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

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Summary

While recent scientific publications have declared that there appears to be no link between immunizations and autism or other serious medical problems, a recent *Journal of Pediatrics* survey of parents with children between the ages of six months and six years old reveals that about 13% of parents used a vaccination plan that varied from the Centers for Disease Control and Prevention-recommended schedule, because of concerns that receiving multiple vaccinations in a short span of time is less safe than delaying certain vaccines. Whether parents follow the government-recommended schedule or an alternative schedule, should their child suffer harm after receiving a vaccination, they must first seek relief through the National Vaccine Injury Compensation Program.

On February 22, 2011, the Supreme Court issued its decision in *Bruesewitz v. Wyeth*, a case involving the scope of the National Childhood Vaccine Injury Act. The Supreme Court considered whether 42 U.S.C. Section 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 had fundamentally differing interpretations of the statute's text and of Congress's intent behind the National Childhood Vaccine Injury Act. This report provides an overview of the structure of the Vaccine Act and the relevant facts of the *Bruesewitz* case. It then examines the opinions of the lower court and the Supreme Court decision. Lastly, this report analyzes the impact of the decision both in terms of its potential effect on preemption jurisprudence and ongoing vaccine litigation. It also discusses past congressional legislation related to the Vaccine Injury Act.

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Introduction

In October 2010, the Supreme Court heard oral arguments for *Bruesewitz v. Wyeth*,[1] a case which involves the scope of the National Childhood Vaccine Injury Act. The issue before the Court was whether 42 U.S.C. Section 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] On February 22, 2011, the Supreme Court issued its decision in *Bruesewitz*, affirming, by a vote of 6-2,[4] the decision of the U.S. Court of Appeals for the Third Circuit that the federal law preempts all design-defect claims against vaccine manufacturers brought by plaintiffs seeking compensation for injury or death caused by the vaccine's side effects.[5]

This report provides an overview of the structure of the Vaccine Act and the relevant facts of the *Bruesewitz* case. It then examines the lower court decisions before reviewing the Supreme Court decision. Finally, it discusses the decision's potential effect on preemption jurisprudence as well as on the existing Vaccine Act litigation.

Background of *Bruesewitz v. Wyeth*

The National Childhood Vaccine Injury Act (Vaccine Act) was enacted in 1986[6] and established a national vaccine program to "achieve optimal prevention of human infectious diseases through immunization and ... against adverse reaction to vaccines."[7] Under the Vaccine Act, the National Vaccine Injury Compensation Program (Compensation Program) was established to handle claims against drug manufacturers for vaccine-related injuries and deaths.[8] The Compensation Program 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).[9] A petitioner is entitled to recover if the affected person (1) received a vaccine covered by the Vaccine Act; (2) suffered a "covered" injury;[10] and (3) it cannot be shown by a preponderance of the evidence that the

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

[5] Bruesewitz v. Wyeth, 562 U.S. ___ ; 131 S. Ct. 1068 (2011).

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

[7] 42 U.S.C. §300aa-1.

[8] 42 U.S.C. §§300aa-10 *et seq*.

[9] *Id*. at §300aa-12.

[10] 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.

injuries or death were not caused by the vaccine.[11] A petitioner who suffers an off-Table, or non-covered, injury may still recover compensation by proving affirmatively that the vaccine caused the injury.[12] Part B permits a petitioner to decline the result of the Vaccine Court and pursue a civil suit in state or federal district court only after a final judgment is issued by the Vaccine Court.[13] 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.[14] However, Section 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. Section 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.

[11] *Id*. at §§300aa-11, 300aa-13.

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

[13] 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).

[14] *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).

