Furthermore, the U.S. vaccination program itself is commonly called a “*national* immunization system”¹⁸⁶ with the NVPO¹⁸⁷ at the helm. The sheer amount of federal legislation dealing with preventing the spread of infectious disease and encouraging immunization only further undermines the argument that vaccination is, or has ever been, an area of traditional state control.¹⁸⁸ In fact, the Secretary of HHS has explicit statutory authority to take measures to prevent the transmission or spread of communicable diseases between states.¹⁸⁹

The federal government has an overwhelming interest in national vaccination programs and the states play a secondary role when it comes to making vaccine policy decisions. Regulation to promote immunization and combat the spread of communicable diseases is not only implicitly, but explicitly, within the scope of the federal government’s authority. This, therefore, is not one of those traditional areas of state regulation to which the presumption against preemption applies.

The Vaccine Act, through its adoption of comment k, requires a risk-benefit analysis for each federally recommended vaccine and its potential adverse effects before granting liability immunity for vaccine manufacturers. Although the legislative history of the Vaccine Act is unclear as to who should conduct this inquiry, the Vaccine Act itself provides a large role for the federal government in making vaccine-related decisions, and the federal government has demonstrated throughout history an eagerness to assume this role. Congress has already made this determination with respect to most, if not all, cur-

185. See, e.g., 42 U.S.C. § 1396a(62) (2006) (requiring any state requesting medical assistance to implement an immunization program for all pediatric vaccines for all vaccine-eligible children); *id.* § 1396s(a)(2)(A) (requiring “each State [to] establish a pediatric vaccine distribution program”). The required pediatric vaccines are established by the ACIP. *Id.* § 1396s(e), (h)(6).

186. INST. OF MED., *supra* note 180, at 54 (describing changes and problems in the “national immunization system”) (emphasis added).

187. See *supra* note 34 and accompanying text.

188. It has also been argued that the federal government has a “particularly strong” interest in matters relating to other pharmaceutical products, and that the “mantra” that health and safety regulation is a local concern “is a holdover from the days before the federal government became a major financier of medical costs.” David R. Geiger & Mark D. Rosen, *Rationalizing Product Liability for Prescription Drugs: Implied Preemption, Federal Common Law, and Other Paths to Uniform Pharmaceutical Safety Standards*, 45 DEPAUL L. REV. 395, 411 (1996).

189. 42 U.S.C. § 264(a) (2006).

rent childhood vaccines on the market. It has successfully developed policies, procedures, agencies, and programs designed to conduct the necessary risk-benefit analyses, make vaccine-related recommendations, and implement these recommendations throughout the country. Furthermore, conferring this power on Congress, rather than on state courts, does not offend current preemption jurisprudence because national immunization policy is hardly a traditional state matter.

III. CHILDHOOD VACCINE LITIGATION IS PREEMPTED

Congress is the appropriate decisionmaker with respect to vaccine policy and has already conducted the necessary risk-benefit analyses for recommended childhood vaccines so as to qualify them as “unavoidably unsafe.” This Part demonstrates that Congress is better suited than courts and juries to make these types of decisions. Although preempting design defect claims against manufacturers raises some safety concerns, the consequences of adverse jury rulings outweigh these potential safety issues. Thus, any court that faces a design defect claim involving a recommended childhood vaccine should find the claim preempted.

A. CONGRESS IS BEST SUITED TO MAKE VACCINE POLICY DECISIONS

Congress is in a unique position and is particularly well suited for making decisions that would profoundly affect the nation’s vaccination programs. First, Congress has the benefit of pooling the resources of many different government and non-government agencies, including the agencies within the HHS, (the CDC, NIH, FDA, and HRSA), other federal entities (the Department of Defense, USAID, NVPO’s Inter-Agency Vaccine Group (IAVG), and NVAC), as well as various global organizations, consumer groups, and academic institutions.¹⁹⁰ Congress can take advantage of the FDA’s extensive involvement in pre-market and post-market regulation of vaccines¹⁹¹ by using the information garnered through the FDA approval process in conjunction with information obtained from other specialized programs devoted to researching vaccine benefits and safety. Existing safety monitoring programs include those established in

190. *National Vaccine Program Office, supra* note 34.

