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DOES THE NATIONAL CHILDHOOD VACCINE INJURY COMPENSATION ACT REALLY PROHIBIT DESIGN DEFECT CLAIMS?: EXAMINING FEDERAL PREEMPTION IN LIGHT OF *AMERICAN HOME PRODUCTS CORP. V. FERRARI*

Tara Guffrey*

INTRODUCTION

By the time he reached eighteen months of age, Stefan Ferrari had received many of his required childhood vaccines.¹ His parents recall that he was a healthy child who displayed no difficulty communicating verbally.² Following his last set of booster shots, however, Stefan stopped talking.³ Now ten years old, Stefan still has not spoken.⁴

Stefan's parents filed suit against the manufacturers of the various vaccines he received, alleging their son suffered neurological damage from thimerosal, a mercury-containing preservative in the vaccines.⁵ Stefan's parents claim that the vaccines could have been made with a safer, mercury-free preservative, or they could have been manufactured in single-dose vials, which do not require a

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1. Bill Rankin, *Allow Vaccine Suit, Parents Ask Justices; Federal Law a Roadblock: Lawyer for Couple Says Boy Who Hasn't Spoken for Almost Nine Years Deserves Day in Court*, ATLANTA J.-CONST., May 21, 2008, at B1, available at 2008 WLNR 9552686.

2. *Id.*

3. *Id.*

4. *Id.*

5. *Ferrari v. Am. Home Prods. Corp.*, 650 S.E.2d 585, 586 (Ga. Ct. App. 2007), *aff'd*, 668 S.E.2d 236, 243 (Ga. 2008). For a discussion of the use of thimerosal in vaccines and its potential link to severe side effects, see Centers for Disease Control and Prevention, *Mercury and Vaccines (Thimerosal)*, <http://www.cdc.gov/vaccinesafety/updates/thimerosal.htm> (last visited Sept. 25, 2008). The CDC maintains there is no scientific evidence of harm caused by the low doses of thimerosal in vaccines. *Id.* Nevertheless, the CDC and other organizations recommended the removal of thimerosal from childhood vaccines in 1999. Centers for Disease Control and Prevention, *Recommendations Regarding the Use of Vaccines That Contain Thimerosal As a Preservative*, 48 MORBIDITY & MORTALITY WKLY REP. 985, 996-98 (1999). With the exception of some influenza vaccines, thimerosal has not been used as a preservative in routinely recommended childhood vaccines since 2001. Centers for Disease Control and Prevention, *Mercury and Vaccines*, *supra*.

preservative.⁶ In effect, the Ferraris argued the vaccines administered to their son were defectively designed because safer reasonable alternative designs were available.⁷

The adverse effects allegedly suffered by Stefan as a result of vaccination, though rare, are not unheard of.⁸ The use of vaccines throughout the world has undoubtedly led to some of the greatest advancements in public health—the eradication of small pox, the elimination of major disease outbreaks, and the prevention of thousands of deaths annually.⁹ Despite these successes, a small but significant number of children suffer severe injuries each year as a result of vaccination.¹⁰

What is quite unique about Stefan's case, however, is the treatment it received in the Georgia appellate courts in 2007 and 2008. In 2005, the trial court granted summary judgment in favor of the vaccine manufacturers on the majority of the Ferraris' claims, including their design defect claims.¹¹ The Ferraris elected to appeal.¹² In July of 2007, the Georgia Court of Appeals announced its novel decision.¹³ On appeal, the vaccine manufacturers argued the Ferraris' state law design defect claims were preempted by the National Childhood Vaccine Injury Act of 1986 (the Vaccine Act or the Act), and pointed to a series of holdings that support this position.¹⁴ The Court of

6. *Ferrari*, 650 S.E.2d at 588.

7. *See id.* at 587.

8. *See, e.g.*, Elizabeth A. Breen, Note, *A One Shot Deal: The National Childhood Vaccine Injury Act*, 41 WM. & MARY L. REV. 309, 314–15 n.46 (1999–2000) (explaining that of the approximately 10,000 reports of adverse reactions received annually, less than fifteen percent describe serious events or reactions); *id.* at 314 (stating more than 100 million doses of vaccines are administered annually, yet in 1997, fewer than one hundred children died as a direct result of immunization).

9. Frank A. Sloan et al., *The Fragility of the U.S. Vaccine Supply*, 351 NEW ENG. J. MED. 2443, 2443 (2004).

10. *See* H.R. REP. NO. 99-908, at 4 (1986), as reprinted in 1986 U.S.C.C.A.N. 6344, 6345 (“While most of the Nation’s children enjoy greater benefit from immunization programs, a small but significant number have been gravely injured.”).

11. *Ferrari*, 650 S.E.2d at 587.

12. *Id.* at 587.

13. *See id.* at 590 (reversing the trial court’s grant of summary judgment in favor of the defendant vaccine manufacturers on the plaintiffs’ design defect claims and holding that the claims were not preempted under federal law).

14. *Id.* at 588; *see also* Sykes v. Glaxo-SmithKline, 484 F. Supp. 2d 289, 302–03 (E.D. Pa. 2007) (holding plaintiffs’ strict liability and negligent design defect claims against vaccine manufacturers were expressly preempted under the National Childhood Vaccine Injury Act of 1986); Blackmon v. Am.

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Appeals, however, found the preemption clause at issue in the Vaccine Act ambiguous, and in light of recent precedent from the Supreme Court, held the Ferraris' design defect claims were not preempted by federal law.¹⁵ In so doing, the Georgia Court of Appeals became the first court in the United States to interpret the Vaccine Act to allow plaintiffs to bring design defect claims against vaccine manufacturers under traditional tort law theories in state or federal courts.¹⁶

The vaccine manufacturers immediately filed a petition for certiorari, disputing the decision of the Georgia Court of Appeals.¹⁷ In October of 2008, the Georgia Supreme Court affirmed the conclusion reached by the Court of Appeals, albeit on different grounds.¹⁸ Conflicting with the holdings of other state and federal courts throughout the country, the Georgia Supreme Court held that the National Childhood Vaccine Injury Act does not preempt all design defect claims against manufacturers.¹⁹ As a result, the Georgia Supreme Court's decision could open the door for design defect suits against vaccine manufacturers by the parents of children who have suffered adverse side effects from immunization.²⁰

By enacting the National Childhood Vaccine Injury Act of 1986, Congress aimed to both ensure adequate and timely compensation for those suffering from vaccine related injuries and discourage vaccine

Home Prods. Corp., 328 F. Supp. 2d 659, 666 (S.D. Tex. 2004) (holding plaintiffs' negligent design defect claims against several vaccine manufacturers were barred by the National Childhood Vaccine Injury Act); *Militrano v. Lederle Labs.*, 769 N.Y.S.2d 839, 845–46 (N.Y. Sup. Ct. 2003) (finding that the National Childhood Vaccine Injury Act of 1986 barred any design defect claims brought against vaccine manufacturing defendants).

15. *Ferrari*, 650 S.E.2d at 590.

16. Alyson M. Palmer, *High Court Hears Key Case on Vaccine Suits; Manufacturers Ask Georgia Supreme Court to Overturn Lower Appeals Court Decision Finding Vaccine Suits Aren't Automatically Pre-empted by Federal Law*, DAILY REP. (Fulton County, Ga.), May 21, 2008, at 1.

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

18. *See id.* at 243 (holding that the National Childhood Vaccine Injury Act does not preempt all design defect claims against vaccine manufacturers).

19. *See R. Robin McDonald, Court Backs Vaccine Suit in Autism Case; Conflicting with Courts Around the Country, Justices Say Congress Didn't Intend to "Pre-empt All Design Defect Claims"*, DAILY REP. (Fulton County, Ga.), Oct. 7, 2008, at 1.

20. *Id.* (noting that the Georgia Supreme Court's decision may allow the parents of children suffering from autism to bring suits in Georgia alleging that the neurological effects are the result of vaccination).

manufacturers from leaving the market or raising prices by insulating them from certain product liability claims.²¹ This Note examines whether, in light of recent decisions by the Georgia appellate courts, the Vaccine Act preempts a lawsuit for design defect claims against a vaccine manufacturer. Part I discusses the purposes of the Vaccine Act, exploring the circumstances that brought about its enactment and the subsequent case law that has come down in its wake.²² Part II of this Note analyzes the Georgia Supreme Court's decision in *American Home Products Corp. v. Ferrari*, and specifically discusses whether the Court's holding that design defect liability claims under traditional tort law are not preempted by the Vaccine Act is supported by the text of the Vaccine Act and its legislative history.²³ Part III suggests that the inherent ambiguity of the Vaccine Act's preemption of design defect claims must be resolved in favor of vaccine manufacturers by granting vaccines the status of "exceptional products."²⁴ Finally, this Note concludes that Congress's initial goals in passing the Vaccine Act are not met under the theory employed in *Ferrari*, and that the purposes behind the Vaccine Act mandate that design defect claims are preempted by federal law.²⁵

21. See H.R. REP. NO. 99-908, at 7 (1986), as reprinted in 1986 U.S.C.C.A.N. 6344, 6348 ("[T]wo overriding concerns have led to the development of this legislation: (a) the inadequacy—from both the perspective of vaccine-injured persons as well as vaccine manufacturers—of the current approach to compensating those who have been damaged by a vaccine; and (b) the instability and unpredictability of the childhood vaccine market.").

22. See discussion *infra* Part I.

23. See discussion *infra* Part II.

24. See discussion *infra* Part III.

25. See discussion *infra* Part III and Conclusion.

I. BACKGROUND

A. A Brief History of the Case Law Leading to American Home Products Corp. v. Ferrari

1. American Immunization Precedent and Adoption of the National Childhood Vaccine Injury Act of 1986

For more than a century, mandatory immunization and vaccination programs have existed in various forms throughout the United States.²⁶ Federal and state court decisions have consistently held it within the police power of the states to require vaccination of citizens, provided the laws are reasonable.²⁷ Vaccination mandates for children are particularly common, and courts have upheld them even to the extent of denying unvaccinated children access to public and private schools.²⁸ For most American children, vaccination is routine.²⁹

Widespread vaccination against common, yet deadly, childhood infections and diseases has been described as “one of the most spectacularly effective public health initiatives this country has ever undertaken.”³⁰ Vaccination prevents the death of thousands of children each year, substantially reduces the effects resulting from

26. *Jacobson v. Massachusetts*, 197 U.S. 11, 38–39 (1905) (holding a compulsory state statute, which mandated vaccination of all citizens against smallpox, a valid exercise of police power under the Constitution); see also R. Alta Charo, *Politics, Parents and Prophylaxis—Mandating HPV Vaccination in the United States*, 356 NEW ENG. J. MED. 1905, 1905–06 (2007).