In this case, the plaintiffs/petitioners were 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.[15] Hannah was subsequently diagnosed as having residual seizure disorder and developmental delay, for which she will likely 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.[16] 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 FDA approved Wyeth's application for an alternative DPT vaccine, known as ACEL-IMUNE. ACEL-IMUNE does not contain the "whole-cell" component, and is reportedly less likely to cause adverse events.[17] The FDA initially approved Wyeth's ACEL-IMUNE for use in the fourth and fifth doses of the DPT vaccine, but did not approve its use in the first three doses of the DPT vaccine until December 1996.[18] Thus, for her third dose Hannah received the TRI-IMMUNOL vaccine because there were no non-whole-cell 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 off-Table injuries and that the petitioners had not proved causation in fact.[19] 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.[20] 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 and Court of Appeals Decisions

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

- Count I alleged that Wyeth *negligently failed to produce* a safer vaccine despite knowledge of the existence and feasibility of such safer alternatives;
- Count II alleged that Wyeth *negligently failed to warn* of the actual dangers associated with the particular batch of DPT vaccine administered to Hannah;

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

[16] 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.

[17] 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).

[18] The FDA first approved the general acellular pertussis vaccine for use in the first three doses in July 1996 when it approved the license of another pharmaceutical company.

[19] 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.

[20] 42 U.S.C. §§300aa-21(a), (c).

- 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
- 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 vaccine administered to Hannah contained a manufacturing defect that made it "extra-hazardous."[21]

The district court granted Wyeth's motion for summary judgment,[22] concluding that Counts I and III (design defect claims) were preempted by the Vaccine Act and that the plaintiffs failed to raise any genuine issue of material fact as to Counts II and IV (failure to warn and manufacturing defect claims, respectively). The United States Court of Appeals for the Third Circuit (Third Circuit) affirmed the federal district court's decision. On appeal, the Third Circuit addressed three questions presented by the Bruesewitzes: (1) whether Section 22(b)(1) acts as a complete bar to design defect claims; (2) whether the plaintiffs met their burden under Section 22(b)(2) of the Vaccine Act to show that the defendants failed to provide an adequate warning of the alleged dangers of the vaccine; and (3) whether the plaintiffs provided sufficient evidence of a manufacturing defect to survive the defendant's motion for summary judgment.

Design Defect Claims (Counts I + III)

The federal district court agreed with the conclusion and reasoning of three other court decisions that held that the Vaccine Act preempts design defect claims.[23] In holding that the Vaccine Act categorically preempts all design defect claims, it drew four conclusions.[24] First, it held that vaccine manufacturers would not be protected from lawsuits if case-by-case inquiries were permitted. Second, the establishment of a no-fault remedies compensation program suggests that it was Congress's intention to provide manufacturers with immunity, allowing them to improve the safety of their products through the innovation of safer alternative designs.[25] 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, the Vaccine Act preempts state law determinations of whether a vaccine is unavoidably unsafe,[26] because "an FDA-approved vaccine design includes the side-effects of that vaccine, and is therefore, by statutory definition, the unavoidably unsafe product subject to"

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

[22] 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).

[23] *See* Blackmon v. American Home Products Corp., 328 F. Supp. 2d 659 (S.D. Tex. 2004); Sykes v. Glaxo-SmithKline, 484 F. Supp. 2d 290 (E.D. Pa. 2007); Milantrano v. Lederle Labs, 801 N.Y.S.2d 506 (N.Y. App. Div. 2006). In each of these cases, the plaintiffs had asserted that the vaccine was defectively designed.

[24] The district court's conclusions relied upon the four basic conclusions of the district court in *Sykes v. Glaxo-SmithKline*. In *Sykes*, the court found: (1) the purpose of the Vaccine Act to protect vaccine manufacturers from the expense of the tort system would be thwarted by allowing juries to evaluate whether a vaccine was unavoidably unsafe on a case-by-case basis; (2) 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 of §402A of the Restatement (Second) of Torts supports the understanding that the liability of vaccine manufacturers is limited to claims that the vaccine deviated from its FDA-approved design. Sykes, 484 F. Supp. 2d at 301-03.