191. *See supra* notes 46–53 and accompanying text.

subpart C of the Vaccine Act,¹⁹² the Vaccine Adverse Event Reporting System,¹⁹³ the Vaccine Safety Datalink Project,¹⁹⁴ and other programs coordinated through the CDC's Immunization Safety Office.¹⁹⁵ The utilization of a variety of public and private resources may compensate for any areas in which the FDA's surveillance system may be lacking.¹⁹⁶ Involvement of vaccine manufacturers in this process can help assure that those with the best access to information about these products are involved in the post-marketing research and surveillance.¹⁹⁷

Juries, on the other hand, are poorly equipped to deal with such matters. A jury does not enjoy access to the same wealth of information that is available to Congress and may erroneously rely upon faulty scientific studies that lack adequate support.¹⁹⁸ The information a jury can consider is constrained by

192. 42 U.S.C. §§ 300aa-25 to -28 (1986).

193. *Vaccine Adverse Event Reporting System (VAERS)*, CDC <http://www.cdc.gov/vaccinesafety/Activities/VAERS.html> (last modified Dec. 9, 2009).

194. *Vaccine Safety Datalink (VSD) Project*, CDC, <http://www.cdc.gov/vaccinesafety/Activities/VSD.html> (last modified Feb. 17, 2010).

195. *About the Immunization Safety Office*, CDC, http://www.cdc.gov/vaccinesafety/Activities/About_ISO.html (last modified Mar. 23, 2010).

196. Some people have criticized the current post-marketing surveillance system for being too weak, unreliable, and underfunded. *See, e.g.*, U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-09-866, HIGHLIGHTS OF NEW DRUG APPROVAL: FDA NEEDS TO ENHANCE ITS OVERSIGHT OF DRUGS APPROVED ON THE BASIS OF SURROGATE ENDPOINTS (2009) ("Weaknesses in FDA's monitoring and enforcement processes hamper its ability to effectively oversee postmarketing studies."); Catherine D. DeAngelis & Phil B. Fontanarosa, *Prescription Drugs, Products Liability, and Preemption of Tort Litigation*, 300 JAMA 1939, 1940-41 (2008) (describing flaws in the current postmarketing surveillance system and saying that "[t]he FDA is not infallible" and does not have a "crystal ball" with which it can foresee all possible risks); Catherine T. Struve, *The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation*, 5 YALE J. HEALTH POL'Y L. & ETHICS 587, 600-06 (2005) (describing areas in which the FDA's postmarketing surveillance are deficient). *But see Losing Momentum*, *supra* note 14, at 44 (statement of Wayne Pisano, Executive Vice President, Aventis Pasteur North America) ("The FDA/CDC regulatory regimen is comprehensive and well established."); Geiger & Rosen, *supra* note 188, at 396 (arguing that the FDA's extensive regulation is sufficient).

197. *See Wyeth v. Levine*, 129 S. Ct. 1187, 1202 (2009) ("[M]anufacturers have superior access to information about their drugs, especially in the post-marketing phase as new risks emerge."); *Adams v. G.D. Searle & Co.*, 576 So. 2d 728, 733 (Fla. Dist. Ct. App. 1991) ("[A] drug manufacturer is in a better position to monitor the current state of knowledge and technology, as applied to its products, than is the FDA.").

198. For example, the groundbreaking study that linked the measles, mumps, and rubella vaccine to autism has recently been retracted as dishonest and unethical. Gardiner Harris, *Journal Retracts 1998 Paper Linking Au-*

the “inherent limitations of the trial process,” such as rules of evidence and the talents of a few attorneys.¹⁹⁹ Furthermore, a jury is disproportionately exposed to the harmful effects a vaccine design had on a plaintiff, while the thousands of people who benefitted from the vaccine are underrepresented.²⁰⁰ Additionally, a jury may have difficulty finding in favor of “big business” when an innocent, injured child would have to bear the loss.²⁰¹ This is why Congress, and not juries, is responsible for conducting the cost-benefit analyses that affect both individual safety and national policy.