27. *Jacobson*, 197 U.S. at 39 (explaining the primary feature of compulsory vaccination laws which generally imparts reasonableness is an exemption clause for those with medical or contraindications to vaccination). Today, all fifty states offer some form of exemption as part of their vaccination programs. James Colgrove, *The Ethics and Politics of Compulsory HPV Vaccination*, 355 NEW ENG. J. MED. 2389, 2390 (2006). School immunization laws in every state grant exemptions for children with medical contraindications to immunizations. *Id.* Additionally, forty-eight states allow religious exemptions for people with sincere religious opposition to immunization. *Id.* A growing number of states, currently twenty in total, also grant exemptions for parents who claim philosophical convictions against immunization. *Id.*

28. *Zucht v. King*, 260 U.S. 174, 176–77 (1922) (finding a San Antonio city ordinance, which denied admission to both public and private schools to unvaccinated children, a valid exercise of police power).

29. According to the CDC, by the age of five, when children must show proof of immunity to enroll in public schools, the rate of vaccination compliance climbs to more than 95%. Pauline Self, Note, *The HPV Vaccination: Necessary or Evil?*, 19 HASTINGS WOMEN’S L.J. 149, 161 (2008).

30. H.R. REP. NO. 99-908, at 4 (1986), as reprinted in 1986 U.S.C.C.A.N. 6344, 6345.

disease—it even led to the eradication of small pox.³¹ In the early 1980s, however, the country's ability to continue supporting wide-scale vaccination of children was in jeopardy.³² Litigation by children suffering injuries from vaccines increased dramatically, causing vaccine manufacturers to raise prices significantly or leave the market altogether.³³ This resulted in vaccine shortages and an inability to ensure vaccine availability to all American children.³⁴ Congress sought to address this looming problem by enacting the National Childhood Vaccine Injury Act of 1986.³⁵

The goal of the Vaccine Act was twofold: (1) ensure those suffering injuries as a result of vaccination receive compensation in a manner that is more predictable, cost-efficient, and timely than the traditional tort system, and (2) free manufacturers from the threat of large, uncertain tort liability, and thereby encourage them to remain in the market and keep prices low.³⁶ The Vaccine Act established the National Childhood Vaccine Injury Compensation Program, providing a unique avenue of recovery for those suffering injury or

31. Sloan et al., *supra* note 9, at 2443.

32. H.R. REP. NO. 99-908, at 4 (describing how previously unrecognized injuries associated with vaccines were becoming widely known, leading injured parties to seek redress and financial relief from the tort system in increasing numbers).

33. For example, in 1978, only one lawsuit was filed against manufacturers of the diphtheria, tetanus, pertussis (DTP) vaccine. In 1985, however, DTP vaccine manufacturers faced 219 lawsuits. *Militrano v. Lederle Labs.*, 769 N.Y.S.2d 839, 843 (N.Y. Sup. Ct. 2003). Additionally, the costs associated with defending these lawsuits and maintaining sufficient insurance was the primary factor in the increased cost of vaccines. *Id.* The average price of the DTP vaccine in 1984 was eleven cents per dose, whereas in 1986 the price of a dose was \$11.40. *Shackil v. Lederle Labs.*, 561 A.2d 511, 523 (N.J. 1989). Eight dollars in this price increase was attributed to the cost of insurance alone. *Id.* Insurance costs were also a significant factor in the decrease in the number of manufacturers producing DTP, which dropped from five in 1972 to two by 1984. *Id.*

34. See Randall B. Keiser, *Déjà Vu All Over Again? The National Childhood Vaccine Injury Compensation Act of 1986*, 47 FOOD & DRUG L.J. 15, 16 (1992) (explaining that increased costs and decreased availability of vaccines caused levels of immunization to drop, resulting in a corresponding increase in the incidence of disease in some areas of the U.S. during the early 1980s).

35. 42 U.S.C. §§ 300aa-1 to -34 (2000). The Act is divided into two parts. Part I of the Act establishes the National Vaccine Program, which is charged with overseeing federal vaccine-related research, testing, licensing, production, and distribution, and improving the nation's immunization programs. *Id.* §§ 300aa-1 to -6. Part II of the Act establishes the National Vaccine Injury Compensation Program, which includes the creation of a vaccine injury compensation trust fund and outlines the procedures, requirements, and conditions under which injured parties may recover. *Id.* §§ 300aa-10 to -34.

36. See H.R. REP. NO. 99-908, at 7, as reprinted in 1986 U.S.C.C.A.N. 6344, 6348.

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death as a result of vaccination.³⁷ Under the Act's procedural requirements, an injured individual seeking compensation must first file a petition in the Court of Federal Claims.³⁸ The petitioner does not have the burden of proving fault or causation;³⁹ he need only show that he received a vaccine covered by the Act and then suffered certain symptoms or side effects within a defined period of time to make out a *prima facie* case for compensation.⁴⁰ Awards are drawn from a fund financed by an excise tax on each vaccine dose.⁴¹

The Vaccine Act prohibits an injured individual from filing a civil action for damages before first filing a petition and seeking judgment from the Court of Federal Claims.⁴² The petitioner may then either accept the Federal Claims Court's judgment (and any award) and abandon his tort rights,⁴³ or reject the judgment and retain his tort rights.⁴⁴ If a plaintiff elects to reject the judgment of the Court of Federal Claims, he may pursue his tort law claims in state or federal court, subject to certain limitations spelled out in the Vaccine Act.⁴⁵ In § 300aa-22(a) the Act specifically provides that once a claimant opts out of the Court of Federal Claims process, "State law shall apply to a civil action brought for damages for a vaccine-related

37. 42 U.S.C. § 300aa-10(a).

38. Section 300aa-11(a)(2)(A) provides the following:

No person may bring a civil action for damages in an amount greater than \$1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, and no such court may award damages in an amount greater than \$1,000 in a civil action for damages for such a vaccine-related injury or death, unless a petition has been filed . . . for compensation under the Program for such injury or death.

39. *Id.* §§ 300aa-11 to -14; *see also* *Shalala v. Whitecotton*, 514 U.S. 268, 270 (1995) (explaining that a claimant is eligible for compensation by introducing proof of actual causation, but alternatively, compensation can also be awarded if the claimant meets the requirements of the Vaccine Injury Table without proving causation).

40. 42 U.S.C. §§ 300aa-11 to -14.

41. *Id.*; *see also* I.R.C. § 9510 (2006) (establishing procedures for maintenance of the fund).

42. 42 U.S.C. § 300aa-11.

43. If the claimant elects to accept compensation and abandon his tort rights, the Act transfers these rights to the federal government via subrogation. 42 U.S.C. § 300aa-17.

44. *Id.*; *see also* §§ 300aa-11(a)(2)(A)(i), 300aa-21(b) (stating the claimant may reject the judgment of the Court of Federal Claims and retain his tort rights; alternatively, the claimant may keep his tort rights by withdrawing his petition if the Court moves too slowly or a decision is unreasonably delayed).

45. *See id.* § 300aa-21.

injury or death.”⁴⁶ This statement, however, is followed by a caveat in § 300aa-22(b): “No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death . . . 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.”⁴⁷ In effect, this section of the Vaccine Act places limits on a potential plaintiff’s right to bring a design defect claim against a vaccine manufacturer.⁴⁸ Congress modeled subsection (b) specifically after comment k to section 402A of the Restatement (Second) of Torts.⁴⁹ Thus, it is clear the Vaccine Act preempts state law to some extent, but still expressly reserves a role for state courts.⁵⁰

2. *Struggling to Apply the Vaccine Act: Interpretation of § 300aa-22(b)*

Subsequent courts interpreting the Vaccine Act have struggled to determine the extent to which traditional tort law remedies for design defect claims are preempted by the language of § 300aa-22(b).⁵¹ Courts have declared that the limitation, on its face, is ambiguous.⁵²

46. See *id.* § 300aa-22(a).

47. *Id.* § 300aa-22(b)(1) (emphasis added). Additionally, § 300aa-22(b)(2) presumes that a vaccine is accompanied by proper warnings and directions so long as the manufacturer complied with all applicable requirements under the Federal Food, Drug and Cosmetic Act. Finally, § 300aa-22(c) states that no vaccine manufacturer will be held liable in a civil action for failing to provide direct warnings to the injured party.

48. Keiser, *supra* note 34, at 30.

49. See H.R. REP. NO. 99-908, at 25–26 (1986), as reprinted in 1986 U.S.C.C.A.N. 6344, 6366 (stating that § 300aa-22(b) sets forth the principle contained in comment k of Section 402A of the Restatement (Second) of Torts).

50. 42 U.S.C. § 300aa-22(b); see also *Schafer v. Am. Cyanamid Co.*, 20 F.3d 1, 3 (1st Cir. 1994) (“[T]he Act modifies, but does not eliminate, the traditional tort system, which Congress understood to provide important incentives for the safe manufacture and distribution of vaccines.”).

51. See *Bruesewitz v. Wyeth, Inc.*, 508 F. Supp. 2d 430, 440 (E.D. Pa. 2007) (noting the two alternative interpretations put forth by plaintiffs and defendant manufacturers); *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 299 (E.D. Pa. 2007) (finding § 300aa-22(b) has two “plausible” meanings and noting that the plain text of the Vaccine Act does not resolve the proper interpretation); *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 659, 663 (S.D. Tex. 2004) (discussing two possible conflicting interpretations of § 300aa-22(b)); *Am. Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236, 239 (Ga. 2008) (acknowledging that two alternative, plausible readings exist with regard to preemption under § 300aa-22(b)); *Militrano v. Lederle Labs.*, 769 N.Y.S.2d 839, 843 (N.Y. Sup. Ct. 2003) (stating that on its face, the meaning of § 300aa-22(b) “is not entirely clear”).

52. *Militrano*, 769 N.Y.S.2d at 843.

