The National Childhood Vaccine Injury Act and Preemption: An Overview of *Bruesewitz v. Wyeth*

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December 20, 2010

Congressional Research Service
7-5700
www.crs.gov
R41538

CRS Report for Congress
Prepared for Members and Committees of Congress

c11173008

Summary

On October 12, 2010, the Supreme Court heard oral arguments for *Bruesewitz v. Wyeth*, a case involving the scope of the National Childhood Vaccine Injury Act. The Supreme Court faces consideration of whether 42 U.S.C. § 300aa-22(b)(1) of the act precludes all vaccine design defect claims even if the vaccine's side effects were avoidable, or whether the vaccine manufacturer has to show on a case-by-case basis that the side effects could not have been avoided by some alternatively designed vaccine. Both parties have fundamentally differing interpretations of the statute's plain meaning and of Congress's intent. This report provides an overview of the structure of the Vaccine Act and the relevant facts of the *Bruesewitz* case. It then examines the district court and court of appeals decisions before discussing the arguments made by the parties before the Supreme Court. Finally, the report looks at some of the potential consequences that might result from the Court's decision in favor of either the Bruesewitzes or Wyeth. This report will be updated pending the Supreme Court's decision.

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Introduction

On October 12, 2010, the Supreme Court heard oral arguments for *Bruesewitz v. Wyeth*,[1] a case involving the scope of the National Childhood Vaccine Injury Act. The issue before the Court is whether 42 U.S.C. § 300aa-22(b)(1) of the act precludes all vaccine design defect claims even if the vaccine's side effects were avoidable,[2] in other words whether the section preempts vaccine design defect claims categorically, or whether the vaccine manufacturer has to show on a case-by-case basis that the side effects could not have been avoided by some alternatively designed vaccine.[3]

This report provides an overview of the structure of the Vaccine Act and the relevant facts of the *Bruesewitz* case. It then examines the district court and court of appeals decisions before reviewing the arguments made by the parties before the Supreme Court. Finally, it discusses some of the potential consequences that might result from the Court's decision in favor of either the Bruesewitzes or Wyeth.

Background of *Bruesewitz v. Wyeth*

The National Childhood Vaccine Injury Act (Vaccine Act) was enacted in 1986[4] and established a national vaccine program to "achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reaction to vaccines."[5] Under the Vaccine Act, the National Vaccine Injury Compensation Program (NVCIP) was established to handle claims against drug manufacturers for vaccine-related injuries and deaths.[6] NCVIP has two parts. Part A creates a mandatory forum for the administration of claims by requiring individuals who seek compensation, including the injured party's legal representative, to file a petition in the United States Court of Federal Claims (Vaccine Court).[7] A petitioner is entitled to recover if the affected person (1) received a vaccine covered by the Vaccine Act; (2) suffered a "covered" injury;[8] and (3) it cannot be shown by a preponderance of the evidence that the injuries or death were not caused by the vaccine.[9] A petitioner who suffers a non-covered injury may still recover compensation by proving affirmatively that the vaccine caused the injury.[10] Part B permits a petitioner to decline the result of the Vaccine Court and pursue a civil suit in state or

[1] Bruesewitz v. Wyeth, 561 F.3d 233 (3d Cir. 2009), *cert. granted*, 559 U.S. __ (2010); 2010 U.S. LEXIS 2266 (U.S. March 8, 2010) (No. 09-152).

[2] Brief for Petitioner at i, Bruesewitz v. Wyeth, No. 09-152 (May 24, 2010).

[3] Brief for Respondent at i, Bruesewitz v. Wyeth, No. 09-152 (July 23, 2010).

[4] P.L. 99-660; 100 State 3743, 3756-84 (1986), *codified at* 42 U.S.C. § 300aa-1 *et seq.*

[5] 42 U.S.C. § 300aa-1.

[6] 42 U.S.C. §§ 300aa-10 *et seq.*

[7] *Id.* at § 300aa-12.

[8] The Vaccine Act created the "Vaccine Injury Table," which sets forth the "vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration" of vaccines for which individuals may seek compensation. *Id.* at § 300aa-14. For a complete list of covered vaccines and injuries, *see* Department of Health and Human Services, Human Resources and Services Administration, http://www.hrsa.gov/vaccinecompensation/table.htm.

[9] *Id.* at §§ 300aa-11, 300aa-13.

[10] *See* Grant v. Sec'y of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992).

federal district court only after a final judgment is issued by the Vaccine Court.[11] Any subsequent civil action is governed by state law, including the applicable statute of limitations, which is stayed pending the outcome of the suit filed in the Vaccine Court.[12] However, § 300aa-22 places limitations on subsequent civil actions, and it is this section that is at issue in *Bruesewitz v. Wyeth*.

42 U.S.C. § 300aa-22 (§ 22) provides:

(a) General Rule. Except as provided in subsections (b), (c), and (e) State law shall apply to a civil action brought for damages for vaccine-related injury or death.

(b) Unavoidable adverse side effects; warnings

(1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, *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*. (emphasis added)

(2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. §§ 301 et seq] and section 262 of this title (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless the plaintiff shows—

(A) that the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 300aa-23(d)(2) of this title, or

(B) by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).

(c) Direct Warnings. No vaccine manufacturer shall be liable for civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer.

(d) Construction.—[omitted]

(e) Preemption. No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part.

In this case, plaintiffs/petitioners are the parents of Hannah Bruesewitz. They filed a claim with the Vaccine Court in April 1995, seeking compensation on behalf of their daughter, who suffered from several seizures shortly after receiving the third of five recommended doses of the diphtheria-pertussis-tetanus (DPT) vaccine on April 1, 1992.[13] Hannah was subsequently diagnosed as having residual seizure disorder and developmental delay, for which she will likely

[11] 42 U.S.C. § 300aa-21. Upon issuance of a special master's decision, each party has 30 days to file a motion to have the United States Court of Federal Claims review the decision. If there is no such motion, the clerk of the United States Court of Federal Claims shall immediately enter a judgment in accordance with the special master's decision. The parties may further obtain review of the judgment in the United States Court of Appeals for the Federal Circuit. *Id*. at §§ 300aa-12(e)-(f). Once judgment has been entered by the United States Court of Federal Claims or by the Court of Appeals for the Federal Circuit, a petitioner may give notice to the court that it will file a civil action in a state or federal district court. *Id*. at § 300aa-21(a).