Second, congressional decisionmaking is conducive to providing the uniformity and predictability that is needed to maintain the stability of the vaccine market. The driving forces behind the Vaccine Act in 1986 were this sort of unpredictability,²⁰² and the necessity for a “consistent national policy in protecting our children against preventable diseases.”²⁰³ When manufacturers are unable to predict their potential liability, they may become more hesitant to enter or remain in the market.²⁰⁴ If they do continue marketing their products, they will inevitably face higher insurance premiums and will recoup litigation and insurance expenses by raising vaccine prices, thus hindering access to vaccines.²⁰⁵ Jury determinations of a vaccine’s risks and benefits, on a case-by-case basis, offer the manufacturers no clarity on their liability in future cases.²⁰⁶

tism to Vaccines, N.Y. TIMES, Feb. 3, 2010, at A9, available at 2010 WLNR 2234157.

199. Grundberg v. Upjohn Co., 813 P.2d 89, 98 (Utah 1991).

200. Reigel v. Medtronic, Inc., 128 S. Ct. 999, 1008 (2008).

201. H.R. REP. NO. 99-908, at 26 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6367. *But see* Struve, *supra* note 196, at 590 (stating that juries are not overly eager to award damages against business defendants).

202. H.R. REP. NO. 99-908, at 7.

203. *Id.* at 5.

204. See Kellen F. Cloney, Note, *AIDS Vaccine Manufacturers v. Tort Regime: The Need for Alternatives*, 49 WASH. & LEE L. REV. 559, 570 (explaining that “strict liability encourages timidity on the part of manufacturers because of the uncertainty of what may be found to be a defect”).

205. These types of litigation-driven price increases were a major factor in passing the Vaccine Act. See CHILDHOOD IMMUNIZATIONS, *supra* note 32, at 60–66 (discussing the drastic rise in vaccine prices leading up to the Vaccine Act); H.R. REP. NO. 99-908, at 6 (explaining that manufacturers were having difficulty procuring affordable product liability insurance as a result of the increasing numbers of lawsuits).

206. See Grundberg v. Upjohn Co., 813 P.2d 89, 98 (Utah 1991) (finding that a trial court is not the proper forum in which to conduct a risk-benefit analysis of a drug).

Such unpredictable assessments of a vaccine's risks and benefits threaten the supply of vaccines and continued vitality of the national vaccine program.

Additionally, a system in which each state has a different requirement for vaccine design would reduce the likelihood that such products would ever be developed. Vaccine research and development is complex and time-consuming, and manufacturers may simply be unable to "tailor their complex products and product descriptions to fifty-plus different jurisdictions."²⁰⁷ Imagine the difficulties vaccine manufacturers would face if they were required to use a different preservative for their vaccines in each state or if some states required some components that were banned in other states. While today the issue might be the use of thimerosal as a preservative, it is easily foreseeable that in the near future other preservatives or vaccine components could be attacked, too.²⁰⁸ Vaccine manufacturers cannot be expected to overhaul their product design with every new jury verdict. Even if manufacturers could and were willing to design different vaccines for each state, the increased delays and costs of vaccine production and marketing would harm the public.²⁰⁹

B. ARE WE SACRIFICING SAFETY FOR SUPPLY?

The strongest argument for preserving tort litigation for vaccine designs is that such litigation is necessary to maintain and improve the safety of vaccines. It is possible that granting "blanket immunity from tort liability would remove an incentive for developing safer designs."²¹⁰ Furthermore, tort law may help serve as a useful adjunct to FDA surveillance, filling in