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In doing so, two plausible readings of the section have been suggested.⁵³ The first possible reading posits that any injury caused by a vaccine covered under the Act is deemed “unavoidable” as a matter of law, provided the vaccine was properly prepared and accompanied by adequate warnings.⁵⁴ This reading of the statute essentially provides a complete bar to state tort suits premised on a design defect theory.⁵⁵ Alternatively, the second possible reading of the limitation posits that the section could be read as barring design defect claims only where the side effects are determined, on a case-by-case basis, to be unavoidable.⁵⁶ This reading permits juries in individual cases to determine whether a vaccine could have been designed better so as to avoid the injury suffered.⁵⁷

To resolve the ambiguity and decide which of the two interpretations is accurate, courts have looked to Congress’s legislative intent in enacting the Vaccine Act.⁵⁸ Most courts believe the legislative history of the Act strongly supports a construction that

53. See, e.g., *Blackmon*, 328 F. Supp. 2d at 663.

54. See, e.g., *Sykes*, 484 F. Supp. 2d at 299 (“[D]efendants construe this section of the Vaccine Act to impose a total bar on design defect claims arising from vaccine-related injuries so long as the vaccine was produced in accordance with FDA-approved specifications.”).

55. Not surprisingly, this is the interpretation advocated by vaccine manufacturers. See, e.g., *Sykes*, 484 F. Supp. 2d at 299; *Blackmon*, 328 F. Supp. 2d at 663; *Ferrari*, 668 S.E.2d at 237; *Militrano*, 769 N.Y.S.2d at 843–44. This interpretation is attractive to manufacturers because it implies that Congress entrusted the determination of whether a vaccine design is safe to the expertise of federal health agencies, rather than juries. *Sykes*, 484 F. Supp. 2d at 299.

56. See, e.g., *Militrano*, 769 N.Y.S.2d at 844 (explaining that determination on a case-by-case basis would involve an inquiry into whether a covered vaccine could have been designed better so as to avoid the injury being suffered by the claimant).

57. This, of course, is the interpretation argued for by plaintiffs. See, e.g., *Sykes*, 484 F. Supp. 2d at 299; *Blackmon*, 328 F. Supp. 2d at 663; *Ferrari*, 668 S.E.2d at 237; *Militrano*, 769 N.Y.S.2d at 844. This interpretation is asserted by plaintiffs because it allows a jury, rather than a federal agency, to determine whether a particular side effect was unavoidable. *Blackmon*, 328 F. Supp. 2d at 665. A plaintiff can demonstrate the design defect was not unavoidable by showing that a reasonable alternative design was feasible. *Id.*

58. See *Sykes*, 484 F. Supp. 2d at 299 (“I will look at the legislative history of the Act and any other relevant extrinsic material to decipher Congress’s intent in enacting 42 U.S.C. § 300aa-22(b)(1).”); *Blackmon*, 328 F. Supp. 2d at 664 (“The legislative history also supports a construction of § 300aa-22(b) that would bar all defective design claims under the conditions outlined in the statute.”); *Militrano*, 769 N.Y.S.2d at 844 (“Resolution of these competing interpretations requires a tripartite analysis of the legislative history of the Act, the Restatement (Second) of Torts, and the case law that existed at the time the Act was enacted.”); see also *Oklahoma v. New Mexico*, 501 U.S. 221, 235 n.5 (1991), in which the U.S. Supreme Court asserts that when interpreting an ambiguous statute, the Court has consistently examined legislative history and other extrinsic material.

would bar all defective design claims under state law.⁵⁹ For example, they often point to a passage in the Report of the Committee on Energy and Commerce that states the following:

Vaccine-injured persons will now have an appealing alternative to the tort system. Accordingly, if they cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings [they] should pursue recompense in the compensation system, not the tort system.⁶⁰

Thus, for several years, courts throughout the United States that have decided the issue applied the first reading of the statute—that injuries caused by covered vaccines are unavoidable as a matter of law—and dismissed state tort law claims premised on design defect theories as preempted by the Vaccine Act.⁶¹

3. Everything Changes: The Georgia Appellate Courts Decide Ferrari

In 2007, the Georgia Court of Appeals released its opinion in *Ferrari v. American Home Products Corp.*⁶² In its analysis, the Court of Appeals relied heavily upon a case recently decided by the U.S. Supreme Court, *Bates v. Dow Agrosciences LLC*.⁶³ *Bates* examined federal preemption of state tort law claims under a different federal act, the Federal Insecticide, Fungicide, and Rodenticide Act

59. E.g., *Militrano v. Lederle Labs.*, 810 N.Y.S.2d 506, 508 (N.Y. App. Div. 2006) (noting the legislative history suggests that Congress clearly intended to bar all design defect claims). See generally H.R. REP. NO. 99-908, at 26 (1986), as reprinted in 1986 U.S.C.C.A.N. 6344, 6367 (explaining that it would be very difficult for a jury, upon seeing a child who has been injured by a vaccine, to find in favor of the manufacturer, even if the vaccine had been made as safely as anyone could reasonably have expected).

60. H.R. REP. NO. 99-908, at 26, as reprinted in 1986 U.S.C.C.A.N. 6344, 6367.

61. See *Ferrari v. Am. Home Prods. Corp.*, 650 S.E.2d 585, 588 (Ga. Ct. App. 2007) (“Only a handful of courts have addressed the scope of the preemption clause found in 42 U.S.C. § 300aa-22, and each has concluded, after examining the legislative history of the Vaccine Act, that the issue of whether side effects are ‘unavoidable’ cannot be litigated in civil actions.”).

62. 650 S.E.2d 585 (Ga. Ct. App. 2007).

63. *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005).

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(FIFRA).⁶⁴ The portion of FIFRA at issue in *Bates* was declared clear, unambiguous, and susceptible to only one plausible meaning.⁶⁵ However, the Court noted that when a statute is ambiguous, courts have a duty to accept the reading that *disfavors* preemption.⁶⁶ The Georgia Court of Appeals opined that *Bates* changed traditional preemption analysis, thus drastically altering the viability of vaccine design defect claims in state tort proceedings.⁶⁷ The Court of Appeals determined that (1) there is no longer a rebuttable presumption against preemption, but a duty to accept the reading of an express preemption statute that disfavors preemption;⁶⁸ and (2) preemption analysis ends with an examination of the statutory language alone and no consultation of legislative history.⁶⁹ Because the Vaccine Act is susceptible to two plausible readings, courts have a duty to accept the reading that disfavors preemption—despite any legislative intent indicating the contrary.⁷⁰ Thus, under this analysis, plaintiffs' design defect claims against vaccine manufacturers are not preempted by the Vaccine Act.⁷¹

64. 7 U.S.C. § 136 (2000).

65. *Bates*, 544 U.S. at 448–49 (noting there was no plausible alternative interpretation of the statute at issue, thus implying the statute was unambiguous).

66. *Id.* at 449 (“Even if Dow had offered us a plausible alternative reading of § 136v(b)—indeed, even if its alternative were just as plausible as our reading of that text—we would nevertheless have a duty to accept the reading that disfavors pre-emption. . . . In areas of traditional state regulation, we assume that a federal statute has not supplanted state law unless Congress has made such an intention ‘clear and manifest.’” (quoting *N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995))).

67. *Ferrari*, 650 S.E.2d at 589.

68. In other words, if a statute is ambiguous in any way, the court must apply the interpretation that disfavors preemption and allows state law causes of action to proceed. *Id.*

69. Legislative history, as well as any other relevant extrinsic materials, cannot be consulted under the court of appeals interpretation of *Bates*. *Id.*

70. The court of appeals recognized the novelty of the decision it fashioned:

While this result differs from that reached by other courts addressing the preemptive effect of the Vaccine Act, none of those courts addressed the impact of *Bates* on the analysis of ambiguous express preemption clauses. We recognize that this result is anomalous given the clear legislative history to the contrary, but we are constrained to follow the Supreme Court’s explicit guidance in *Bates*.

Id. at 590.

71. According to the court of appeals, because two plausible, alternative readings of the Vaccine Act exist, and one of these readings disfavors federal preemption of state law tort claims, there is a duty to accept this interpretation, and thereby allow design defect claims to proceed in state courts. *Id.*

In October of 2008, the Georgia Supreme Court affirmed the Court of Appeals decision in a unanimous opinion.⁷² The reasoning relied on by the Georgia Supreme Court, however, was quite different than that employed by the Court of Appeals. First, the Georgia Supreme Court determined that the Court of Appeals erred in holding that *Bates* precludes the use of legislative history in preemption analysis.⁷³ Rather than drastically altering the traditional preemption analysis, as the Court of Appeals advocated, *Bates* instead offered a strong affirmation of the presumption against preemption in products liability cases, and demonstrated that this presumption applies except in the narrowest of circumstances.⁷⁴

The Georgia Supreme Court then proceeded with a far-reaching examination of both the specific language of the Vaccine Act and its legislative history.⁷⁵ The court examined comment k to section 402A of the Restatement (Second) of Torts and determined that the majority of jurisdictions that have adopted the comment have done so on a case-by-case basis, electing not to grant blanket immunity to product manufacturers.⁷⁶ Furthermore, the Georgia Supreme Court interpreted the legislative reports behind the Vaccine Act's passage to leave open the possibility of design defect suits, refuting the claims of other courts that there is clear legislative history to the contrary.⁷⁷ The Georgia Supreme Court's decision allows plaintiffs, including the Ferraris, to bring design defect claims against vaccine manufacturers with juries deciding, on a case-by-case basis, whether a particular side effect was unavoidable or if a safer alternative design existed for the vaccine.⁷⁸

72. *Am. Home Prods. Corp. v. Ferrari*, 668 S.E.2d 234 (Ga. 2008).

73. *Id.* at 238–39 (“[T]he Court of Appeals took ‘one part of the *Bates* ruling out of its context, and [gave] it broader scope than is appropriate.’” (quoting *Bruesewitz v. Wyeth*, 508 F. Supp. 2d 430, 444 (E.D. Pa. 2007))).

74. *Id.* at 239.

75. *Id.* at 238–43.

76. *Id.* at 239 (concluding most states that adopted comment k, including Georgia, did so in a limited manner).

77. *Id.* at 243–44 (citing cases that admit it is possible Congress left open the possibility of design defect claims for vaccines covered by the Act).

