Bruesewitz v. Wyeth, Inc.: An Innocuous Injection of Sense Into the Disputed National Childhood Vaccine Injury Act

I. Introduction

In trading his black robe and gavel for a theoretical white coat and stethoscope, Justice Scalia acts as statutory surgeon and guardian of public health by injecting a clear and conclusive solution to a contested statutory provision in the National Childhood Vaccine Injury Act ("NCVIA"). Set against the backdrop of "‘one of the greatest achievements’ of public health in the 20th century,"1 Bruesewitz v. Wyeth, Inc. presents a textual conflict colored by economic, administrative, and public interests.2 By affirming the Court of Appeals for the Third Circuit3 and holding that the NCVIA preempts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects,4 Justice Scalia restores a necessary equilibrium between public confidence and interest in high vaccination rates5 and the economic stability of manufacturers in producing and developing vaccines.6

This note argues that the majority opinion in Bruesewitz achieves this balance through a holistic approach evoking historically-documented Congressional intentions7 complemented by the practical needs and concerns of federal agencies, vaccine
manufacturers, and the public at large. Part II provides a historical perspective of the conflicting precedent that positioned the Court to seize Bruesewitz as a chance to craft a timely and necessary solution to a looming national crisis. Part III evaluates the techniques and sources used to resolve the linguistic conflict at issue, as well as the impact of political and economic overtones on the Court’s decision. Part IV outlines the positive legacy that Bruesewitz will leave by protecting the “fragile” yet indispensable gains from widespread vaccination.

II. Perspective: Symptoms of an Impending Crisis

Justice Breyer heralded widespread vaccination as “one of the most spectacularly effective public health initiatives this country has ever undertaken.”9 While the federal premarket approval process has gone unchanged for the majority of the past century,10 public attitudes towards vaccination have remained anything but static.11 Vaccines became “victims of their own success”;12 as public comfort in their efficacy overshadowed the dangers of disease, fears of serious injury upon or shortly following injection paralyzed the vaccine markets.13 An epidemic of vaccine-related tort suits swept the nation.14 Fear of injury and lack of compensation drove vaccination rates to dangerous lows,15 and vaccine manufacturers hurriedly exited the market in fear of unchecked liability.16
In response, Congress enacted the NCVIA in 1986 to avert a national vaccination crisis by establishing a no-fault compensation program for vaccine-related injuries “designed to work faster and with greater ease than the civil tort system.”\textsuperscript{17} Claimants across the country took issue – not with the “Vaccine Court’s” procedure,\textsuperscript{18} but with the NCVIA’s blanket preemption of design defect claims against manufacturers.\textsuperscript{19} Yet prior to the nation’s highest bench granting certiorari to hear Bruesewitz, preceding federal and state court decisions failed to prescribe a uniform policy towards preemption.\textsuperscript{20} Multiple jurisdictions – including Texas,\textsuperscript{21} Pennsylvania,\textsuperscript{22} and New York\textsuperscript{23} – ruled that the NCVIA provided blanket preemption of any defective design claims under state law.\textsuperscript{24}

A notable and noisemaking departure from this pro-preemption trend came courtesy of the Georgia courts in Ferrari \textit{v. American Home Products Corp.}\textsuperscript{25} The parent-plaintiffs claimed their son suffered neurological damage from a preservative used in vaccines manufactured by the defendant.\textsuperscript{26} The trial court found that the plaintiffs’ design defect claims were preempted by the NCVIA.\textsuperscript{27} However, the Court of Appeals reversed and ruled for plaintiffs, holding that \textit{Bates v. Dow Agrosciences} mandated it “accept a reading [of the NCVIA] that disfavors preemption.”\textsuperscript{28}

The Supreme Court of Georgia granted certiorari and affirmed the Court of Appeals’ judgment in favor of the
manufacturer-defendants, but on different grounds: upon evaluating the statute’s text and Congressional intent, the court found that “such a manufacturer cannot be held liable for defective design if it is determined, on a case-by-case basis, that a particular vaccine was unavoidably unsafe.”

The Ferrari-elucidated duty to disfavor preemption, espousal of a case-by-case approach, advocacy of state sovereignty, and a call for clear Congressional intent to supplant a state law in a traditionally state-governed area directly opposed the rulings of courts across the country. As an unquestioned childhood rite of passage became a hotly-contested cause célèbre, Bruesewitz presented the United States Supreme Court with an opportunity to cure the multi-circuit split rooted in federalism and the public good.