[12] *Id*. at §§ 300aa-22(a), 21(c), 16(c). For description of typical litigation life cycle of a vaccine-related suit, *see* Miles E. Coleman, An Overview of the National Childhood Vaccine Injury Act, 21 *S. Carolina Lawyer* 41 (May 2010).

[13] Pertussis is the disease also commonly known as whooping cough.

require medical care for the remainder of her life. The DPT vaccine that Hannah received was marketed by Wyeth (and its predecessors) under the trade name TRI-IMMUNOL and approved in 1948.[14] TRI-IMMUNOL contained whole, inactivated pertussis cells ("whole-cell") that effectively reduced pertussis infections and associated deaths, but it was linked to a variety of adverse events. In December 1991, the Food and Drug Administration (FDA) approved Wyeth's application for an alternative DPT vaccine, known as ACEL-IMUNE. This vaccine, which contains an "acellular pertussis component" rather than the "whole-cell," reportedly is less likely to cause adverse events.[15] The FDA initially approved Wyeth's ACEL-IMUNE for use in the fourth and fifth doses of the DPT vaccine, but did not approve the general acellular pertussis vaccine for use in the first three doses until July 1996, when it approved the license of another pharmaceutical company. Wyeth's ACEL-IMUNE vaccine did not receive approval for use in the first three doses until December 1996. Thus, for her third dose Hannah received the TRI-IMMUNOL vaccine because there were no acellular pertussis vaccines commercially available at the time. Wyeth, the defendant/respondent, voluntarily discontinued manufacturing TRI-IMMUNOL in 1998.

Although the plaintiffs filed their complaint with the Vaccine Court, alleging that Hannah suffered covered injuries, the Vaccine Court held a hearing in July 2002 and concluded in December 2002 that Hannah's injuries were not covered injuries and that the petitioners had not proved causation in fact.[16] On February 14, 2003, the plaintiffs did not accept the Vaccine Court's judgment to dismiss the claim with prejudice, and subsequently brought suit in the Philadelphia County Court of Common Pleas in October 2005. Wyeth removed the action on the basis of diversity jurisdiction to the United States District Court for the Eastern District of Pennsylvania.

United States District Court Claims and Decisions

In district court, the plaintiffs sued for damages to Hannah Bruesewitz, costs, punitive damages, and other legal equitable relief. They alleged four counts against Wyeth:

1. Count I alleged that Wyeth *negligently failed* to produce a safer vaccine despite knowledge of the existence and feasibility of such safer alternatives;
2. Count II alleged that Wyeth *negligently failed to warn* of the actual dangers associated with the particular batch of DPT vaccine administered to Hannah;
3. Count III asserted *strict liability for design defect*, in the existence or feasibility of safer alternative designs for the vaccine rendered the vaccine administered to Hannah defective and unreasonably dangerous; and
4. Count IV asserted *strict liability for manufacturing defect*, in that, in addition to the unreasonable danger due to the alleged design defect, the particular dose of

[14] The National Health Institute first issued a product license for TRI-IMMUNOL in 1948 to American Cyanamid Company (Cyanamid). Lederle Laboratories, an unincorporated division of Cyanamid, produced TRI-IMMUNOL. In 1994, American Home Products Corporation (AHPC) acquired Cyanamid, but later changed its name to Wyeth in March 2002.

[15] Brief for Petitioner at 17-19, Bruesewitz v. Wyeth, No. 09-152 (May 24, 2010); *but see* Brief for Respondent at 18-20, Bruesewitz v. Wyeth, No. 09-152 (July 23, 2010).

[16] Bruesewitz v. Sec'y of Dep't of HHS, No. 95-0266V, 2002 WL 31965744 at *1 (Fed. Cl. December 20, 2002). Approximately one month before the plaintiffs filed their petition with the Vaccine Court, new regulations that were effective on March 10, 1995, deleted residual seizure disorder as a Table Injury for the DPT vaccine. *Id.* at *17 n.1.

> vaccine administered to Hannah contained a manufacturing defect that made it "extra-hazardous."[17]

Wyeth made a motion for summary judgment[18] on grounds that (1) the Vaccine Act preempted tort claims for the allegedly defective design of a covered vaccine, (2) § 22(c) bars the petitioners' failure-to-warn claim, and (3) there are no genuine issues of fact for trial with respect to any claims not found to be preempted by the Vaccine Act. In sum, the district court granted Wyeth's motion for summary judgment, concluding that Counts I and III were preempted by the Vaccine Act and that plaintiffs failed to raise any genuine issue of material fact as to Counts II and IV.

Design Defect Claims (Counts I + III)

To determine whether the Vaccine Acts bars the plaintiffs from claiming a design defect under state tort law, the district court examined analogous cases, two from federal district courts and two from intermediate state appellate courts, that reached different conclusions. Using similar reasoning, three courts held that the Vaccine Act preempts design defect claims. In *Blackmon v. American Home Products Corp*,[19] the federal district court found that the main purpose of the Vaccine Act is to protect the national vaccine supply by protecting manufacturers from the "inconsistencies of the 50-state tort system," [20] while still providing vaccine-injured individuals with a remedy. The *Blackmon* court also concluded that Congress intended to incorporate the liability principles of the Restatement (Second) of Torts § 402A comment k[21] into the Vaccine Act, because "without a complete bar to design defect claims, § 22(b)(1) would be stripped of all meaning."[22] While the court in *Blackmon* acknowledged that comment k of the Restatement

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[17] Bruesewitz, 508 F. Supp. 2d 430, 435 (E.D. Pa. 2007).