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

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

immunity under the liability principles of the Restatement (Second) of Torts Section 402A comment k.[27]

The Third Circuit upheld the district court's decision, but stated that further analysis was warranted. In particular, the court found Sections 22(a) and (b) to contain express preemption[28] language because, like other provisions in federal law,[29] it "conveys a clear intent to override state law civil action claims in particular, defined circumstances."[30] The court of appeals stated that whether the plaintiffs' claims fell within the scope of preemption "hinge[d] on the word 'unavoidable.'"[31] The 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." The defendant, on the other hand, argued that the language "preempts all claims arising from allegations of design defect."[32] The court resolved to look at the language, structure, and legislative history of the act to ascertain the scope of preemption created by Section 22(b), concluding that it could not make such a determination from the statutory text alone.

The Court of Appeals found that the Report from the House Committee on Energy and Commerce (Commerce Report) supported the conclusion that the Vaccine Act preempts all design

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[27] *Id*. at 446. 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.... 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.... Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous.... 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.

The court in *Blackmon* acknowledged that comment k of the Restatement only applies to strict liability. However, 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." Blackmon, 328 F. Supp. 2d at 665.

[28] Bruesewitz v. Wyeth, 561 F. 3d 233, 240-41 (3d Cir. 2009) [hereinafter Bruesewitz II]. 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). 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. Bruesewitz II, 561 F.3d at 251.

[29] For example, 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 Supreme Court in *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001) had construed this provision as express preemption provisions.

[30] Bruesewitz II, 561 F.3d at 243.

[31] *Id*. at 245.

[32] *Id*.

defect claims.[33] In the court's analysis, most importantly, the Commerce Report "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).[34] According to the court, any reading of the provision to permit state courts to make case-by-case determinations would exacerbate the "very problems which led to instability in the vaccine market and which caused Congress to intervene."[35] The court acknowledged but did not find reliable a subsequent Report from the House Committee on the Budget (Budget Report) which implicates that whether vaccines are unavoidably unsafe "is [a question] left to the courts to determine in accordance with applicable law."[36] It primarily found "the views of a subsequent Congress [to] form a hazardous basis for inferring the intent of an earlier one"[37] 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.[38] The Third Circuit concluded that the Commerce Report and other legislative history strongly indicate Congress's intention to preempt the specific claims asserted by the plaintiffs, as it had determined "that DPT manufacturers should be shielded from liability for injuries arising from the whole-cell pertussis vaccine."[39]

Failure-to-Warn Claim (Count II) + Manufacturing Defect (Count IV)

The Court of Appeals affirmed the district court's decision to dismiss the Bruesewitzes' claim that the manufacturer withheld information from doctors about particularly dangerous batches of vaccines. If a failure-to-warn claim is not precluded,[40] the Vaccine Act grants the manufacturer the presumption of a proper warning if the manufacturer shows that it complied with the proper FDA requirements. 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 show "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]."[41] In the Bruesewitzes' case, the courts held that Wyeth was entitled to the presumption of proper warning, but concluded that the plaintiffs

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

[34] Bruesewitz II, 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).

[35] *Id*. at 249.

[36] *Id*. (*citing* H.Rept. 100-391, pt. l at 691 (1987)). The court found the Budget Report's repeated use of the term "the Committee" problematic because it was unclear whether this referred to the Commerce and Energy 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. *Id*. at 250.

[37] *Id*. at 250 (quotation marks omitted) (*citing* United States v. Price, 361 U.S. 304, 313 (1960)).

[38] *Id*.

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

[40] Section 22(c) of the Vaccine Act "clearly bars failure-to-warn claims based on a failure to directly warn the injured party's legal representative"; however, the court in *Blackmon* found that allegations of failure-to-warn "doctors and medical intermediaries" are not subject to the prohibition of §22(c). Bruesewitz I, 508 F. Supp. 2d. at 447 (*citing* Blackmon, 328 F. Supp. 2d at 666).

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

failed to provide any clear and convincing evidence sufficient for a reasonable jury to find in their favor.[42]

The federal district court also dismissed the plaintiffs' strict liability claim that the particular dose administered to Hannah contained a manufacturing defect that made it "extra-hazardous."[43] While the Vaccine Act did not bar such a claim, the court concluded that none of the evidence offered by the plaintiffs demonstrated that the product was defective or that "the specific lot caused *any* of the adverse reactions, let alone the specific reaction suffered by Hannah."[44] The Third Circuit affirmed the decision of the district court.