78. *Ferrari*, 668 S.E.2d at 243.

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B. The Importance of Defining the Scope of Federal Preemption Under the Vaccine Act

This Note focuses on the extent to which federal law, and the Vaccine Act specifically, preempts a state law tort claim against a vaccine manufacturer for design defects, and whether the Georgia Supreme Court's decision in *Ferrari* correctly determined that Congress did not intend to preempt all design defect claims against vaccine manufacturers with the passage of the Vaccine Act. The resolution of this question has significant ramifications for vaccine manufacturers, potential tort plaintiffs, and the American public as a whole.⁷⁹ An interpretation of the Vaccine Act that opens up vaccine manufacturers to potential liability for design defects will likely lead to an increase in litigation, and a return to the days when both plaintiffs and defendants faced uncertain and unpredictable results in the traditional tort system. Furthermore, the specter of large and uncertain liability could once again result in significant price increases for vaccines—or even worse, the complete unavailability of some vaccines.

II. ANALYZING THE TEXT AND LEGISLATIVE HISTORY OF § 300AA-22(B)(1)

Only a handful of courts have examined whether the Vaccine Act preempts all claims that a vaccine was defectively designed.⁸⁰ With the exception of the Georgia Court of Appeals and the Georgia

79. Elizabeth A. Yi, Editorial, *Vaccine Lawsuit Hazards*, WASH. TIMES (D.C.), June 8, 2008, at B5.

80. At the time the Georgia Supreme Court opinion was issued, two federal District Courts and two states other than Georgia had examined the question in published opinions. The United States District Court for the Eastern District of Pennsylvania first explored the question in *Sykes v. Glaxo-SmithKline* in March of 2007, 484 F. Supp. 2d 289 (E.D. Pa. 2007), and again in *Bruesewitz v. Wyeth, Inc.* in August of 2007, 508 F. Supp. 2d 430 (E.D. Pa. 2007). The United States District Court for the Southern District of Texas examined the issue in *Blackmon v. American Home Products Corp.* in 2004, 328 F. Supp. 2d 659 (S.D. Tex. 2004). In 2003, a New York state trial court explored vaccine design defect preemption in *Militrano v. Lederle Laboratories*, 769 N.Y.S.2d 839 (N.Y. Sup. Ct. 2003). Most recently, the Philadelphia Court of Common Pleas tackled the issue in 2008 in *Wright v. Aventis Pasteur, Inc.*, No. 3861, 2008 Phila. Ct. Com. Pl. LEXIS 221 (Phila. Ct. Com. Pl. Aug. 27, 2008). Following the Georgia Supreme Court's *Ferrari* opinion, the Third Circuit examined the issue and upheld the district court's dismissal of plaintiffs' design defect claims in *Bruesewitz v. Wyeth, Inc.*, 561 F.3d 233, 251 (3d Cir. 2009).

Supreme Court, every court that has examined the question held that all design defects claims are preempted by the Vaccine Act.⁸¹ Like each of the courts that previously analyzed the issue, however, the Georgia Supreme Court employed a traditional preemption analysis approved by the United States Supreme Court.⁸² The court's analysis began with an extensive examination of the preemptive text of the Vaccine Act, found in § 300aa-22(b), which is based directly on comment k to section 402A of the Restatement (Second) of Torts.⁸³ The analysis then proceeded with an examination of the legislative history associated with the Vaccine Act's passage to decipher Congress's purpose in enacting the statute.⁸⁴

A. Defining Traditional Preemption Analysis

Under the Supremacy Clause of the United States Constitution, state laws that are in opposition to or interfere with federal laws on a particular subject are unenforceable, and thus preempted by and secondary to federal law.⁸⁵ The defendant vaccine manufacturers argue that the Vaccine Act expressly preempts design defect claims by plaintiffs.⁸⁶ Express preemption exists when Congress expressly states in a statute that state law is preempted by federal law.⁸⁷ It is clear from the language of § 300aa-22(b) that Congress intended to

81. See *Bruesewitz*, 508 F. Supp. 2d at 446; *Sykes*, 484 F. Supp. 2d at 303; *Blackmon*, 328 F. Supp. 2d at 666; *Militrano*, 769 N.Y.S.2d at 845-46; *Wright*, 2008 Phila. Ct. Com. Pl. LEXIS 221, at *33; see also *Bruesewitz*, 561 F.3d at 251 (rendering decision following the opinions from the Georgia appellate courts). But see *Ferrari*, 668 S.E.2d at 243; *Ferrari v. Am. Home Prods. Corp.*, 650 S.E.2d 585, 590 (Ga. Ct. App. 2007).

82. *Ferrari*, 668 S.E.2d at 238.

83. *Id.* at 239-43.

84. *Id.* at 240-43.

85. See U.S. CONST. art. VI, cl. 2.

86. See *Ferrari*, 668 S.E.2d at 237 ("[T]he Vaccine Act bars [Appellees'] design defect claims because 'any vaccine-related injury would be deemed "unavoidable" if the vaccine was properly prepared and accompanied by proper warnings.'" (quoting *Ferrari v. Am. Home Prods. Corp.*, 650 S.E.2d 585, 588 (Ga. Ct. App. 2007))).

87. There are three basic instances where preemption occurs: (1) Congress expressly preempts state law, known as "express preemption"; (2) Congress implements a pervasive federal regulatory scheme and Congress's intent to preempt state law is inferred from the extensive nature of the scheme, known as "field preemption"; and (3) state law conflicts with federal law such that it is either impossible to comply with both federal and state law or it would be futile to do so, known as "conflict preemption." *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 296 (E.D. Pa. 2007).

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expressly preempt traditional state tort remedies with the passage of the Vaccine Act.⁸⁸ However, the extent of the scope of the intended preemption under § 300aa-22(b) is unclear from the Vaccine Act, and thus requires interpretation by reviewing courts.⁸⁹

The U.S. Supreme Court has previously specified the traditional analysis that occurs when attempting to “identify the domain expressly preempted” by federal statutory language.⁹⁰ Analysis of the scope of the preemption always begins with an examination of the text of the statute at issue.⁹¹ The interpretation of the statutory text “is informed by two presumptions about the nature of preemption.”⁹² First, it must be presumed that Congress does not nonchalantly preempt state law causes of action, especially in areas traditionally relegated to the states.⁹³ As the Supreme Court explains, “[The analysis] start[s] ‘with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.’”⁹⁴ Second, the purpose of Congress is paramount in understanding the scope of any preemption statute.⁹⁵ The intent of Congress is primarily ascertained from the language of the statute itself and the “statutory framework” surrounding it.⁹⁶

88. 42 U.S.C. § 300aa-22(a) (2006) (“*Except* as provided in subsections (b), (c), and (e) of this section State law shall apply to a civil action brought for damages for a vaccine-related injury or death.”) (emphasis added).

89. *See Ferrari*, 668 S.E.2d at 238; *see also Militrano v. Lederle Labs.*, 769 N.Y.S.2d 839, 843 (N.Y. Sup. Ct. 2003).

90. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 502, 517 (1992).

91. *Medtronic, Inc. v. Lohr*, 518 U.S. 468, 484 (1996) (explaining that any analysis of the scope of preemption must begin with the text at issue).

92. *Id.* at 485.

93. *Id.* (noting there is a “presumption against pre-emption of state police power regulations”).

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

95. *Id.* at 485–86.

96. *Id.* at 486 (“Also relevant . . . is the ‘structure and purpose of the statute as a whole,’ as revealed not only in the text, but through the reviewing court’s reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law.” (quoting *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 98 (1992))).

*B. Applying the Traditional Preemption Analysis to § 300aa-22(b)(1)**1. Textual Analysis: The Importance of Comment k*

Any consideration of the scope of preemption in the Vaccine Act must begin with an examination of the text of the preemptive statutory language itself.⁹⁷ The preemptive language at issue occurs in § 300aa-22(b)(1), which states “[n]o vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death . . . 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.”⁹⁸ Congress modeled § 300aa-22(b)(1) after comment k to section 402A of the Restatement (Second) of Torts.⁹⁹ Therefore, any examination of the text of § 300aa-22(b)(1) necessarily must also explore comment k.¹⁰⁰ Section 402A provides for strict liability in product liability cases, and comment k addresses products deemed “unavoidably unsafe.”¹⁰¹ Comment k recognizes there are some products that are incapable of being made completely safe for their intended use because it is beyond the present state of technology or human knowledge to do so.¹⁰² However, these unavoidably unsafe products are often quite

97. *Medtronic*, 518 U.S. at 485.

98. 42 U.S.C. § 300aa-22(b)(1) (2006).

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

100. *Militrano v. Lederle Labs.*, 769 N.Y.S.2d 839, 844 (N.Y. Sup. Ct. 2003).

101. *Am. Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236, 239 (Ga. 2008).

102. The full text of comment k states the following:

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification

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useful.¹⁰³ The comment uses the vaccine for the Pasteur treatment of rabies as an example.¹⁰⁴ Despite the inherent risks in the vaccine, the disease itself invariably leads to death.¹⁰⁵ Thus, it is preferable to accept the risks inherent in the vaccine rather than the risks associated with rabies.¹⁰⁶

Comment k explicitly distinguishes the three basic types of product liability claims: design defect, manufacturing defect, and packaging or marketing defect.¹⁰⁷ Comment k effectively posits that an unavoidably unsafe product, such as a vaccine, is not defectively designed if it is properly manufactured and accompanied by adequate warnings and directions.¹⁰⁸

Unfortunately, comment k—like § 300aa-22(b)(1)—is susceptible to ambiguous interpretation. One possibility is that a case-by-case analysis is necessary to determine whether a *particular product* is unavoidably unsafe, and that it could have been made safer by an alternative design.¹⁰⁹ A second possibility is that all products falling within a particular category, such as vaccines, are considered unavoidably unsafe, and thus strict liability for design defects is completely barred.¹¹⁰ At the time the Vaccine Act was adopted, incorporating comment k into § 300aa-22(b)(1), the case law was divided as to which analysis was the appropriate one to apply.¹¹¹

that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

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

103. *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 835 (Neb. 2000).

104. *Bruesewitz v. Wyeth, Inc.*, 508 F. Supp. 2d 430, 445 (E.D. Pa. 2007).