[18] Summary judgment is a preverdict "judgment granted on a claim about which there is no genuine issue of material fact and upon which the movant is entitled to prevail as a matter of law." *Black's Law Dictionary* 1449 (7th ed. 1999).

[19] 328 F. Supp. 2d 659 (S.D. Tex. 2004). In *Blackmon*, plaintiffs asserted strict products liability and negligence against several vaccine companies for alleged injuries, claiming that the defendants' products were defectively designed and that safer alternatives existed at the time the drugs were administered. *Id.* at 663.

[20] Blackmon, 328 F. Supp. 2d at 665.

[21] Restatement (Second) of Torts § 402A cmt. k (1965) states:

> *Unavoidable unsafe products.* 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 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.

[22] Blackmon, 328 F. Supp. 2d at 665. "In the [*Blackmon*] court's view, allowing a case-by-case determination of unavoidability would undercut not only the protections the Vaccine Act provides vaccine manufacturers, but also, the broader 'comprehensive regulatory scheme, administered by the FDA, to control the design and distribution of (continued...)

applies only to strict liability, it concluded that § 22(b)(1) would preclude a design defect claim under all theories of liability because the section grants immunity in a "civil action for damages."[23]

A later case, *Sykes v. Glaxo-SmithKline*, which arose in the same federal district as *Bruesewitz*, adopted the reasoning of the *Blackmon* court when it granted the pharmaceutical company's motion for summary judgment and held that the Vaccine Act preempts all design defect claims.[24] The third court—a state appellate court—in New York also held that the Vaccine Act preempts all design defect claims. In *Milantrano v. Lederle Labs*, the state appellate court, noting that "[p]reemption is a question of Congressional intent," found that the committee report for the Vaccine Act made clear that Congress intended to preclude all design defect claims with respect to vaccines covered by the Vaccine Act.[25]

On the other hand, the *Bruesewitz* court noted that the Georgia Court of Appeals in *Ferrari v. American Home Products* rejected that the Vaccine Act preempted all design defect claims even though it agreed with *Sykes* and *Blackmon* that "the legislative history of the Vaccine Act clearly demonstrates congressional intent to completely preempt design defect claims."[26] The Georgia appellate court in *Ferrari* found that the Supreme Court's decision in *Bates v. Dow Agrosciences*[27] precluded it from examining legislative history because there was no longer a rebuttable presumption against preemption but rather "a duty to accept the reading (of the Vaccine Act) that disfavors pre-emption."[28] The district court in *Bruesewitz* rejected the *Ferrari* court holding, finding that the *Bates* ruling does not require a court to automatically accept a plausible interpretation of a statute which disfavors preemption and that the *Ferrari* holding had taken the *Bates* ruling out of context, giving it broader scope than appropriate.[29] Notably, since the district court's decision in *Bruesewitz*, the Georgia Supreme Court has upheld the Georgia Court of Appeals ruling, though it also disagreed with the lower court's application of the *Bates* decision.[30]

The federal district court found that the case did not "materially deviate" from the precedents examined, as all the plaintiffs had asserted that a vaccine was defectively designed. Using the *Sykes* decision as guidance (see note 24), the district court drew four conclusions in holding that the Vaccine Act categorically preempts all design defect claims. First, it held that vaccine

(...continued)

prescription drugs, including vaccines.'" Bruesewitz, 508 F. Supp. 2d at 441.

[23] Blackmon, 328 F. Supp. 2d at 666.

[24] Sykes v. Glaxo-SmithKline, 484 F. Supp. 2d 290 (E.D. Pa. 2007). In *Sykes*, the court based its ruling on four basic conclusions: (1) the purpose of the Vaccine Act to protect vaccine manufacturers from the unpredictability and expense of the tort system would be thwarted by allowing juries to decide design defect claims by evaluating whether a vaccine was unavoidably unsafe on a case-by-case basis; (2) through the Vaccine Act, Congress delegated to the Department of Health and Human Services, rather than the jury system, the role of assuring improvements in the quality, effectiveness, and safety of vaccines; (3) the Vaccine Act protects manufacturers from design defect claims in particular; and (4) comment k supports the understanding that the liability of vaccine manufacturers is limited to claims that the vaccine deviated from its FDA-approved design. Bruesewitz, 508 F. Supp. at 441 (*citing* Sykes, 484 F. Supp. 2d at 301-03).

[25] 801 N.Y.S.2d 506 (N.Y. App. Div. 2006).

[26] Bruesewitz, 508 F. Supp. 2d at 444.

[27] 544 U.S. 431 (2005).

[28] Ferrari v. Am. Home Prods. Corp., 650 S.E.2d 585, 589 (Ga. Ct. App. 2007).

[29] Bruesewitz, 508 F. Supp. 2d at 444.

[30] Ferrari v. Am. Home Prods. Corp.,668 S.E.2d 236 (Ga. 2008).

manufacturers would not be protected from lawsuits if it allowed for case-by-case inquiries. Second, the purpose of the Vaccine Act and its establishment of a no-fault remedies compensation program suggests that "Congress intended to provide an umbrella under which manufacturers would improve the safety of their products while remaining immune from design defect claims made possible by the successful innovation of safer alternative designs."[31] Third, the compensation scheme reflects a balance Congress struck "between the policy of widespread distribution of childhood vaccines and the need to compensate those injured affecting that policy." Lastly, although the district court stated that comment k "suggests ... that the question of whether a particular vaccine is unavoidably unsafe ... is a question of fact for a jury to determine," it found § 22(b) to be broader than comment k, so that the Vaccine Act preempts state law determinations of whether a vaccine is unavoidably unsafe.[32] It examined the compensation program in light of the FDA's role with vaccines, holding that "an FDA-approved vaccine design includes the side-effects of that vaccine, and is therefore, by statutory definition, the unavoidably unsafe product subject to comment k immunity."[33]