207. Geiger & Rosen, *supra* note 188, at 396.

208. For example, the preservative phenol "is corrosive and causes chemical burns" and can cause "systemic poisoning." *Agency for Toxic Substances & Disease Registry*, U.S. DEPARTMENT HEALTH HUM. SERVICES, <http://www.atsdr.cdc.gov/mhmi/mmg115.html> (last updated Aug. 14, 2010). Another agent used in vaccines, 2-phenoxyethanol, also may cause serious injuries. Daniel Dunkin, *2-Phenoxyethanol: A Toxic Vaccine Antibacterial*, ASSOCIATED CONTENT (July 23, 2008), http://www.associatedcontent.com/article/887293/2phenoxyethanol_a_toxic_vaccine_antibacterial.html?cat=5.

209. See *Brown v. Superior Court*, 751 P.2d 470, 479 (Cal. 1988) (explaining that withholding a drug from the public until all dangerous side effects are known "would not serve the public welfare," and that "public policy favors the development and marketing of beneficial new drugs" even when there are serious risks involved).

210. *Am. Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236, 242 (Ga. 2008).

gaps in FDA regulation²¹¹ and assisting the FDA in its task of monitoring vaccine safety.²¹²

Although litigation might incentivize continued research and testing,²¹³ these safety incentives already exist.²¹⁴ The FDA can revoke licenses if it discovers that a product is unsafe²¹⁵ and the Vaccine Act itself mandates continued research and reporting.²¹⁶ There is no need to impose litigation on top of already demanding requirements and effective incentives. This is best demonstrated by the fact that even in the absence of design defect claims in the years since the Vaccine Act was enacted, vaccines remain safer than ever.²¹⁷

Meanwhile, the costs of preserving this avenue of litigation are enormous. A single jury verdict finding a particular vaccine to be defective in design could deprive all residents of that state the ability to obtain that vaccination, at least during the time it would take to develop and obtain FDA approval of an alternate design.²¹⁸ Any business-savvy manufacturer would immediately remove its product from that jurisdiction in order to avoid continued liability exposure.²¹⁹ Replacement of a “defective” vaccine can take years, since the altered product would have to undergo a complete round of testing and licensure.²²⁰ Deprivation of one state’s residents of a vaccine has broader implications than just the public health of that state. Communicable diseases spread across state lines easily, and an unvaccinated population in one state can easily affect the health and lives of residents of every other state.²²¹ It is the federal government’s

211. See DeAngelis & Fontanarosa, *supra* note 196, at 1939.

212. See Struve, *supra* note 196, at 591.

213. Okianer Christian Dark, *Is the National Childhood Vaccine Injury Act of 1986 the Solution for the DTP Controversy?*, 19 U. TOL. L. REV. 799, 838 (1988).

214. See Paul A. Offit, *Lawsuits Won't Stop Pandemics*, WALL ST. J., Dec. 1, 2005, at A16 (arguing that tort litigation plays no role in pushing vaccine manufacturers to produce better, safer vaccines).

215. 42 U.S.C. § 262(a)(2)(A) (2006).

216. *Id.* § 300aa-25 (2006).

217. *Immunization Vaccine Safety*, CDC (Jan. 21, 2009), http://www.cdc.gov/vaccines/pubs/downloads/f_vacsafe.pdf (“The United States currently has the safest, most effective vaccine supply in history.”).

218. Willett, *supra* note 50, at 397.

219. See *id.*

220. *Losing Momentum*, *supra* note 14, at 40 (statement of Wayne Pisano, Executive Vice President, Aventis Pasteur North America) (explaining that “[a]ny change to a vaccine is a complex endeavor” and that it takes about two years to replace an existing product).

221. For example, in 1994, one out-of-state tourist at a ski resort caused an outbreak of measles affecting 247 people in nine different states. CDC, *Inter-*

role to prevent the spread of communicable diseases,²²² and it is not sound public policy to allow one jury to risk the lives of all Americans.