The Supreme Court Decision in *Bruesewitz*

The only issue the Supreme Court agreed to review is whether Section 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. After hearing oral arguments on October 12, 2010, the Supreme Court issued its decision on February 22, 2011, affirming by a vote of 6-2 the Third Circuit's holding that the Vaccine Act expressly preempts all design defect claims against manufacturers.[45]

Justice Scalia, writing for the majority, found that the text of the Vaccine Act supports an interpretation that the provision at issue preempts all design defect claims, and that this textual reading is supported by the structure of the act. Justice Sotomayor, writing a dissenting opinion, concluded the opposite. The opinions addressed several of the points raised during oral arguments, such as the potential for a superfluous interpretation of the provision, the purpose of the Vaccine Act, and the motivation for vaccine manufacturers to keep their products as up-to-date as science and technology permit.

Textual Interpretation

The Court did not perform the same preemption analysis as the Third Circuit; rather, it began by directly focusing on interpreting the text of Section 22(b)(1), which relieves vaccine manufacturers of liability, "if the injury or death resulted from the side-effects that were unavoidable *even though the vaccine was properly prepared and was accompanied by proper*

[42] In support of their failure-to-warn claim, the plaintiffs identified the lot that produced the dose of TRI-IMMUNOL administered to Hannah as well the Vaccine Adverse Event Reporting System 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. The plaintiffs had 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 I, 508 F. Supp. 2d at 448; Bruesewitz II, 561 F.3d at 254-254.

[43] Bruesewitz I, 508 F. Supp. at 435 (*citing* Pl. Am. Comp. ¶ 37). The plaintiffs asserted that the dose administered to Hannah had "an inappropriate balance between neuro-toxins and endo-toxins in the pertussis vaccine." *Id*. Wyeth disputed this allegation 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*. at 449.

[44] *Id.* at 451.

[45] Bruesewitz v. Wyeth, 562 U.S. __ ; 131 S. Ct. 1068 (2011). Chief Justice Roberts and Justices Kennedy, Thomas, Breyer, and Alito joined in Justice Scalia's majority opinion. Justice Sotomayor wrote a dissenting opinion, which Justice Ginsburg joined.

directions and warning"[46] (emphasis added). Noting that products liability law traditionally establishes three grounds for liability—that is, defective manufacture, inadequate directions or warnings, or defective design—the Court stated that if all three grounds for liability were intended to be preserved, "it would be strange to mention specifically only two, and leave the third to implication."[47] The Court concluded that the provision itself "suggests that the *design* of the vaccine is a given, not subject to question in the tort action"[48] (emphasis in the original). In the Court's reading, the "even though" clause "delineates the preventative measures that a vaccine manufacturer must have taken for a side-effect to be considered 'unavoidable' under the statute."[49] Further, the clause is "meant to signal the unexpected: unavoidable side effects [which] persist *despite* best manufacturing and labeling practices"[50] (emphasis in the original). Thus, according to the Court, "[p]rovided that there were proper manufacture and warning, any remaining side effects, including those resulting from design defects, are deemed to have been unavoidable."[51] It also observed that the term "unavoidable" would have little meaning if a manufacturer could be liable for failure to use a different design because "[a] side effect of a vaccine could *always* have been avoidable by use of a differently designed vaccine not containing the harmful element."[52]

Although the lower courts acknowledged that Congress intended to incorporate the principle of comment k of the Restatement, which exempts from strict liability "unavoidably unsafe products," and that it supported the conclusion that design defect claims are preempted, the Court in *Bruesewitz* dismissed the connection. Determining the word "unavoidably," as utilized by comment k, to be very different from "unavoidable," as found in Section 22(b)(1), the Court found no reason to believe that Congress was invoking comment k when enacting Section 22(b)(1).[53] Even though its own analysis concentrated on the text and structure of the Vaccine Act, the Court further addressed points made by the dissent, which relied heavily on the legislative history of the act. Among other things, the Court pointed out that the 1986 Commerce Report counsels injured parties who cannot prove a manufacturing or labeling defect to "pursue

[46] 42 U.S.C. §300aa-22(b)(1).