105. *Id.*

106. *Id.*

107. *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 659, 664 (S.D. Tex. 2004) (recognizing the three basic types of product liability claims: (1) design defect, (2) manufacturing defect, and (3) inadequate labeling or a failure to warn).

108. *Id.*

109. *Militrano v. Lederle Labs.*, 769 N.Y.S.2d 839, 844 (N.Y. Sup. Ct. 2003).

110. *Id.* at 845.

111. *Id.* at 844 (noting that at the time the Vaccine Act was adopted, courts had yet to reach a consensus on the meaning of comment k or its application in design defect litigation); *see also Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 835 (Neb. 2000) (noting that comment k has been

a. Jurisdictions Favoring “Blanket Immunity” Under Comment k

Some jurisdictions reject a case-by-case determination of whether certain side effects are unavoidable, instead holding that any prescription drug is unavoidably unsafe by definition, thereby barring strict liability claims for design defects.¹¹² These jurisdictions argue that unavoidably unsafe products, as contemplated by comment k, are not defectively designed as a matter of law and grant “blanket immunity” to their manufacturers.¹¹³ These courts generally justify an exception from strict liability by focusing on the product’s value to society.¹¹⁴

b. Jurisdictions Favoring a Limited Application of Comment k

Other jurisdictions, however, conclude that a case-by-case analysis is appropriate to determine whether a prescription drug is unavoidably unsafe.¹¹⁵ These courts believe society’s interest in marketing and developing prescription drugs is adequately protected without resorting to blanket immunity for drug manufacturers.¹¹⁶ Thus, the trier of fact is responsible for determining whether, on a case-by-case basis, a particular product is unavoidably unsafe.¹¹⁷ Most jurisdictions following the case-by-case approach use a risk-utility balancing analysis to determine whether the benefits of a product outweigh its known risks.¹¹⁸ As part of this analysis, the trier of fact must consider whether there was any reasonable alternative

interpreted in a variety of ways and that there is wide-scale disagreement among the courts concerning its application).

112. See, e.g., *Brown v. Superior Court*, 751 P.2d 470, 477, 480 (Cal. 1988); *Grundberg v. Upjohn Co.*, 813 P.2d 89, 90 (Utah 1991).

113. *Freeman*, 618 N.W.2d at 836.

114. *Brown*, 751 P.2d at 480.

115. *Am. Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236, 239 (Ga. 2008).

116. *Freeman*, 618 N.W.2d at 836 (noting that providing blanket immunity from strict liability under comment k is widely criticized).

117. *Id.*

118. *Bryant v. Hoffman-La Roche, Inc.*, 585 S.E.2d 723, 727 (Ga. Ct. App. 2003) (“[T]he benefits of the product must outweigh its known risks on the date the product is distributed before the manufacturer can avoid strict liability.”).

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design that would have accomplished the product's purpose with less risk to the consumer.¹¹⁹

c. The Georgia Supreme Court's Textual Interpretation of § 300aa-22(b)(1) in Light of Comment k

In *Ferrari*, the Georgia Supreme Court determined that § 300aa-22(b) does not preempt all design defect claims against vaccine manufacturers. The court began its analysis with a textual interpretation of comment k. In examining comment k, the Georgia Supreme Court first acknowledged the two conflicting interpretations of comment k, and determined there is much disagreement regarding its application.¹²⁰ The court then noted that most of the states that have adopted comment k have done so on the case-by-case basis.¹²¹ The court further explained that other courts examining comment k in the context of design defect litigation under the Vaccine Act erroneously construed the comment to support an interpretation of § 300aa-22(b)(1) as rejecting the case-by-case analysis.¹²² For example, one court held that a rejection of the case-by-case determination of whether a certain side effect was unavoidable “mirrors this established area of tort law for unavoidably unsafe products.”¹²³ The Georgia Supreme Court pointed out that this was an erroneous interpretation because the law surrounding comment k was far from established and agreed upon—and in fact, the majority of jurisdictions *favor* the more limited, case-by-case approach.¹²⁴

After explaining where previous courts had erred in their interpretation of comment k, the Georgia Supreme Court proceeded with a thorough analysis of the text of § 300aa-22(b)(1) in light of the

119. *Id.*

120. *Ferrari*, 668 S.E.2d at 239.

121. *Id.*

122. *Id.* (stating both *Sykes* and *Blackmon* erred in their construction of comment k and used this erroneous construction to support their interpretations of the Vaccine Act).

123. *Id.* (arguing that *Sykes*, in particular, erred in its interpretation).

124. *Id.* at 239–40 (commenting that *Bruesewitz* also acknowledged the *Sykes* court's misunderstanding of comment k).

correct interpretation of comment k.¹²⁵ The Court explained that the conditional nature of § 300aa-22(b)(1) contemplates situations in which side effects will occur that are avoidable, and for which the manufacturer may be liable.¹²⁶ For example, § 300aa-22(b)(1) insulates a manufacturer from civil liability if the vaccine-related injury or death “resulted from side effects that were unavoidable.”¹²⁷ It certainly was within Congress’s power to omit this clause, and instead make immunity to civil litigation conditional on proper preparation and adequate warnings only.¹²⁸ This is not how Congress chose to construct the statute, however. Instead, Congress composed the statute to bar liability for side effects that are “unavoidable by means other than proper manufacturing and packaging.”¹²⁹ This means if a particular side effect could have been avoided by employing a feasible alternative design, liability is not completely barred.¹³⁰

2. Legislative History Analysis

Following its extensive analysis of the text of § 300aa-22(b)(1), the Georgia Supreme Court then examined the legislative history behind the Vaccine Act to ensure that its interpretation aligned with congressional intent.¹³¹ Although previous courts reasoned the legislative history of the Vaccine Act strongly favors preemption of all design defect claims against vaccine manufacturers, the Georgia Supreme Court disagreed.¹³²

125. *Id.* (“An analysis of the language and intent of 42 U.S.C. § 300aa-22(b)(1), unhindered by the mistakes of *Blackmon* and *Sykes*, shows that Congress not only adopted comment k, but understood that comment in the same way that *Bruesewitz* and the great majority of other courts came to understand it.”).

126. *Ferrari*, 668 S.E.2d at 240.

127. 42 U.S.C. § 300aa-22(b)(1) (2006).

128. *Ferrari*, 668 S.E.2d at 240.

129. *Id.*

130. *Id.* (“[T]he last clause of subsection (b)(1) was necessary to ensure that its bar to liability would not apply to the manufacturing and packaging process, but only to side effects which were not avoidable by a safer design.”).

131. *Id.* at 240–42.

132. *See, e.g., id.* at 240 (refuting the Georgia Court of Appeals assertion that there is “clear legislative history” supporting a statutory construction that bars all design defect claims).

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The jurisdictions declaring the legislative history behind the Vaccine Act favors a blanket preemption analysis rely on the following sentence: “Accordingly, if [vaccine-injured persons] cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings [they] should pursue recompense in the compensation system, not the tort system.”¹³³ These courts argue that this passage clearly demonstrates Congress’s intent to relegate defective design claims to the compensation system established in the Vaccine Act, rather than the traditional tort system.¹³⁴ However, the Georgia Supreme Court points out that the Committee did not state the Vaccine Act compensation system was mandatory.¹³⁵ Rather, the system should be viewed as an alternative to the traditional tort system.¹³⁶ Viewing this particular passage in light of the alternative nature of the compensation system, the Georgia Supreme Court concluded the Committee meant only that “if a vaccine-injured person does not have a claim for a manufacturing or warning defect, he should find the compensation system appealing even though he is authorized to attempt to prove the existence of a safer design in the tort system.”¹³⁷ By no means, however, does this passage mean that all design defect claims against vaccine manufacturers are preempted.¹³⁸

An additional passage from the Committee report upon which the Georgia Supreme Court relied states the following:

133. See H.R. REP. NO. 99-908, at 26 (1986), as reprinted in 1986 U.S.C.C.A.N. 6344, 6367.

134. See *Bruesewitz v. Wyeth, Inc.*, 561 F.3d 233, 248 (3d 2009); *Bruesewitz v. Wyeth, Inc.*, 508 F. Supp. 2d 430, 442 (E.D. Pa. 2007); *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 300 (E.D. Pa. 2007); *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 659, 664–65 (S.D. Tex. 2004) (stating this passage “indicates rather clearly the Committee’s intent to relegate design defect claims to the compensation system”); *Militrano v. Lederle Labs.*, 769 N.Y.S.2d 839, 845 (N.Y. Sup. Ct. 2003); *Wright v. Aventis Pasteur, Inc.*, No. 3861, 2008 Phila. Ct. Com. Pl. LEXIS 221, at *31–32 (Phila. Ct. Com. Pl. Aug. 27, 2008).

135. *Ferrari*, 668 S.E.2d at 242–43 (noting the legislative history does not indicate that use of the alternative compensation system is required).

136. H.R. REP. NO. 99-908, at 26, as reprinted in 1986 U.S.C.C.A.N. 6344, 6367 (stating potential tort plaintiffs “now have an appealing alternative to the tort system”).

137. *Ferrari*, 668 S.E.2d at 241.

138. *Id.*

The Committee has set forth Comment [k] in this bill because it intends that the principle in Comment [k] regarding “unavoidably unsafe” products, i.e. those products which in the present state of human skill and knowledge cannot be made safe, apply to the vaccines covered in the bill and that such products not be the subject of liability in the tort system.¹³⁹

Ironically, other courts rely on this exact passage to support the position that the Vaccine Act does preempt all defective design claims.¹⁴⁰ This passage appears to be susceptible to two different interpretations.¹⁴¹ On the one hand, it clearly adopts comment k.¹⁴² Such an adoption is subject to an interpretation that the majority view of comment k applies, meaning vaccines should be examined on a case-by-case basis to determine whether they are unavoidably unsafe.¹⁴³ This is the interpretation advocated by the Georgia Supreme Court.¹⁴⁴ On the other hand, the passage clearly exempts vaccines from tort liability if they are deemed “unavoidably unsafe.”¹⁴⁵ As this passage demonstrates, so much of the interpretation of the legislative history behind the Vaccine Act is

139. H.R. REP. NO. 99-908, at 26, *as reprinted in* 1986 U.S.C.C.A.N. 6344, 6367.

140. *See* Sykes v. Glaxo-SmithKline, 484 F. Supp. 2d 289, 300 (E.D. Pa. 2007); *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 659, 664–65 (S.D. Tex. 2004); *Militrano v. Lederle Labs.*, 769 N.Y.S.2d 839, 845–46 (N.Y. Sup. Ct. 2003).