III. Analysis: Diagnosis, Prescription, and Prevention

The majority opinion in Bruesewitz is both prescriptive and preventive, and its decision a timely one: although state courts can beneficially serve as judicial “laboratories for experimentation,” public health is an urgent national priority, not a lab rat with a renewable supply. Bruesewitz originated when parent-plaintiffs, who claimed manufacturer-defendant Wyeth’s DTP vaccine prompted their daughter’s residual seizure disorder and developmental delay, rejected the NCVIA-created Vaccine Court’s unfavorable judgment and filed suit in
Pennsylvania state court. Wyeth removed the case to United States District Court for the Eastern District of Pennsylvania, which granted manufacturer-defendants summary judgment on the design defect claim. Parent-plaintiffs appealed, but the United States Court of Appeals for the Third Circuit affirmed the district court’s holding that the NCVIA preempted any state law causes of action. The United States Supreme Court granted certiorari to hear the case.

A. A Prescriptive Approach: Preemption Prevails

The NCVIA’s preemption of state claims lies at the core of the Bruesewitz debate. “Preemption analysis starts with the assumption that the historic police powers of the states are not to be superseded . . . unless that was the clear and manifest purpose of Congress.” “The purpose of Congress is the ultimate touchstone in every pre-emption case.” In his majority opinion, joined by Justices Kennedy, Thomas, Alito, Breyer, and Chief Justice Roberts, Justice Scalia insists the court “must make do with giving the term its most plausible meaning under the traditional tools of statutory interpretation” and chastises the dissent for “burying” unfavorable trifles of legislative history. He rejects the dissent’s use of post-enactment legislative history, cautioning that “permitting the legislative history of subsequent funding
legislation to alter the meaning of a statute would set a dangerous precedent."  

Looking beyond a statute’s four corners is common when courts decide preemption issues. Justice Breyer’s concurrence approaches the preemption issue with a wider lens. Although he agrees with the dissent’s use of a broader range of outside sources, Breyer claims “these other sources reinforce the [majority’s] conclusion.” Breyer looks to Committee Reports on the bill as “[t]he authoritative source for finding the legislature’s intent.” Breyer places great weight on the House Committee Report 99-908, issued by the Committee on Energy and Commerce, which supported Congress’ intention to preempt state claims by positing that state court juries are an improper vehicle for vaccine design defect claims.

**B. A Prescriptive Approach: Silence is Golden**

Also at issue was whether the statute calls into question the vaccine’s design when establishing a complete defense. Scalia grounds his opinion in the statute’s text: “the language of the provision thus suggests that the design of the vaccine is a given, not subject to question in the tort action.” He points to the “triumvirate of grounds for liability” before concluding that “the statute fails to mention design-defect liability by deliberate choice, not inadvertence.” Scalia characterizes the NCVIA’s silence regarding design-defect
liability as “[reflecting] a sensible choice to leave complex epidemiological judgments about vaccine design to the FDA and the National Vaccine Program rather than juries.”

Justice Sotomayor’s dissent, joined by Justice Ginsburg, criticizes Scalia’s approach, instead advocating the evaluation of an alternative design “that would eliminate the side effect of the vaccine without compromising its cost and utility.” Scalia responds by contrasting this “amorphous test” with Congress’ otherwise “micromanag[ing]” policy towards manufacturers, and points to the Court’s role as a judicial organ rather than a regulatory agency tasked with estimating statistics and appropriating funds. He further notes that design defects “do not merit a single mention in the NCVIA or the FDA’s regulations.” Breyer employs legislative history to support the majority’s conclusion: “The [House Committee] Report . . . says nothing at all about who – judge, jury, or federal safety agency – should decide whether a safer vaccine could have been designed.”

C. A Preventive Approach: Protecting Parties

The documented and demonstrable threat of disrupting vaccination programs provoked the Court to take preventive action in the name of protecting public safety, facilitating agency activity, and safeguarding vaccine supply. Both experts and agencies agree on the importance of vaccination: “Given that
the risks of not vaccinating children far outweigh the unknown and much smaller risk, if any, of exposure to [toxic-containing] vaccines over the first 6 months of life, clinicians and parents are encouraged to immunize all infants even if the choice of individual vaccine products is limited for any reason.”

The Court’s decision in Bruesewitz delineates the role of federal agencies in disease prevention through vaccination. Regulation of the Food and Drug Administration ("FDA") is a direct manifestation of Congressional intent. The Congressionally-tasked agency “pervasively regulate[s] the [vaccine] manufacturing process, down to the requirements for plumbing and ventilation systems.” The benefits spurred by design defect torts – namely promoting development and providing compensation – are achieved through Congressionally-enacted legislation and directives to agencies. Scalia characterizes Sotomayor’s criticism that the FDA and NCVIA “cannot alone spur adequate innovation” as “beside the point.”