[47] Bruesewitz, 131 S. Ct. at 1075-1076 (*citing* W. Keeton, d. Dobbs, R. Keeton, & D. Owen, Prosser, and Keeton on Law of Torts 695 (5th ed. 1984)).

[48] *Id*. at 1075.

[49] *Id*.

[50] *Id*. at 1077. Specifically, the Court notes that "even though" is a concessive subordinating conjunction and that the dissent's reading of the "even though" clause treats it as a coordinating junction like "and" that links together independent ideas. *Id*. It disagreed with the dissent's treatment of the word "even though," stating that the dissent's treatment makes preemption "turn equally on unavoidability, proper preparation, and proper labeling." *Id*.

[51] *Id*. 1075.

[52] *Id*. The dissent criticized this assertion by noting that this reading "entirely ignores the fact that removing the 'harmful element' will often result in a less effective or entirely ineffective vaccine." According to the dissent, the legislative history of the Vaccine Act makes clear that a side effect is "unavoidable" only "where there is no feasible alternative design that would eliminate the side effect of the vaccine without compromising its cost and utility." *Id*. at 1094 (dissenting opinion).

[53] *Id*. at 1077 (majority opinion). Notably, the Court stated that comment k "creates a special category of 'unavoidably unsafe products,' while the statute refers to 'side effects that were unavoidable.'" *Id*. The dissent spent much time arguing that the legislative history—the 1986 Commerce Report—demonstrates Congress's intent to codify the principle in comment k, meaning that "unavoidable" is best understood as a term of art that incorporates the commonly understood meaning of "unavoidably unsafe" products. *Id*. at 1088-1091 (dissenting opinion). Furthermore, that many courts in 1986, in applying comment k to the term "unavoidable," interpreted it to require a "case-specific showing that the product was 'quite incapable of being made safer for its intended use,'" did not have any bearing on the Court's conclusion. *Id*. at 1077 (majority opinion).

recompense in the compensation system, not the tort system."[54] While the dissent asserted that the 1987 Budget Report is the proper and authoritative guide to the meaning of Section 22(b)(1),[55] the Court immediately critiqued the dissent for using "post-enactment legislative history," stating that it is "not a legitimate tool of statutory interpretation," and that "[t]hose who voted on the relevant statutory language were not necessarily the same persons who crafted statements in the later [Budget] Report."[56]

Lastly, the Court acknowledged the critique that its interpretation would render part of Section 22(b)(1) superfluous, specifically the words "the injury or death resulted from side effects that were unavoidable even though," because Congress could have more simply stated that liability would be barred "if ... the vaccine was properly prepared and was accompanied by proper directions and warnings."[57] In addition to highlighting that the dissent's interpretation has superfluity problems of its own,[58] the Court noted that the rule against giving a portion of text an interpretation which renders it superfluous only applies "if verbosity ... can be eliminated by giving ... the remainder of the text, a competing interpretation," which the Court declared could not be done in this instance.[59]

Structural Argument

In addition to the text of the provision, the majority found that the structure of the Vaccine Act and of vaccine regulation generally supported its conclusion that Section 22(b)(1) preempts all design defect claims. In general, the majority found that

1. the lack of guidance for design defects in contrast to the extensive regulation of manufacturing and warning labels, two of the grounds for liability mentioned in the Vaccine Act, "strongly suggests that design defects were not mentioned because they are not a basis for liability";[60]
2. the Vaccine Act provides its own means of improving vaccine design, the establishment of the National Vaccine Program, and the possibility of license revocation if the FDA concludes the vaccine is unsafe demonstrate that

[54] *Id*. at 1081 (*citing* H.Rept. 99-908 at 26).

[55] *Id*. at 1092 (dissenting opinion). Specifically, the dissent highlighted a passage in the 1987 Budget Report as stating "the codification of Comment (k) ... was not intended to decide as a matter of law the circumstances in which the vaccine should be deemed unavoidably safe." *Id*.