141. The interpretation advocated by the Georgia Supreme Court argues that this passage “bolsters” a construction of the Vaccine Act that does not preempt all design defect claims. *Ferrari*, 668 S.E.2d at 242. On the other hand, the United States District Court for the Southern District of Texas claims the passage suggests Congress intended that the Vaccine Act absorb all design defect claims. *Blackmon*, 328 F. Supp. 2d at 664–65.

142. H.R. REP. NO. 99-908, at 26, *as reprinted in* 1986 U.S.C.C.A.N. 6344, 6367.

143. *See Militrano*, 769 N.Y.S.2d at 845 (arguing Congress is presumed to have known of the debate surrounding comment k when it was adopted in the Vaccine Act).

144. *Ferrari*, 668 S.E.2d at 242. *But see Militrano v. Lederle Labs.*, 810 N.Y.S.2d 506, 508 (N.Y. App. Div. 2006) (“While the initial language in the House Committee Report with respect to Comment k . . . appears to leave open the possibility of a design defect claim with respect to vaccines covered by the Vaccine Act, the balance of the House Committee’s discussion of the issue clearly establishes Congress[s] determination that the Comment k defense bars all such claims . . .”).

145. H.R. REP. NO. 99-908, at 26, *as reprinted in* 1986 U.S.C.C.A.N. 6344, 6367.

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dependent upon which explanation of comment k is accepted, and the Committee report does not clearly identify which it preferred.¹⁴⁶

In addition to exploring the 1986 Committee report on the Vaccine Act to decipher congressional intent, the Georgia Supreme Court also examined subsequent legislative history in an attempt to glean additional evidence of the purpose behind the Act.¹⁴⁷ Recognizing that the exact same committee that originally considered the Vaccine Act and produced the 1986 report also produced a subsequent report in 1987, the Georgia Supreme Court examined this report “to ‘shed[] light on allegedly ambiguous language’” in the Vaccine Act.¹⁴⁸ The 1987 report states unequivocally that “the codification of Comment (k) of the Restatement (Second) of Torts was not intended to decide as a matter of law the circumstances in which a vaccine should be deemed unavoidably unsafe.”¹⁴⁹ Instead, such determinations should be left to courts, to be made in accordance with “applicable law.”¹⁵⁰ This statement appears to support the Georgia Supreme Court’s assertion that § 300aa-22(b)(1) does not bar all design defect claims as a matter of law.¹⁵¹

Additionally, the Georgia Supreme Court pointed to a rejected amendment to the Vaccine Act that was discussed in the 1987 Committee report to further support its interpretation that Congress did not intend to impose an automatic bar on design defect claims.¹⁵² The Court noted that an amendment that would have stated that “failure to develop [a] safer vaccine was not grounds for liability was rejected by the Committee during its original consideration of the

146. *Id.* (stating the Committee intended that the principle in comment k regarding unavoidably unsafe products apply to vaccines, but neglecting to mention which of the two competing interpretations of comment k should apply).

147. *Ferrari*, 668 S.E.2d at 241.

148. *Id.* (quoting *Grapevine Imps. v. United States*, 71 Fed. Cl. 324, 335 (2006)).

149. *Id.* (referencing H.R. REP. NO. 100-391(I), at 691 (1987), as reprinted in 1987 U.S.C.C.A.N. 2313-1, 2313-365).

150. *Id.*

151. The statement referenced by the Georgia Supreme Court appears to expressly reserve a position for the courts in determining whether vaccines are unavoidably unsafe. Such a statement would support the Georgia Supreme Court’s theory that all design defect claims are not preempted by federal law. *Id.*

152. *Id.*

[Vaccine] Act.”¹⁵³ From the rejection of this proposed amendment, the Court infers that Congress did not intend “to include the provisions embodied in the rejected amendment.”¹⁵⁴ Thus, Congress did not intend to grant blanket immunity to manufacturers for design defects.¹⁵⁵ This is a plausible interpretation of the meaning of the rejected amendment. However, another plausible interpretation is that Congress did not want to hold manufacturers accountable for failing to find safer alternatives to their products as currently designed, not necessarily that they are liable for design defect claims.

After extensively examining the text of § 300aa-22(b)(1), and attempting to determine the congressional intent behind this statutory provision from the relevant legislative history, the Georgia Supreme Court held the Vaccine Act “clearly does not preempt all design defect claims against vaccine manufacturers, but rather provides that such a manufacturer cannot be held liable for defective design if it is determined, on a case-by-case basis, that the particular vaccine was unavoidably unsafe.”¹⁵⁶ Granting such widespread immunity “would ‘have the perverse effect of granting complete [tort] immunity from design defect liability to an entire industry.’”¹⁵⁷ This conclusion is supported by the legislative history behind the Vaccine Act. Unfortunately, an opposite conclusion can also be garnered from the legislative history behind the Act.¹⁵⁸ These contradictory conclusions are the result of Congress’s reliance on comment k in fashioning the preemptive language of § 300aa-22(b)(1). Because comment k itself is susceptible to differing interpretations, and Congress does not expressly state which interpretation it favored, it is unlikely the

153. *Ferrari*, 668 S.E.2d at 241 (quoting H.R. REP. NO. 100-391(I), at 691, *as reprinted in* 1987 U.S.C.C.A.N. 2313-1, 2313-365).

154. *Id.* (quoting NORMAN J. SINGER & J.D. SHAMBIE SINGER, 2A SUTHERLAND STATUTES AND STATUTORY CONSTRUCTION § 48:18 (7th ed. 2008)).

155. *Id.* at 242.

156. *Id.*

157. *Id.* at 243 (quoting *Doyle v. Volkswagenwerk Aktiengesellschaft*, 481 S.E.2d 518, 521 (Ga. 1997)).

158. Courts other than the Georgia Supreme Court have examined the legislative history behind the Vaccine Act and have reached a different conclusion. *E.g.*, *Bruesewitz v. Wyeth, Inc.*, 508 F. Supp. 2d 430, 442 (E.D. Pa. 2007); *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 300 (E.D. Pa. 2007); *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 659, 664 (S.D. Tex. 2004); *Militrano v. Lederle Labs.*, 769 N.Y.S.2d 839, 845 (N.Y. Sup. Ct. 2003).

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debate on the scope of the Vaccine Act's preemption of design defect claims will end without intervention by the U.S. Supreme Court.¹⁵⁹

III. PROPOSAL: GRANTING "EXCEPTIONAL PRODUCT" STATUS TO NECESSARY CHILDHOOD VACCINES

The decision in *American Home Products Corp. v. Ferrari* has upset the uniformity of vaccine design defect litigation in the United States, and requires resolution to ensure that the Vaccine Act is applied fairly and consistently throughout the states. To ensure vaccine manufacturers are not subject to differing standards in various states, vaccines should be deemed "exceptional products" of great social significance, and granted limited immunity from design defect suits. Such a designation is compatible with Congress's purposes in enacting the Vaccine Act and would help protect the nation's supply of childhood vaccines.

A. The Ramifications of Ferrari—A Loss of Uniformity

The Georgia Supreme Court's decision in *American Home Products Corp. v. Ferrari* threatens to have far reaching ramifications for vaccine manufacturers, potential tort plaintiffs suffering vaccine-related injuries, and the American public as a whole.¹⁶⁰ Since the enactment of the Vaccine Act, vaccine manufacturers have remained relatively sheltered from design defect litigation.¹⁶¹ The Georgia Supreme Court's interpretation of the Vaccine Act has renewed the

159. The Georgia Supreme Court appears to suggest this at the close of its opinion, stating that "we must reject such a far-reaching interpretation of 42 U.S.C. § 300aa-22 (b)(1), at least until the Supreme Court of the United States has spoken on the issue." *Ferrari*, 668 S.E.2d at 243.

160. Yi, *supra* note 79 ("If even one state . . . opens its courts to civil suits against vaccine manufacturers, [the] carefully crafted federal system [established by the Vaccine Act] would be disrupted.").

161. See Sloan et al., *supra* note 9, at 2444 (explaining that the National Childhood Vaccine Injury Act of 1986 protected vaccine manufacturers from litigation until relatively recently); see also Paul Howard, *On Vaccines, Immune to Reason*, WASH. POST, THINK TANK TOWN, Oct. 12, 2007, <http://www.washingtonpost.com/wp-dyn/content/article/2007/10/11/AR2007101101597.html>.

industry's concerns about liability.¹⁶² An increase in vaccine litigation will likely result in a repeat of the conditions that led Congress to adopt the Vaccine Act in the first place—more manufacturers may elect to leave the market, resulting in higher prices and shortages of necessary and critical vaccines.¹⁶³

The fear of vaccine shortages is well founded. With only five companies producing all of the routine vaccines for the United States, the country has experienced shortages several times in recent years.¹⁶⁴ The profit margin on vaccine development and production is relatively low.¹⁶⁵ Manufacturers cannot justify production of vaccines if they fail to bring in profits.¹⁶⁶ The increase in litigation that will likely result from the *Ferrari* decision will inflate operating costs for manufacturers, further decreasing profit margins.

As the Georgia Supreme Court itself contemplated, it is highly likely the United States Supreme Court will be required to determine the scope of the preemptive language in § 300aa-22(b).¹⁶⁷ With the enactment of the Vaccine Act, Congress created a single statutory framework, applicable nationwide.¹⁶⁸ As the litigation landscape now stands, the Georgia Supreme Court's decision upsets the uniformity

162. Associated Press, *Couple Can Sue Vaccine Company, Court Says: Lawsuit Claims Mercury Preservative in Shot Responsible for Child's Autism*, MSNBC.COM, Oct. 7, 2008, <http://www.msnbc.msn.com/id/27065692/> [hereinafter *Couple Can Sue*].

163. See Sloan et al., *supra* note 9, at 2444 (noting that a surge of lawsuits in the 1980s led to concerns about the supply of childhood vaccines, and the recent surge in thimerosal litigation has renewed the industry's concerns about liability).