Failure-to-Warn Claim (Count II)

The *Bruesewitz* court then addressed the plaintiffs' claim that the manufacturer withheld information from doctors about particularly dangerous batches of vaccines. Although § 22(c) of the Vaccine Act "clearly bars failure-to-warn claims based on a failure to directly warn the injured party's legal representatives," the plaintiffs argued that this section does not preclude their particular claim since the court in *Blackmon* found that allegations of failure-to-warn "doctors and medical intermediaries" are not subject to the prohibition of § 22(c).[34] Therefore, assuming that the plaintiffs' failure-to-warn claim is not precluded, the Vaccine Act grants the manufacturer the presumption of a proper warning if the manufacturer shows that it complied with the proper FDA requirements. Once the manufacturer meets the burden, the plaintiffs then must present evidence that the manufacturer "engaged in fraud or wrongful withholding of information" from the Secretary of Health and Human Services (HHS) either during or after the approval process, or "by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with [the laws and regulations regarding drug approval proceedings]."[35]

In the Bruesewitzes' case, the federal district court concluded that Wyeth was entitled to the presumption of proper warning because the evidence presented demonstrated licensing and label approval from the FDA.[36] It stated, however, that the plaintiffs failed to provide any clear and convincing evidence that the "vaccine dose in question was materially different from any other vaccine dose for which the warning had been approved."[37] Therefore, the plaintiffs' failure-to-warn claim was also dismissed as they failed to produce evidence raising issues of material fact.

[31] Bruesewitz, 508 F. Supp. 2d at 445.

[32] *Id.* at 445-46.

[33] *Id.* at 446.

[34] *Id.* at 447 (*citing* Blackmon, 328 F. Supp. 2d at 666).

[35] *Id.* at 447 (*citing* 42 U.S.C. §§ 300aa-22(b)(2)(A) and (B)).

[36] Because the plaintiffs in *Bruesewitz* did not allege fraud or wrongful withholding of information from the Secretary of HHS, they were required to show by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding compliance with the law.

[37] In support of their failure-to-warn claim, the plaintiffs identified which lot produced the dose of TRI-IMMUNOL (continued...)

Manufacturing Defect Claim (Count IV)

The fourth complaint the plaintiffs asserted was a strict liability claim for a manufacturing defect, specifically that the particular dose administered to Hannah contained a manufacturing defect that made it "extra-hazardous."[38] Wyeth conceded that the Vaccine Act did not bar such a claim; therefore, under Pennsylvania law, a plaintiff alleging a product manufacturing defect based on a theory of strict liability must show (1) the product was defective, (2) the defect was the proximate cause of the plaintiffs' injuries, and (3) the defect causing the injury existed when the product left the seller's hand.[39] Although the plaintiffs presented some evidence, the court concluded that none of the evidence offered demonstrated that the product was defective[40] or that "the specific lot caused *any* of the adverse reactions, let alone the specific reaction suffered by Hannah."[41] Due to this lack of evidence, the court dismissed the manufacturing defect claim in favor of the defendant.

United States Court of Appeals Claims and Decisions

The Bruesewitzes appealed the decision of the lower court to the United States Court of Appeals for the Third Circuit. The court of appeals affirmed the judgment of the district court to grant the motion for summary judgment in favor of Wyeth, and further analyzed the conclusions reached by the district court. Based on the district court's decision, the plaintiffs' appeal presented the court of appeals with three questions:

> (1) whether § 22(b)(1) acts as a complete bar to design defect claims;
>
> (2) have the plaintiffs in this case met their burden under § 22(b)(2) of the Vaccine Act to show that defendants failed to provide an adequate warning of the alleged dangers of the vaccine; and
>
> (3) have the plaintiffs provided sufficient evidence of a manufacturing defect to survive the defendant's motion for summary judgment.

(...continued)

administered to Hannah as well the Vaccine Adverse Event Reporting System (VAERS) report confirming deaths and other adverse events associated with the lot. Lots associated with deaths and adverse reactions are sometimes referred to as "hot lots." However, according to the evidence, a "hot lot" is not defined by the total number of adverse incidents, but rather by the rate at which those incidents occurred. Plaintiffs have produced no evidence from which a trier of fact could infer that the dose in question originated in a lot of vaccine associated with a disproportionate number of adverse health effects. Bruesewitz, 508 F. Supp. 2d at 448.

[38] *Id.* at 435 (*citing* Pl. Am. Comp. ¶ 37). The plaintiffs assert that the dose administered to Hannah had "an inappropriate balance between neuro-toxins and endo-toxins in the pertussis vaccine." *Id.*

[39] *Id.* at 449.

[40] Wyeth disputed the plaintiffs' allegation of an inappropriate balance between neuro-toxins and endo-toxins by submitting the Declaration of Dr. Mary B. Ritchy, Ph.D, who stated that "The pertussis bacterium does not contain a recognized 'neuro-toxin' component." *Id.*

[41] The court believed that the plaintiffs' own evidence negated the possibility that one could draw an inference from a VAERS report that the vaccine caused the reaction. *Id.* at 451.

Design Defect Claims

Although the district court had concluded that the plaintiffs' design defect claims (Counts I and III) were preempted by the Vaccine Act, the court of appeals stated that the lower court's analysis warranted further examination because "the District Court did not explicitly lay out a framework for coming to [its four] conclusions [in support of finding preemption], nor did it state whether they were predicated on express, implied or field preemption grounds."[42] Because of this "ambiguity" the plaintiffs, on appeal, argued that the district court's decision was "based on some kind of implied or field preemption," and therefore in violation of the principle that "a district court may not grant judgment *sua sponte* on grounds not requested by the moving party," because the defendants had only raised express preemption in their motion for summary judgment. Disagreeing with the plaintiffs' characterization of the district court's decision, the court of appeals found that it must answer four questions related to the preemption of the design defect claims: (1) whether § 22(b) constitutes an express preemption provision; (2) whether the court can use traditional tools of statutory interpretation, including legislative history, when construing such a provision; (3) whether this provision preempts plaintiffs' design defect claims; and (4) whether the district court's decision is consistent with this analysis.