[56] *Id*. at 1081 (majority opinion).

[57] *Id*. at 1078.

[58] The Court stated that the dissent's interpretation renders the passage "even though the vaccine was properly prepared ..." superfluous because it would have been sufficient for Congress to say "if the injury or death resulted from side effects that were unavoidable," if Congress, under the dissent's interpretation, requires a case-by-case determination of avoidable side effects. In response, the dissent stated the "even though" clause establishes two additional prerequisites—proper manufacturing and proper labeling—to qualify for exemption from liability under §22(b)(1). Thus, under the dissent's interpretation a vaccine manufacturer, even if it demonstrated that the side effects were unavoidable, would still have to prove that it properly manufactured and labeled the vaccine. *Id*. at 1091 (dissenting opinion).

[59] *Id*. at 1095 (majority opinion). In other words, because the passage "if the injury or death ... unavoidable" cannot be interpreted to require a case-specific determination of avoidable injuries under the Court's interpretation, the Court is therefore not prevented from reading §22(b)(1) in such a manner that renders the aforementioned phrase superfluous.

[60] *Id*. at 1079.

Section 22(b)(1)'s "silence regarding design-defect liability was not inadvertent";[61] and

3. the Vaccine Act's *quid pro quo* structure—that is, manufacturers fund the act's compensation fund from their sales, in exchange for avoiding costly tort litigation—would have little meaning if manufacturers are still liable for claims of design defect.[62]

The dissent took issue with the majority's structural arguments. Primarily, it disagreed with the majority's assertion that Congress intended to preempt design defect claims because the Vaccine Act, according to the majority, provided its own means of assuring improvements in vaccine design. Rather, the dissent stated: "neither the Act nor any other provision of federal law places a legal *duty* on vaccine manufacturers to improve the design of their vaccines to account for scientific and technological advances."[63] Absent clear statutory language, the dissent did not believe that Congress intended "to eliminate the traditional incentive and deterrence functions served by state tort liability in favor of a federal regulatory scheme providing only carrots and no sticks,"[64] and that the majority's decision leaves a "regulatory vacuum in which no one ... ensures that vaccine manufacturers adequately take account of scientific and technological advancements."[65] To this, the majority responded that the Court has never suggested that it was more likely to find preemption only if the compensation scheme or "the congressional substitute operated like the tort system."[66]

Analysis of the *Bruesewitz* Decision

Prior to the decision, supporters of the respondent Wyeth, including the American Academy of Pediatrics, American Medical Association, and Infectious Diseases Society of America, argued that a decision in favor of the Bruesewitzes would leave vaccine manufacturers vulnerable to numerous lawsuits, and "could drive vaccine manufacturers from the market and halt future production and development of childhood vaccines in this country."[67] In contrast, supporters of the Bruesewitzes, such as the National Vaccine Information Center and the Vaccine Injured Petitioners Bar Association, have argued that the approximate 5,000 claimants in Vaccine Court who claim that there is a relationship between autism and the mumps, measles, and rubella (MMR) vaccine and/or other thimerosal-containing vaccines would have no recourse if the Court decided in favor of Wyeth.[68] They further argued that the "practical effect of the Third Circuit's

[61] *Id*. at 1080.

[62] *Id*. at 1079-1080.

[63] *Id*. at 1097 (dissenting opinion).

[64] *Id*. at 1098-1099. In the dissent's view, "the normal competitive forces that spur innovation and improvements to existing product lines in other markets [] operate with less force in the vaccine market, particularly for vaccines that have already been released and marketed to the public." *Id*.

[65] *Id*. at 1101.

[66] *Id*. at 1079 (majority opinion).

[67] 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.