While the Bruesewitz plaintiff-parents contend that liability encourages responsibility and catalyzes development, Scalia’s counterargument is stronger: “Taxing vaccine manufacturers’ product to fund the compensation program, while leaving their liability for design defect virtually unaltered, would hardly coax manufacturers back into the market.” The majority’s decision to place a blanket ban on design defect
claims puts a full stop to an otherwise endless, destructive cycle where litigation fears decrease vaccination supply, discourage development, and increase the danger posed to the unvaccinated public.

**IV. Comment: A Healthier Future**

The majority’s opinion in Bruesewitz marks the start of a healthier future for vaccine manufacturers, the public at large, and our federal system. By establishing a national standard of preemption for design defect claims, the Bruesewitz decision promotes judicial efficiency in two ways: first, it enlarges the incentive for claimants to use the NCVIA-established Vaccine Court. The Vaccine Court is narrowly tailored in purpose, expert driven, and highly successful: “99.8% of successful vaccine court claimants have accepted their awards, foregoing any tort remedies against vaccine manufacturers.” The majority opinion reinforces the Vaccine Court’s legitimacy. Second, the Bruesewitz holding eliminates forum-shopping predicated on state court opinion. Without a national standard, litigants would flock to jurisdictions like Georgia, in hopes of having their design defect tort claims heard in state court. The resulting docket crowding would place unwanted pressure on the courts and vaccine manufacturers alike.

Breyer highlights the necessity of finding a solution: “Silence cannot tell us to follow those states where juries
decided the design-defect question.”76 If Congressional intent is indeed the “touchstone” of preemption, and legislative history illuminates that Congress’ underlying purpose is to protect children,77 then wide-reaching prophylactic steps, such as agency promotion of research and development, will prove more effective than post-symptomatic, plaintiff-by-plaintiff retrospective remedies like compensation.

Although Justice Kagan took no part in the decision,78 she would undoubtedly side with the majority. During her time as Solicitor General, she publicly disagreed with the Ferrari decision,79 noted vaccines’ benefits outweighed their costs,80 and cautioned that suits in state court directly threatened research and development.81 Justice Kagan’s allegiance to the plurality’s argument would only strengthen the Court’s 7-2 decision in favor of preemption.

V. Conclusion

Bruesewitz v. Wyeth enabled the Supreme Court to assess and address a conflict that, without resolution, would have resulted in a duly dangerous upsurge of litigation and “resurgence” in preventable diseases.82 By puncturing the multi-circuit split and injecting a dose of textual decisiveness, administrative assurance, and concern for the public good, Justice Scalia’s majority opinion wholly cures an invisible yet credible threat poised to paralyze our nation.
Justice Scalia champions the contributions of vaccination to American public health: “The elimination of communicable diseases through vaccination became ‘one of the greatest achievements’ of public health in the 20th century.” Bruesewitz v. Wyeth Inc., No. 09-152, slip op. at 1 (Feb. 22, 2011).


Bruesewitz, No. 09-152, slip op. at 19.

Id.

See id at 3 (“[V]accines are effective in preventing outbreaks of disease only if a large percentage of the population is vaccinated.”).

Id.

See id. slip op. at 3 (Breyer, J., concurring) (“The authoritative source for finding the legislature’s intent lies in the Committee Reports on the bill.”).

Id. at 4.

Id. at 3.

Bruesewitz, slip op. at 1 (majority opinion).

Id. at 2.

Id.
See id.

14 See id. From 1978 to 1981, only nine product-liability suits were filed against manufacturers of the DTP vaccine. By the end of the decade, this same category of suits ballooned to over 200 each year. Id.

15 Id. at 3.

16 Crippled by the growing threat of litigation, two of the three DTP vaccine manufacturers exited the domestic market, and the sole remaining manufacturer estimated its potential liability exceeded its annual sales by a factor of 200. Id. at 3.

17 Id. at 3.

18 Park, supra note 2, at 2.

19 See 42 U.S.C. § 300aa-22(b)(1) (2006) ("... 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").

20 Bruesewitz, slip op. at 6.

Id. (citing Bruesewitz v. Wyeth, Inc., 508 F. Supp. 2d 430 (E.D. PA 2007) (residual seizure and developmental delay allegedly caused by vaccine preservative); Sykes v. Glaxo-SmithKline, 484 F. Supp. 2d 289 (E.D. PA 2007) (neurological and neuro-development injuries allegedly caused by preservatives in ante-partum and direct vaccinations)).

Id. (citing Miltrano v. Lederle Labs., 769 N.Y.S.2d 839 (2003) (allergic reaction allegedly caused by vaccination)).