164. See *id.* at 2443 (noting that in 2001–2002, the United States experienced shortages in the supply of eight of the eleven recommended childhood vaccines); see also Arthur E. Foulkes & Nicolas Heidon, *Vaccine Shortage Leads to the FDA's Doorstep*, INVESTOR'S BUS. DAILY, Oct. 22, 2004, available at <http://www.independent.org/newsroom/article.asp?id=1374> (explaining that severe vaccine shortages from 2000 to 2003 forced forty-nine states to implement rationing for common, yet critical, vaccines).

165. For an overview of the many factors that contribute to the low financial returns on vaccine development and production, see Sloan et al., *supra* note 9, at 2443–44. The article outlines the costly process associated with developing a new vaccine, describes the stringent FDA regulations relating to production, and explains how litigation expenses contribute to make vaccines high-risk, low return investments for manufacturers. *Id.*

166. See *id.* at 2444.

167. *Am. Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236, 243 (Ga. 2008).

168. *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 301 (E.D. Pa. 2007) (“Congress [did not] leave vaccine design standards open to reexamination under the laws of each state, with the potential for interstate conflict: the Vaccine Act sets one rule, applicable nationwide” (quoting *Ferrari v. Am. Home Prods. Corp.*, No. 02-VS-031404-F, slip op. at 10 (State Ct. of Fulton County, Ga., Nov. 30, 2005))).

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of how the Vaccine Act has previously been interpreted in federal and state courts.¹⁶⁹ Such interstate conflict exposes vaccine manufacturers to potentially inconsistent tort regimes.¹⁷⁰

The opinions of both the Georgia Supreme Court and the federal and state courts that have previously ruled on the preemptive effect of the Vaccine Act are well reasoned and point to ample legislative history to support their decisions—and yet they come to opposite conclusions. This divergence is due to the two conflicting interpretations of § 300aa-22(b) of the Vaccine Act: the interpretation favored by the Georgia Supreme Court requires a determination, on a case-by-case basis, of whether the adverse side effects from a particular vaccine are unavoidable,¹⁷¹ and the interpretation advanced by other state and federal courts posits that vaccine injuries are unavoidable and subject to preemption so long as the vaccine was properly prepared and accompanied by proper directions and warnings.¹⁷² As has been demonstrated, these differing interpretations are the result of the disagreement regarding the application of comment k, which was expressly adopted by § 300aa-22(b).¹⁷³ Thus, any resolution of whether the Vaccine Act preempts design defect claims must not only look to Congress's primary objectives in enacting the Vaccine Act—to ensure the stability of the childhood vaccine market, while also compensating the claims of vaccine-injured children in a predictable manner—but also to the underlying meaning of comment k.

169. *Couple Can Sue*, *supra* note 162.

170. See Brief for Pacific Legal Foundation as Amicus Curiae Supporting Petitioners at 16, *Am. Home Prods. Corp. v. Ferrari*, 129 S. Ct. 2786 (Apr. 7, 2009) (No. 08-1120) (“Absent federal preemption against the possibility of state tort claims, pharmaceutical companies operating nationwide are subject to differing legal standards because courts throughout the fifty states may answer the same liability questions differently . . .”).

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

172. *Id.* at 239.

173. *Id.* at 239–40; see also *Militrano v. Lederle Labs.*, 769 N.Y.S.2d 839, 844–45 (N.Y. Sup. Ct. 2003).

B. The “Exceptional Products” Doctrine

The Eighth Circuit has put forth a persuasive analysis of comment k’s application in products liability cases that may, at least in part, resolve the dilemma.¹⁷⁴ The court’s analysis first notes that the policy behind comment k acknowledges that some unreasonably dangerous products benefit society to such an extent that placing the risk of injury on the consumer, rather than the manufacturer, is justified, so long as the product is properly manufactured and accompanied by adequate warnings.¹⁷⁵ However, the court goes on to explain that the language of comment k suggests that only “exceptional products” should be exempt from strict liability.¹⁷⁶ Specifically, comment k uses the vaccine for the Pasteur treatment of rabies as an example to imply that only products with exceptional social need fall within the comment’s exception.¹⁷⁷ The Eighth Circuit concludes its theory by surmising that the “unavoidably unsafe exception should apply only upon a showing of exceptional social need.”¹⁷⁸

C. Applying the “Exceptional Products” Doctrine to Vaccines

Such an application of comment k could easily be applied to vaccines, and doing so would ensure that the two ultimate goals of Congress in enacting § 300aa-22(b) of the Vaccine Act are still met. It is undisputed that vaccines can cause severe side effects in some individuals.¹⁷⁹ Yet vaccines are also enormously important to the

174. LITIGATING TORT CASES § 60:27 (Roxanne Barton Conlin & Gregory S. Cusimano eds., 2008).

175. *Hill v. Searle Labs.*, 884 F.2d 1064, 1068–69 (8th Cir. 1989). Note that comment k itself only addresses liability premised on a theory of strict liability. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965). Courts, however, have unanimously agreed that Congress’s adoption of the comment in § 300aa-22(b) is applicable to liability premised on both strict liability and negligence. *See, e.g.*, *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 303 (E.D. Pa. 2007).

176. *Hill*, 884 F.2d at 1069.

177. *Id.* (“[T]he example given—the vaccine for the Pasteur treatment of rabies—suggests that only special products, those with exceptional social need, fall within the gamut of comment k.”).

178. The Court then added that a showing of exceptional social need “should be determined on a case-by-case basis.” *Id.* The solution proposed in this paper, however, suggests that a showing of exceptional social need does not have to be determined on a case-by-case basis in the courts, but can also be determined via congressional action, such as the Vaccine Act.

179. H.R. REP. NO. 99-908, at 6 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 6344, 6346–47.

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well-being of society as a whole.¹⁸⁰ Just as comment k recognizes the need for the Pasteur treatment of rabies, despite its potential for lethal side effects, “The Vaccine Act reflects a congressional determination that the disappearance or unavailability of childhood vaccines would cause far greater harm than the inevitable but limited injuries caused by the vaccines themselves.”¹⁸¹ Given the exceptional need of society for the availability of affordable childhood vaccines, it would be reasonable to apply the “unavoidably unsafe” exception to the routine childhood vaccines covered in the Vaccine Act and deem these particular vaccines “exceptional products” that are shielded from design defect suits by statute.¹⁸² Furthermore, the scope of the exemption from litigation could be limited to only those side effects recognized in the Vaccine Act’s “Vaccine Injury Table,” thereby ensuring that manufacturers only receive immunity from suit in instances where Congress has determined there is an important social need.

This application of comment k to § 300aa-22(b) of the Vaccine Act is consistent with Congress’s ultimate concerns in enacting the comprehensive statute. It is reasonable to infer Congress intended an interpretation of the Vaccine Act that protects manufacturers from design defect suits because doing so would encourage more manufacturers to remain in the market.¹⁸³ As one court noted,

[T]he Vaccine Act’s purpose of protecting vaccine manufacturers from the unpredictability and expense of the tort system would be thwarted by allowing juries to decide on a case-by-case basis whether a vaccine was unavoidably unsafe because “[t]he manufacturers would again be subjected to the

180. *Id.* at 5–6, as reprinted in 1986 U.S.C.C.A.N. 6344, 6345–46.

181. *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 659, 663 (S.D. Tex. 2004).

182. For example, in *Hill v. Searle Laboratories*, the product at issue was an intrauterine contraceptive device (an IUD). 884 F.2d 1064, 1065 (8th Cir. 1989). The court determined the product did not qualify as an “exceptional product” because alternative methods of birth control were available and there was no showing that IUDs in general were exceptionally beneficial to society. *Id.* at 1069–70. Congress has determined, on the other hand, that vaccines are vitally important to America’s public health. H.R. REP. NO. 99-908, at 5, as reprinted in 1986 U.S.C.C.A.N. 6344, 6346.

183. See *Blackmon*, 328 F. Supp. 2d at 665; *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 302 (E.D. Pa. 2007).

unpredictability and expense of the tort system and companies would be dissuaded from remaining or entering the vaccine market.”¹⁸⁴

Allowing case-by-case inquiries by juries would not protect vaccine manufacturers from expensive and unpredictable litigation.¹⁸⁵ Yet Congress clearly stated this was one of the primary goals addressed by the Vaccine Act.¹⁸⁶ Thus, to ensure Congress’s goal of encouraging manufacturers to enter or remain in the vaccine market is met, the only reasonable interpretation of § 300aa-22(b) is that it absolutely protects manufacturers from design defect claims.¹⁸⁷ An approach allowing a case-by-case inquiry “would defeat the protection the Vaccine Act was intended to provide to the vaccine manufacturers and, in turn, to the supply of childhood vaccines.”¹⁸⁸

Additionally, the classification of childhood vaccines as “exceptional products” shielded from design defect liability for a limited set of side effects that are deemed “unavoidable” is compatible with Congress’s second goal of ensuring reliable and timely compensation for those injured by vaccines. In granting manufacturers limited liability from design defect suits for “unavoidable” side effects under § 300aa-22(b), Congress did not eliminate compensation for vaccine-injured children.¹⁸⁹ Rather, the Vaccine Act provides for compensation through an alternative to the traditional tort system—an alternative that is designed to be consistent, predictable, and timely.¹⁹⁰ Moreover, the injured individual need not prove causation or fault, and alleged defective

184. *Wright v. Aventis Pasteur, Inc.*, No. 3861, 2008 Phila. Ct. Com. Pl. LEXIS 221, at *23 (Phila. Ct. Com. Pl. Aug. 27, 2008) (quoting *Sykes*, 484 F. Supp. 2d at 301–02).

185. *Bruesewitz v. Wyeth, Inc.*, 508 F. Supp. 2d 430, 445 (E.D. Pa. 2007).

186. H.R. REP. NO. 99-908, at 6–7, as reprinted in 1986 U.S.C.A.N. 6344, 6347–48.

187. *Sykes*, 484 F. Supp. 2d at 301–02 (“[T]he purpose of the Vaccine Act would not be served if defective design claims could be tried before juries.”).

188. *Wright*, 2008 Phila. Ct. Com. Pl. LEXIS 221, at *31.

189. *Id.* at *23; see also 42 U.S.C. §§ 300aa-10 to -34 (2006).