[68] National Vaccine Injury Compensation Program (NVIC) - About the Omnibus Autism Proceeding, http://www.hrsa.gov/vaccinecompensation/omnibusautism.html. NVIC argued 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 10) 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 (continued...)

opinion ... [was] to deny justice to [the Bruesewitzes and other claimants] in the Vaccine Program whose cases cannot be fully litigated given the restrictions built into the Program."[69] Although Wyeth argued that a decision in its favor would still leave the Bruesewitzes with the ability to pursue failure-to-warn and manufacturing defect claims, supporters for the Bruesewitzes argued that "in practice, manufacturers rely on precedents that all but subsume manufacturing defect claims and failure to warn claims into design defect claims."[70]

The Supreme Court's decision in *Bruesewitz* arguably has a greater practical, rather than jurisprudential, impact as it could have affected either the ability of manufacturers to continue in the vaccine industry or affected the ongoing and future proceedings of individuals seeking compensation under the Vaccine Act. Given the Court's decision in favor of Wyeth, it remains to be seen how this will influence the ongoing claims of individuals asserting a link between autism and MMR and/or thimerosal-containing vaccines, that is, the Omnibus Autism Proceedings.[71] By August 2010, the U.S. Court of Appeals for the Federal Circuit had affirmed the decisions of the U.S. Court of Federal Claims in two test cases.[72] Both test cases were in favor of HHS and specifically examined the issue of causation, as is required by the Vaccine Act for off-Table injuries. Similar decisions were reached with other test cases.[73] With the Omnibus Autism Proceedings concluded,[74] some claimants may have the option of pursuing their claims against the manufacturers in civil court. But they are precluded from asserting a design defect claim under any theory of negligence. The experience of the Bruesewitzes, whose failure-to-warn and manufacturing defect claims were dismissed for lack of evidence, may further foreshadow the difficulties that current claimants could face in bringing successful claims against the vaccine

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without compensation. *See* 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).

[69] Brief of Vaccine Injured Petitioners Bar Association (VIPBA), 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. 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." *Id*. at 21.

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

[71] The Omnibus Autism Proceedings were formed to address the approximately 5,000-plus autism claims pending before the Vaccine Court. A panel of attorneys representing various petitioners identified three general theories of causation: (1) that vaccines containing thimerosal, when combined with the MMR vaccine, can cause autism; (2) that vaccines containing thimerosal alone can cause autism; and (3) that the MMR vaccine alone can cause autism. The panel selected three test cases each for each theory of causation asserted, and assigned each test case to a separate Special Master for adjudication. *See* U.S. Court of Federal Claims, Office of Special Masters, *The Autism Proceedings*, http://www.uscfc.uscourts.gov/sites/default/files/autism.background.2010.pdf.

[72] *See* Hazlehurst v. Sec'y of HHS, 605 F.3d 1343 (Fed. Cir. 2010) (affirming decision of lower court to deny the petition, given lack of evidence to prove causation between the MMR vaccine and development of autism); Cedillo v. Sec'y of HHS, 617 F.3d 1328 (Fed. Cir. 2010) (affirming decision of lower court to deny petition, given lack of evidence to prove causation between the MMR vaccine in conjunction with thimerosal-containing vaccines and development of autism).

[73] For theory number two—establishing causation of thimerosal-containing vaccines only—the Special Masters rejected the petitioners' petitions. *See* Mead v. Sec'y of HHS, Decision of Special Master Campbell-Smith, Case No. 03-215V (Mar. 12, 2010); King v. Sec'y of HHS, Decision of Special Master Hastings, Case No. 03-584V (March 12, 2010); and Dwyer v. Sec'y of HHS, Decision of Special Master Vowell, Case No. 03-1202V (March 12, 2010).