First, the court of appeals found the language of §§ 22(a) and (b) to mirror different provisions in federal law that the Supreme Court had characterized as express preemption provisions.[43] Therefore, based on prior jurisprudence, the court concluded that the language of these sections contains express preemption clauses as it "conveys a clear intent to override state law civil action claims in particular, defined circumstances."[44] Second, the court found that it could not construe the scope of preemption created by § 22(b)—"*if the injury or death resulted from side effects that were unavoidable*"—from the statutory text alone. Rather, it resolved to look at the language, structures, purpose, and legislative history of the Vaccine Act to ascertain the scope of preemption.

Third, to determine whether the provision preempts plaintiffs' design defect claims (i.e., the scope of preemption), the court of appeals initially found that the structure of the provision was open to two possible interpretations because the scope of preemption "hinge[d] on the word

[42] Bruesewitz v. Wyeth, 561 F. 3d 233, 240-41 (3d Cir. 2009). Generally there are three types of preemption: express, implied, or field preemption. Express preemption exists where a federal law contains explicit language of Congress's intention to preempt state law. In such cases, courts are often called upon to "identify the domain expressly pre-empted by that language." *Medtronic, Inc v. Lohr*, 518 U.S. 470 484 (1996) (internal quotation marks and citations omitted). Implied preemption arises when state law conflicts with a federal statute when it is "impossible for a private party to comply with both state and federal requirements," *English v. General Electric, Co.*, 496 U.S. 72, 78-9 (1990), or when state law "stands as an obstacle to the accomplishment and execution of the full purpose and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). Field preemption arises when state law occupies a "field reserved for federal regulation." *United States v. Locke*, 529 U.S. 89, 111 (2000).

[43] The court found the language of § 22(b)—"[n]o vaccine manufacturer shall ..."—to be similar to the Federal Cigarette Labeling and Advertising Act's "No statement relating to smoking and health other than the statement required by section 1333 of this title, shall be required on any cigarette package." 15 U.S.C. § 1334. The court found § 22(a)—"[e]xcept as provided ... State law shall apply ..."—to be similar to a federal railroad safety provision which provided "A state may adopt or continue in force any law ... until such time as the Secretary has adopted a rule ... covering the subject matter of such State requirement. A state may adopt or continue in force an additional or more stringent law ... when not incompatible with any Federal law ... " 45 U.S.C. § 434 (repealed 1994). The Supreme Court in *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001) and *CSX Transportation, Inc., v. Easterwood*, 507 U.S. 658 (1993), respectively, had construed each of the aforementioned provisions as express preemption provisions.

[44] Bruesewitz, 561 F.3d at 243.

'unavoidable.'"[45] According to the court of appeals' reading, the first construction would result in the preemption of some design defect claims, because § 22(a) "displaces state law only as defined in subsections (b), (c), and (e)" and that in reading these provisions together "it becomes clear that Congress intended that subsections (b) and (c) should be an outright bar to some claims."[46] The second reading considered the Georgia Supreme Court's decision in *Ferrari* that the language of § 22(b) is conditional, which "implies that some vaccine-related injuries and deaths may be avoided," and that if Congress had intended to preempt all design defect claims, it could have done so by omitting the "unavoidable" clause.[47] The court of appeals disagreed with the *Ferrari* court's construction, finding it contrary to the structure of the act. Moreover, the court pointed out that when Congress enacted the Vaccine Act in 1986, several courts had already barred strict liability design defect claims against prescription drug manufacturers under state law. Thus, the court of appeals believed that the *Ferrari* court's construction of § 22 "could create an awkward dichotomy in the case law of [such] states—their courts would be required to engage in case-by-case analysis of all strict liability and design defect claims brought under the Vaccine Act, while barring strict liability design defect claims against prescription drug manufacturers."[48]

Although it found congressional intent to support the first construction of the provision, the court turned to the legislative histories relied upon by the plaintiffs and defendant to determine whether the Vaccine Act preempts only strict liability design defect claims or those also based in negligence. The defendant relied upon the committee report (Commerce Report) from the House Committee on Energy and Commerce (Energy and Commerce Committee), which had jurisdiction over the Vaccine Act.[49] The court found that the Commerce Report supported the conclusion that the Vaccine Act preempts all design defect claims, including those based in negligence. In the court's analysis, most importantly, the Commerce Report made clear that "the Vaccine act reflected the *principle* of Restatement (Second) of Torts § 402A, comment k" and "stated in precise and certain terms that its reference to comment k and the language of 22(b) results in immunity for liability for all design defects, whether liability rests on theories of strict liability or negligence" (emphasis in the original).[50] According to the court, any reading of the provision to permit state courts to make case-by-case determinations would undermine "the objectives extolled by the Commerce Report" and exacerbate the "very problems which led to instability in the vaccine market and which caused Congress to intervene."[51] The plaintiffs, on the other hand, relied upon the committee report (Budget Report) from the House Committee on the Budget that accompanied the subsequent 1987 legislation to fund the compensation program. The Budget Report most notably stated: "The Committee stresses that there should be no misunderstanding that the Act undertook to decide as a matter of law whether vaccines were unavoidably unsafe or not. This question is left to the courts to determine in accordance with

[45] *Id.* at 245. On the one hand, plaintiffs argued that it "expressly precludes only those state tort claims involving vaccines with side effects first shown to be 'unavoidable,'" and that "avoidability must first be determined on a case-by-case basis." On the other hand, the defendant argued that the language "preempts all claims arising from allegations of design defect." *Id.*

[46] *Id.*

[47] *Id.* (*citing* Am. Home Prods. Corp. v. Ferrari, 668 S.E.2d 236 (Ga. 2008)).