190. *Sykes*, 484 F. Supp. 2d at 297; see also Brief for the United States as Amicus Curiae at 4, *Am. Home Prods. Corp. v. Ferrari*, 129 S. Ct. 2786 (Jan. 29, 2010) (No. 08-1120) (noting the Court of Federal Claims awards compensation to approximately one-third of all claimants, and that the average award exceeds \$750,000).

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design claims are compensated under this alternative no-fault system.¹⁹¹ Classifying childhood vaccines as “exceptional products” and limiting those who suffer vaccine-related injuries to the alternative no-fault system for design defect claims strikes a balance between the two congressional objectives of the Vaccine Act: compensating injured individuals and protecting vaccine manufacturers from excessive tort liability.¹⁹²

An application of comment k to § 300aa-22(b) of the Vaccine Act that grants routine childhood vaccines status as legislatively-determined “exceptional products” and limits design defect claims against the manufacturers of these vaccines for side effects that the Vaccine Act deems “unavoidable” is necessary to ensure the Act’s efficacy. This interpretation does not necessarily protect manufacturers from all design defect suits, but from suits that are premised on liability for side effects that have been deemed “unavoidable” by the Vaccine Act.¹⁹³ If a particular vaccine is covered by the Vaccine Act, and the alleged harmful side effect is listed in the Vaccine Injury Table, the manufacturer would be protected from a design defect suit. A case-by-case inquiry would be prohibited. Alternatively, if a vaccine is not covered by the Act, or if a vaccine is covered under the Act but the alleged harmful side effect suffered by the plaintiff is not listed in the Vaccine Injury Table, the plaintiff is not barred from filing a design defect suit against the vaccine manufacturer.¹⁹⁴ This interpretation ensures that the federal government’s efforts to establish a uniform national standard for childhood vaccines under the Vaccine Act are served.¹⁹⁵ Finally, the “exceptional products” interpretation gives credence to Congress’s

191. *Sykes*, 484 F. Supp. 2d at 297.

192. *Wright*, 2008 Phila. Ct. Com. Pl. LEXIS 221, at *23.

193. In *Ferrari*, the Georgia Supreme Court specifically noted that the Vaccine Act does not necessarily protect manufacturers from design defect suits, but rather protects them from liability for unavoidable side effects. *Am. Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236, 242 (Ga. 2008).

194. Additionally, the Vaccine Act could be revised to list side effects that scientific evidence strongly suggests are not the result of vaccination, such as autism, and stipulate that vaccine manufacturers are not subject to design defect claims for these particular side effects, as well.

195. *Bruesewitz v. Wyeth, Inc.*, 508 F. Supp. 2d 430, 440 (E.D. Pa. 2007) (“[T]he policy of the Vaccine Act is to protect the national vaccine supply by protecting manufacturers from the potential inconsistencies of the 50-state tort system . . .”).

ultimate goals in enacting the Act: protection of America's supply of childhood vaccines and compensation for the small number of children who are invariably harmed by immunization.¹⁹⁶

CONCLUSION

The National Childhood Vaccine Injury Act of 1986 was enacted to protect the interests of both the American public, by preserving the supply of necessary and critical childhood vaccines, and of vaccine-injured individuals, by ensuring they receive adequate compensation for their suffering.¹⁹⁷ Congress determined that the best method of achieving both these crucial goals was to limit potential plaintiffs' remedies in tort claims based on state law causes of action when their theory of recovery is based on an alleged design defect.¹⁹⁸ Unfortunately, the scope of the preemptive language of the Vaccine Act, found in § 300aa-22(b), is ambiguous and subject to two differing interpretations.¹⁹⁹ These differing interpretations occur because § 300aa-22(b) is modeled after comment k to section 402A of the Restatement (Second) of Torts, which itself has been the subject of disagreement among courts.²⁰⁰ As a result, several courts have concluded § 300aa-22(b) of the Vaccine Act imposes a total bar on design defect claims arising from vaccine-related injuries.²⁰¹ In *American Home Products Corp. v. Ferrari*, however, the Georgia Supreme Court decided that the Vaccine Act only bars design defect claims if the injuries are deemed, on a case-by-case basis, unavoidable.²⁰²

The Georgia Supreme Court's decision has led to interstate conflict as to whether the Vaccine Act provides an absolute bar to design defect claims under state law, and resulted in inconsistent application

196. H.R. REP. NO. 99-908, at 5 (1986), as reprinted in 1986 U.S.C.C.A.N. 6344, 6348.

197. See discussion *supra* Part I.A.1; *supra* note 36.

198. See discussion *supra* Part I.A.1.

199. See discussion *supra* Part I.A.2.

200. See discussion *supra* Part II.B.1.

201. See discussion *supra* Part I.A.2; *supra* note 80 and accompanying text.

202. See discussion *supra* Part I.A.3; discussion *supra* Part II.B.1.c; discussion *supra* Part II.B.2.

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of the Vaccine Act on a nationwide level.²⁰³ Furthermore, *Ferrari* will likely lead to an increase in vaccine design defect litigation, increasing the costs of vaccine production for manufacturers.²⁰⁴ Escalating litigation costs may also lead some manufacturers to leave the vaccine manufacturing market altogether, further threatening the nation's already fragile supply of childhood vaccines.²⁰⁵ The Vaccine Act sought to prevent just such a scenario by shielding manufacturers from certain types of litigation—namely design defect claims—while also ensuring adequate and timely compensation for vaccine-injured individuals.²⁰⁶

The two goals of the Vaccine Act can be properly effected by applying an application of comment k to § 300aa-22(b) that classifies vaccines as special products of exceptional social importance.²⁰⁷ By granting routine childhood vaccines an “exceptional products” status, the Supreme Court can ensure the “unavoidably unsafe” exception applies to these vaccines and shield them from design defect suits by statute.²⁰⁸ Although it is unclear from the legislative history underlying the Vaccine Act which interpretation of comment k Congress intended to adopt when enacting § 300aa-22(b),²⁰⁹ it is quite clear that Congress sought to protect the supply of childhood vaccines available to the American public by insulating vaccine manufacturers from certain forms of tort liability.²¹⁰ An interpretation of comment k, and thus § 300aa-22(b), that recognizes the importance of childhood vaccines by classifying them as “exceptional products” serves Congress’s intent, while still ensuring compensation for vaccine-injured children.

In the meantime, Stefan Ferrari and his family may soon be able to pursue their claims against the vaccine manufacturers at the trial

203. See discussion *supra* Part III.A; *supra* notes 160–161 and accompanying text; *supra* notes 168–170 and accompanying text.

204. See discussion *supra* Part III.A; *supra* note 164 and accompanying text.

205. See discussion *supra* Part III.A; *supra* notes 160–163 and accompanying text.

206. See discussion *supra* Part I.A.1.

207. See discussion *supra* Part III.B.

208. See discussion *supra* Part III.C.

209. See discussion *supra* Part II.B.1; *supra* note 146 and accompanying text.

210. See discussion *supra* Part I.A.1; see also H.R. REP. NO. 99-908, at 26 (1986), as reprinted in 1986 U.S.C.C.A.N. 6344, 6367.

court level in the Georgia courts.²¹¹ They may have to wait a bit longer, however—shortly after the Georgia Supreme Court’s decision, the vaccine manufacturers filed a petition for certiorari in the United States Supreme Court.²¹²

211. See McDonald, *supra* note 19, at 1.

212. Petition for Writ of Certiorari, *Am. Home Prods. Corp. v. Ferrari*, 129 S. Ct. 2786 (Mar. 5, 2009) (No. 08-1120). Shortly thereafter, on March 27, 2009, the Third Circuit issued its opinion in *Bruesewitz v. Wyeth, Inc.* 561 F.3d 233 (3d Cir. 2009). In that decision, the Third Circuit affirmed the district court’s holding that 42 U.S.C. § 300aa-22(b) expressly preempts design defect claims against vaccine manufacturers. *Id.* at 428. Following briefing by the parties and amici curiae in *Ferrari*, the United States Supreme Court invited the Solicitor General to file a brief expressing the views of the United States. *Am. Home Prods. Corp. v. Ferrari*, 129 S. Ct. 2786 (2009) (No. 08-1120). However, before the Solicitor General filed her brief, the Ferraris filed a supplemental brief with the Court, notifying it that they had voluntarily dismissed the design defect claims against the petitioners without prejudice. Supplemental Brief for Respondents at 1, *Am. Home Prods. Corp. v. Ferrari*, 129 S. Ct. 2786 (Oct. 7, 2009) (No. 08-1120). Thus, the Ferraris argued, the case was moot and the petition for certiorari should be dismissed. *Id.* at 2. The petitioners quickly filed their own supplemental brief in response, urging the Court to grant the writ of certiorari, or, in the alternative, hold the case pending resolution of *Bruesewitz* (which, by this time, also had a petition for certiorari pending with the U.S. Supreme Court). Supplemental Brief for Petitioners at 6, *Am. Home Prods. Corp. v. Ferrari*, 129 S. Ct. 2786 (Oct. 20, 2009) (No. 08-1120). The petitioners argued the Ferraris’ voluntary dismissal without prejudice did not render the case moot, because Georgia law allows the Ferraris to refile their claims at any time for at least nine more years. *Id.* at 2. Furthermore, the judgment of the Georgia Supreme Court had not been vacated, and therefore stands as binding precedent in Georgia. *Id.* at 1. Finally, on January 29, 2010, the Solicitor General filed her brief on behalf of the United States. Brief for the United States as Amicus Curiae, *Am. Home Prods. Corp. v. Ferrari*, 129 S. Ct. 2786 (Jan. 29, 2010) (No. 08-1120). The brief urged the Supreme Court to grant the petition for a writ of certiorari in *Bruesewitz*, and to hold the petition for a writ of certiorari in *Ferrari* pending the disposition of *Bruesewitz*, or, in the alternative, to dismiss the *Ferrari* petition (because of the potential mootness question). *Id.* at 1. The Solicitor General stated the “Supreme Court of Georgia erred,” and that the court’s *Ferrari* opinion “frustrates Congress’s intent to stabilize the market for vaccines critical to children’s health.” *Id.* at 7. Because the issue presented in *Ferrari* and *Bruesewitz* is “pressing,” the Solicitor General urged the Court to review the question presented. *Id.* Thus, serious ramifications from the Georgia Supreme Court’s *Ferrari* opinion are quite likely, unless the Supreme Court intervenes by granting certiorari in *Bruesewitz* or *Ferrari*.