See id.

See id. ("Recently, the Georgia Supreme Court deviated from this line of authority, holding that defective design claims are not preempted by the Vaccine Act.")


Id.

Bates v. Dow Agrosciences LLC, 544 U.S. 431, 449 (2005). The Bates court noted "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."

Id.

Id.

Id. at 237-8 ("[W]e nevertheless affirm the judgment of the Court of Appeals because a full examination of both the text of
42 U.S.C. § 300aa-22(b)(1) and the congressional intent behind it shows that the Vaccine Act does not preempt all design defect claims,"

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

32 *Id.* at 237.

33 *Id.* at 238.

34 See *id.* at 238.

35 *Id.*; see also *Shirley & Gregory*, supra note 21 ("This presumption is heightened with health or safety issues, as these are traditionally fields governed by state law").

36 *Park*, supra note 2, at 3.

37 Wyeth itself did not manufacture the DTP vaccine; in 1994, Wyeth acquired Lederle Laboratories, the DTP vaccine’s manufacturer, and stopped producing the vaccine in 1998. *Bruesewitz*, slip op. at 6.

38 *Id.*

39 *Id.*

40 See *id.* ("...holding that the Pennsylvania law providing those causes of action was preempted by 42 U.S.C. §300aa(22)(b)(1)").

41 *Id.*

42 *Id.*
43 Shirley & Gregory, supra note 21 (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)).


45 Bruesewitz, slip op. at 6 ("Permitting the legislative history of subsequent funding legislation to alter the meaning of a statute would set a dangerous precedent."); see also id. at 17 ("Post-enactment legislative history (a contradiction in terms) is not a legitimate tool of statutory interpretation" because it is retrospective and bears no effect on how Congress votes).

46 Id. at 17.

47 Id.

48 Id. at 18.

49 Beck/Hermann, supra note 44.

50 Bruesewitz, slip op. at 1 (Breyer, J., concurring) (" . . . legislative history, statutory purpose, and the views of the deferral administrative agency, here supported by expert medical opinion,").

51 Id.

52 Id.

Beck/Hermann, supra note 44 ("A court or jury will undoubtedly find it difficult to rule in favor of the 'innocent' manufacturer if the equally 'innocent' child has to bear the risk of loss with no other possibility of recompense.").


Bruesewitz, slip op. at 7 (majority opinion).

Id. at 8 ("Products liability law establishes a classic and well known triumvirate of grounds for liability: defective manufacture, inadequate directions or warnings, and defective design.").

Id.

Id. at 15.

Bruesewitz, slip op. at 1 (Sotomayor, J., dissenting).

Id. at 15.

Bruesewitz, slip op. at 8 (majority opinion); see also id. at 14 ("The lack of guidance for design defects combined with the extensive guidance for the two grounds of liability specifically mentioned in the Act strongly suggests that design defects were not mentioned because they are not a basis for liability.").

See id. at 8.

Id. at 13.

Bruesewitz, slip op. at 2 (Breyer, J., concurring).
See id. at 4 ("Even a brief period when vaccination programs are disrupted can lead to children’s deaths.").

See Bruesewitz, slip op. at 13 (majority opinion) ("Striking the right balance between safety and efficacy is especially difficult with respect to vaccines, which affect public as well as individual health.").


See Bruesewitz, slip op. at 13 (majority opinion).

Id.

The Congressionally-enacted NCVIA compensation regime prescribes fixed no-fault compensation amounts for claimants who can meet certain prima facie criteria in proving their claim. See id. at 3.

See Bruesewitz, slip op. at 7 (Breyer, J., concurring) ("[HHS] is ‘likely to have a thorough understanding’ of the complicated and technical subject matter of immunization policy, and it is comparatively more ‘qualified to comprehend the likely impact of state requirements.’” (citing Geier v. Am. Honda Motor Co., Inc., 529 U.S. 861, 883 (2000))).

Bruesewitz, slip op. at 16 (majority opinion).
74 Id.


76 Bruesewitz, slip op. at 3 (Breyer, J., concurring).

77 See id.

78 See Bruesewitz, slip op. at 19 (majority opinion).

79 Park, supra note 2, at 4 (Justice Kagan, in her role as Solicitor General, “concluded that the act preempts all design claims.”).

80 See id. (“In her brief, [Kagan] notes that vaccines are a prime example of the kind of product that provides widespread benefits at the cost of a relatively small number of adverse reactions.”).

81 See id. (“Solicitor General Kagan noted litigation could derail research into promising vaccine development strategies that offer potentially significant advantages in safety and effective use.”).

82 Bruesewitz, slip op. at 5 (Breyer, J., concurring).