[48] *Id.* at 246.

[49] H.Rept. 99-908 (1986).

[50] Bruesewitz, 561 F. 3d at 247-8 (*citing* H.Rept. 99-908 at 25-26) ("If the [injured individuals] 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." *Id.* at 26).

[51] Bruesewitz, 561 F.3d. at 249.

applicable law."[52] The court of appeals found the Budget Report problematic in that it repeatedly used the term "the Committee" but was not clear if it referred to the Energy and Commerce Committee from 1986, which had jurisdiction over the Vaccine Act, or the Budget Committee, which played no role in the drafting or passage of the act.[53] Furthermore, it found "the views of a subsequent Congress [to] form a hazardous basis for inferring the intent of an earlier one"[54] and that without more, it had no grounds to conclude whether the Budget Report was an accurate reflection of what had transpired in committee or of Congress's motivations underlying the enactment of the Vaccine Act in 1986.[55]

The court found that the Commerce Report and other legislative history indicated that Congress intended to preempt the specific claims asserted by the plaintiffs. Both the Commerce Report and a background report issued by the staff of the Energy and Commerce Committee contained numerous references to the DPT vaccine, its development, the side effects, hurdles in clinical testing, and the high number of lawsuits against the only two producers of the vaccine.[56] According to the court, these two reports taken together strongly indicate that "Congress weighed the various concerns related to the pertussis vaccine and concluded that DPT manufacturers should be shielded from liability for injuries arising from the whole-cell pertussis vaccine."[57]

Lastly, with respect to design defect claims, the court of appeals found that the district court's decision was consistent with an express preemption analysis and rejected the plaintiffs' claim that the district court's decision was based on implied or field preemption grounds or that it violated well-settled principles of summary judgment.[58]

Failure-to-Warn Claim and Manufacturing Defect Claim

In reviewing the district court's decision on the plaintiffs' failure-to-warn claim, the court of appeals needed only to examine whether the plaintiffs had presented clear and convincing evidence that Wyeth had not exercised due care. The statute shifted the burden to plaintiffs to overcome the presumption that the manufacturer complied with warning requirements if they could show that "(2) the manufacturer 'failed to exercise due care.'" The plaintiffs made two arguments against the district court's decision on its failure-to-warn claim, one of which the court of appeals immediately dismissed as it was based on Wyeth first showing that a safer design was available before the presumption could apply. The second argument was whether the evidence relied upon by the plaintiffs to show that the dose Hannah received came from a "hot lot" raised an issue of fact. Of note, the plaintiffs relied upon the affidavit of Dr. Marks, who asserted that batches of vaccines associated with injuries and death are sometimes called a "hot lot." He, in turn, based his opinion on an HHS memorandum discussing the investigation of "potential hot lots" and that investigators needed first to identify the number of doses administered in order to determine whether a particular vaccine lot qualifies as a "hot lot." (See also note 37). However, the plaintiffs supplied no further evidence, and accordingly, the court of appeals agreed with the

[52] *Id.* (*citing* H.Rept. 100-391, pt. l at 691 (1987)).

[53] *Id.* at 250.

[54] *Id.*(quotation marks omitted) (*citing* United States v. Price, 361 U.S. 304, 313 (1960)).

[55] *Id.*

[56] *Id.* at 251 (*citing* Staff of H. Comm. on Energy & Commerce, 99th Cong., *Childhood Immunizations*, at III (1986)).

[57] *Id.*

[58] *Id.* at 251.

district court that the plaintiffs did not meet their burden because the evidence they presented was merely a scintilla and not "sufficient for a reasonably jury to find in their favor."[59]

With respect to the plaintiffs' manufacturing defect claim, the court of appeals did not review it in much detail because the plaintiffs had "predicated their argument for manufacturing defect on the fact that Hannah's vaccine came from a 'hot lot.'"[60] The court of appeals, having determined that the plaintiffs did not produce enough evidence from which a jury could conclude that Hannah was administered a vaccine from a "hot lot," agreed with the district court's judgment to dismiss the manufacturing defect claim.

Arguments to the Supreme Court and Potential Consequences

On October 12, 2010, the Supreme Court heard the oral arguments of the petitioners, the Bruesewitzes, and respondent, Wyeth. The only issue the Court agreed to review is whether § 22(b)(1) precludes all design defect claims or whether a vaccine manufacturer must show on a case-by-case basis that the side effects at issue could not have been avoided by some differently designed vaccine.

Oral Argument

At oral argument, both counsels for the petitioners and defendant faced difficult questions from the Justices.[61] The phrase in question was "... 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."[62] Questioning primarily revolved around the possible interpretations of the term "unavoidable" and the potential consequences for vaccine manufacturers and victims from such interpretations.

Counsel for the petitioners advanced their argument that while Congress provided several defenses for manufacturers, each is to apply on a case-by-case basis and "[t]here are no absolute provisions that preclude a State law claim."[63] Because petitioners' counsel argued that a manufacturer could be held liable for side effects that were not "unavoidable," which he defined as effects that could be prevented by using a different vaccine design, given current scientific knowledge, Justices Scalia and Alito queried whether his interpretation of "unavoidable" would then render the latter half of the phrase "even though...." as surplus. Counsel countered that it was not surplus because it was consistent with the intent behind comment k of the Restatements in that if "there is no way in science we can design a safer product, there *will be* a defense to a claim of strict liability unless or provided that the product is properly manufactured and warned

[59] *Id.* at 253-54.

[60] *Id.* at 255.

[61] Justice Elena Kagan recused herself from this hearing. Robert Barnes, "Justices Split on Childhood-Vaccine Case," Wash. Post, October 13, 2010 at A2.