C. DESIGN DEFECT LITIGATION SHOULD NOT BE PERMITTED

The real policy question underlying this debate is simply whether it is worth risking the loss of all vaccines from the market for at least a few years, or possibly forever, in order to preserve the slim effect design defect litigation has on incentivizing safety improvements. The answer is a resounding no. There are already numerous incentives to encourage continued research and reporting of vaccine safety. The potential incremental increased incentive that litigation might provide is not worth the enormous public health consequences it entails.

Protecting vaccine manufacturers does not mean those injured by vaccines will have no recourse. They continue to have access to the Vaccine Court and they may continue to assert tort claims other than design defect where appropriate. If the Vaccine Act's compensation system is not functioning adequately,²²³ then Congress can make the necessary changes that will improve that system so as to provide faster or easier compensation to victims of vaccines.²²⁴ Meanwhile, it is better to err on the side of protecting the nation from a resurgence of communicable diseases, than it is to err on the side of preserving a particular tort claim for a select group of individuals at the expense of the national vaccine supply.

Through examining the numerous federal legislative acts governing vaccine policy, as well as the broad scheme of federal control over the national immunization program, it becomes apparent that Congress has already taken charge of the policy decisions involving childhood vaccine research and administra-

state Measles Transmission from a Ski Resort—Colorado, 1994, 43 MORBIDITY & MORTALITY WKLY. REP. 627, 627 (1994).

222. 42 U.S.C. § 264(a) (2006).

223. It is debatable whether the compensation system is satisfactory. Compare *The National Vaccine Injury Compensation Program: Is It Working as Congress Intended? Hearing Before the H. Comm. on Gov't Reform*, 107th Cong. 6–13, 140–45 (2001) (statement of Rep. Dan Burton) (claiming that the program is working as Congress intended), with *The Continuing Oversight of the National Vaccine Injury Compensation Program: Hearing Before the H. Comm. on Gov't Reform*, 107th Cong. 95–98 (2002) (statement of Ron Homer, Attorney) (critiquing the program as too adversarial).

224. Congress has evaluated the Vaccine Program on several occasions, making various changes. See, e.g., H.R. REP. NO. 106-977 (2000) (recommending improvements to the Vaccine Program).

tion. Therefore, while the Vaccine Act does not preempt all vaccine design defect litigation, it does preempt design defect litigation for the federally encouraged routine childhood vaccines. These vaccines have already undergone the required case-by-case analysis and any court facing a claim involving one of these vaccines should find the claim preempted.

CONCLUSION

Vaccines are one of the most important medical advancements in history. The federal government has greatly contributed to the success of the nation's immunization efforts through vaccine-related legislation and the creation of federal agencies tasked with evaluating the safety and effectiveness of routine childhood vaccines. This success, however, has recently been threatened by litigation concerning the preemptive scope of the Vaccine Act. *Bruesewitz v. Wyeth* presents the question of whether the Act preempts all design defect claims or instead requires a case-by-case analysis of each vaccine. The parties, unfortunately, completely ignore the question of whether the required case-by-case analysis has already been performed with respect to routine childhood vaccines.

The Act's use of the word "unavoidable" suggests that some case-by-case analysis is required before design defect litigation can be precluded, but the appropriate body for conducting this analysis is Congress and the institutions and agencies through which it works. Congress has always taken the lead in regulating national vaccine policy and must continue to do so to ensure the stability that is required to maintain the supply of vaccines in the market. Not all vaccine-related design defect claims are preempted by the Vaccine Act, but such claims related to routine, federally encouraged childhood vaccines *are* preempted. Congress has already determined that the benefits of these vaccines outweigh their risk, thus rendering them "unavoidably unsafe."

Allowing such design defect claims could cripple the nation's immunization programs. This is an unacceptable risk considering that those individuals harmed by such vaccines already have an adequate means of recompense. Any court facing this question should find that these design defect claims are preempted. If Congress changes its position and decides that public policy does not favor the surrender of such claims, it can easily address this with new legislation, perhaps more clearly drafted.