[62] 42 U.S.C. § 300aa-22(b).

[63] Transcript of Oral Argument at 4, Bruesewitz v. Wyeth, No. 09-152 (argued October 12, 2010).

against."[64] In addition, counsel argued that the respondent's interpretation would render some language surplus because "[t]hey took the concept of unavoidability completely out of the statute."[65] After being pressed by Justice Scalia that his interpretation would be problematic if it meant assessing "unavoidable" in terms of other vaccines which could prompt comparisons with less effective vaccines, petitioners' counsel conceded that alternative designs must be at least as effective as the vaccine in question for liability to attach.[66] Justice Breyer asked whether a holding in the petitioners' favor would undermine Congress's intent by "driving certain vaccines from the market" because of the threat of liability.[67] Counsel emphasized that the "vast majority" of people accept the Vaccine Court's judgment and that many do not pursue a state law claim because "it's difficult to win these kinds of cases in State courts."[68] However, Chief Justice Roberts pointed out that the threat of liability also includes the size of the judgments since "[i]t doesn't take too many $60 million verdicts to make you come out on the other side of your calculus."[69] Toward the end of his argument, petitioners' counsel emphasized, possibly in an effort to assure the Justices, that it would be a rare instance when there is a state lawsuit because the compensation fund takes care of a vast majority of the claims and that "for many vaccines there is no safer alternative," and thus no design defect claim.[70]

Counsel for the respondent reminded the Court that the Vaccine Act was passed "against the backdrop of a wave of tort litigation that threatened to drive manufacturers out," to which Justice Sotomayor pressed counsel to explain why Congress did not just make the Vaccine Court the exclusive remedy.[71] Similarly, Justices Kennedy and Ginsburg asked why Congress did not express its concern about preempting design defect claims using clearer, more direct language.[72] Justices Sotomayor and Kennedy asked what would motivate a manufacturer to act quickly to voluntarily remove a defectively designed drug that still had FDA approval. Counsel responded that in addition to § 27 requiring the Secretary of HHS to promote safer vaccines and reduce the number of side effects, there are "grave consequences if a manufacturer withholds knowledge of adverse effects from the FDA," because it will lose its presumption under § 22(b)(2) that its warnings were correct.[73] However, Justices Sotomayor and Kennedy both countered that the warning need not say that there is a better product or safer alternative.[74] Respondent's counsel indicated that allowing design defect claims to be litigated on a case-by-case basis would be costly because it would require "shadowboxing an infinite number of theories about how there could have been a safer vaccine." Justice Ginsburg contested, seemingly in light of petitioners' argument, that the Vaccine Court allows all but a small number of claims to reach state court.[75]

[64] *Id.* at 8 (emphasis added).
[65] *Id.* at 9.
[66] *Id.* at 11-12.
[67] *Id.* at 16.
[68] *Id.* at 18.
[69] *Id.* at 20.
[70] *Id.* at 22-25.
[71] *Id.* at 25-26.
[72] *Id.* at 28.
[73] *Id.* at 31-32.
[74] *Id.* at 33.
[75] *Id.* at 41-43.

However, respondent's counsel emphasized that the 5,000 claimants who allege a link between autism and vaccine may ultimately pursue state-law remedies.[76]

The Court also heard arguments from the Assistant to the Solicitor General on behalf of the United States, who submitted a brief in support of the respondent. He turned the Court's attention to the role of the Centers for Disease Control and Prevention (CDC) because the no-fault remedy and preemption provisions of the Vaccine Act apply only to categories of vaccines recommended by the CDC for "routine administration to children."[77] The government informed the Court that, in making its recommendations, the CDC looks at whether it "is the most efficacious drug with the least adverse effects," and publishes its findings in its official journal.[78] When pressed by Chief Justice Roberts as to whether the CDC's report makes direct comparisons between types of vaccines, the government seemed to answer that the CDC does not make direct comparisons but rather, by staying engaged in the direction of the research, makes its determinations in a "comparative way" when it recommends one vaccine over another. More importantly, however, the government emphasized that "it would be extraordinary ... to imagine that Congress set up a system in which juries would effectively be second-guessing decisions."[79] Finally, when asked by Justice Ginsburg if, in the petitioners' case, there is any actionable claim for "not disclosing that there were a number of adverse ... reactions to [the] particular lot," the government, consistent with the respondent's argument, said that the petitioners could bring either a labeling claim or a manufacturing defect claim, which the lower courts had dismissed on the facts.[80]

Potential Consequences

Based on the Justices' questioning during oral argument, it is unclear how the Court will decide this case. According to reports, the Court seemed to "struggle to divine the balance Congress had meant to strike" by enacting the law to compensate people injured by vaccines while barring some, but not all, lawsuits against vaccine manufacturers.[81] Notably, only eight Justices are participating and a 4-4 decision would automatically affirm the court of appeal's decision in favor of the respondent, Wyeth.

As has been emphasized by the respondent, other supporters such as American Academy of Pediatrics, American Medical Association, and Infectious Diseases Society of America, as well as other scientists, have argued that a decision in favor of the petitioners will leave vaccine manufacturers vulnerable to numerous lawsuits, "could drive vaccine manufacturers from the market and halt future production and development of childhood vaccines in this country."[82] Furthermore, as the respondent highlighted, there are about 5,000 claimants in Vaccine Court who claim that there is a relationship between the mumps, measles, and rubella vaccine and autism.[83]

[76] *Id.* at 42.

[77] *Id.* at 44-45.

[78] *Id.* at 49.

[79] *Id.* at 52.

[80] *Id.* at 54.

[81] Adam Liptak, "Vaccine Case Before Justices Turn on the Language of the Law," N.Y. Times, October 12, 2010.

[82] Jennifer Couzin-Frankel, "Closely Watched Vaccine Injury Claim Reaches Supreme Court," *Science*Insider October 12, 2010, http://news.sciencemag.org/scienceinsider/2010/10/closely-watched-vaccine-injury.html.

[83] National Vaccine Injury Compensation Program- About the Omnibus Autism Proceeding, http://www.hrsa.gov/vaccinecompensation/omnibusproceeding.htm.

These claims could be the next batch of claims to enter, and possibly overwhelm, the state courts if the Court finds in favor of the petitioner.

Those on the opposing side, such as the National Vaccine Information Center (NVIC), argue that those same 5,000 claimants would have no recourse if the Court decides in favor of the respondent. NVIC argues that because the "overwhelming majority of cases in vaccine court today are 'off-table,'" (i.e., not injuries recognized by the Vaccine Injury Table; see note 8) the parties in those situations are "unable to take advantage of presumptive causation" and ultimately would have to participate in costly, time-consuming causation hearings, which are highly adversarial and generally end without compensation.[84] Likewise, the Vaccine Injured Petitioners Bar Association (VIPBA), in conjunction with other groups, submitted a brief in support of the petitioners and argued that the "practical effect of the Third Circuit's opinion ... is to deny justice to petitioners in the Vaccine Program whose cases cannot be fully litigated given the restrictions built into the Program."[85] Knowing that the tool of discovery in litigation creates incentives for greater vaccine safety, VIPBA emphasized that this "inspired Congress to keep the tort option available as a safety incentive."[86] Even if vaccine manufacturers were to argue that a decision of the Court affirming the Third Circuit opinion would only preclude design defect claims based on theories of both strict liability and negligence, leaving petitioners with the ability to pursue failure-to-warn and manufacturing defect claims, VIPBA noted that "in practice, manufacturers rely on precedents that all but subsume manufacturing defect claims and failure to warn claims into design defect claims."[87] Such parties, therefore, argue that a decision in favor of the manufacturer would have detrimental effects on one's ability to obtain a remedy, or even bring a suit, for "off-table" injury-related vaccine claims.

Though not mentioned during oral arguments, the Court could choose to read the design defect provision narrowly so that it would only preclude strict liability claims like comment k in § 402A of the Restatement. This, however, would depend on how the Court treats the legislative history relied upon by the parties. While the respondents relied upon the Commerce Report from 1986, the petitioners referred to the Budget Report from 1987 to explain the structure and intent of Congress, even though the Budget Report did not accompany the original language of the Vaccine Act. Which document the Supreme Court finds indicative of the legislative history may or may not have ramifications on how it recognizes the persuasiveness of such documents in future cases. Lastly, it will be interesting to see if the Supreme Court considers the Georgia Supreme Court's *Ferrari* decision, which held that § 22(b) requires a case-by-case determination, in deciding this case even though both the U.S. district court and U.S. court of appeals dismissed the Georgia court's reasoning in *Ferrari*.

[84] Brief of *Amici Curiae* National Vaccine Information Center, Its Cofounders and 24 Other Organizations In Support of Petitioners at 14, Bruesewitz v. Wyeth, No. 09-152 (May 24, 2010).

[85] Brief of Vaccine Injured Petitioners Bar Association, The George Washington University Law School Vaccine Injury Clinic, and Zenoria Phillips Deloatch of Moshella F. Roberts, as *Amici Curiae* in Support of Petitioners at 24-25, Bruesewitz v. Wyeth, No. 09-152 (May 24, 2010). They noted that in order for the Vaccine Act to provide "swift and simple justice," Congress put in "[r]estrictions on discovery, evidence, and motion practices ... to speed up the process," but that given these limits, the "Vaccine Program cannot provide satisfactory relief for every family of a vaccine-injured child." *Id.* at 25.

[86] *Id.* at 21.

[87] *Id.* at 24-25 n.8.

Congressional Legislation

Although the Supreme Court in *Bruesewitz* faces a decision of whether the language of the Vaccine Act preempts design defect claims, the measures introduced during the 111th Congress that would amend the act would not appear to directly affect the case pending before the Court. These bills are (1) H.R. 2459, the National Vaccine Injury Compensation Program Improvement Act of 2009, by Representative Dan Burton, and (2) H.R. 4096, the National Vaccine Injury Compensation Program Modernization Act of 2009, by Representative Tom Perriello. Both bills would amend the statute of limitations for filing a petition with the Vaccine Court. Specifically, these bills would extend the period for filing a petition with the Vaccine Court to within two years after the date of the bill's enactment if an injury or death occurs as a result "of a vaccine set forth in the Vaccine Injury Table that is administered after September 30, 1988, and before the date of the [bill's] enactment."[88] The bills would also allow petitions to be filed notwithstanding a previous dismissal for an untimely filing. H.R. 2459 would also address the basis for calculating projected lost earnings, the increase of award in the case of a vaccine-related death, allowing compensation for family counseling expenses as well as interim attorney fees. In the past, Congress has introduced legislation to overturn a decision by the Supreme Court. One prominent decision was *Riegel v. Medtronic*, where the Court held that the Medical Device Amendments of 1976 (MDA) expressly preempted state tort law claims.[89] In the aftermath, legislation was introduced, though not enacted, that would have amended the MDA to provide "[n]othing in this section shall be construed to modify or otherwise affect any action for damages or the liability of any person under the law of the State."[90] Thus, depending upon the Supreme Court's decision in *Bruesewitz*, Congress may choose to revisit the specific language at issue to clarify if the Vaccine Act precludes design defect claims.

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[88] 111th Congress, H.R. 2459, Section 7; H.R. 4096, Section 2 (2009).

[89] 128 S. Ct. 999 (2008). For more information on this case, see CRS Report R40534, *Riegel v. Medtronic, Inc.: Federal Preemption of State Tort Law Regarding Medical Devices with FDA Premarket Approval*, by Vanessa K. Burrows.

[90] 111th Congress, H.R. 1346, Medical Devices Safety Act; S. 540, Medical Devices Safety Act (2009).