[74] *See In Re: Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or Similar Neurodevelopmental Disorder*, Update January 12, 2011, http://www.uscfc.uscourts.gov/sites/default/files/autism/Autism%20Update%201%2012%2011.pdf.

manufacturers. Separately, recent scientific publications, which have declared that there appears to be no link between immunizations and autism or other serious medical problems, may also hinder current and future claimants' ability to prove their claims.[75]

In terms of jurisprudence, it has been observed that "*Bruesewitz* is unlikely to have a broad impact on preemption of common law tort claims given the unique nature of the congressional compensation scheme."[76] Indeed, the Court found preemption in a "hyper-textual analysis," rather than performing a preemption analysis like the Third Circuit, beginning with the traditional presumption against preemption.[77] Similarly, at least one commentator noted that, unlike the prior 2009-2010 Term where the Court's preemption decisions seemed to "duel over the policy arguments that underpin the preemption debate,"[78] the *Bruesewitz* decision and other product liability preemption cases from the 2010-2011 Term demonstrate that the Court "has resigned itself to a narrow, case-by-case approach to the preemption defense."[79] Because of this shift, future questions on whether state tort law claims are preempted "will be resolved not on the basis of broad policy arguments but rather on a case-by-case analysis of specific statutory language, regulatory history, and federal decision-making," and will depend on "which party succeeds in defining the narrative through which a court will view its analysis."[80] On the other hand, others have observed that the decision is consistent with the Court's evolving trend to view tort lawsuits in its preemption decisions as serving a regulatory function (i.e., deterrence or promotion of certain behaviors) rather than a compensatory function (i.e., redressing private wrongs).[81] From

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[75] Rob Stein, "Vaccines are generally safe, National Academy of Sciences says," *Washington Post* (August 25, 2011); CNN Release, *Retracted autism study an 'elaborate fraud,' British journal finds*, January 5, 2011, http://www.cnn.com/2011/HEALTH/01/05/autism.vaccines/index.html.

[76] Mary J. Davis, *The Case Against Preemption: Vaccines & Uncertainty*, 8 Ind. Health L. Rev. 291, 307 (2011).

[77] Bruesewitz II, 561 F.3d at 240 ("[C]ourts must begin their analysis of these [preemption] questions by applying a presumption against preemption. *Cipollone v. Liggett Group*, 505 U.S. 504 (1992). 'In areas of traditional state regulation, we assume that a federal statute has not supplanted state law unless Congress has made its intention 'clear and manifest.' *Bates v. DowAgroSciences*, 544 U.S. 431 (2005).").

[78] Eric G. Lasker, *U.S. Supreme Court Preemption Trilogy: The Sequel*, Washington Legal Foundation: Legal Backgrounder Vol. 26, No. 7 (March 25, 2011). For example, in *Riegel v. Medtronic*, 522 U.S. 312 (2008) and *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), Justice Scalia emphasized a strong policy argument in support of preemption, namely that "juries are ill-equipped to perform the FDA's cost-benefit-balancing function ... [and] tend to focus on the risk of a particular products design or warning label [rather than] the overall benefits of that design or label." *See* Wyeth, 129 S. Ct. at 1229-30. On the other side of the debate, Justice Ginsberg in both *Riegel* and *Wyeth* emphasized the policy argument that FDA regulations and state tort liability operate independently, and that state law offers an additional layer of consumer protection that is complementary to FDA regulation. Lasker, at *2.

[79] Lasker observed that Justice Scalia in *Bruesewitz* focused more on a grammatical analysis of the statutory language and less on building upon his earlier policy arguments in support of preemption. Lasker, *supra* note 78, at *3. Likewise, in *Williamson v. Mazda*, 131 S. Ct. 1131 (2011), another preemption case in the 2010-2011 Term, the Court's decision against a finding of implied preemption was based on narrow grounds; that is, implied preemption turned on the significance or insignificance of the policies underlying a particular regulatory decision. Lasker, *supra* note 78, at *4.

[80] Lasker, *supra* note 78, at *4.

[81] Christina Wells, William E. Marcantel, and Dave Winters, *Preemption of Tort Lawsuits: The Regulatory Paradigm in the Roberts Court*, 40 Stetson L. Rev. 793 (2011). Relying on a regulatory paradigm, it is arguably easier for the Court to read express preemption words such as "laws," "requirements," or "standards," as applying to not only state statutes but tort claims as well. *Id*. at 793, 818. For example, in 1992, the Court in *Cipollone v. Liggett Group*, 505 U.S. 504 (1992), focused on the regulatory effect of tort lawsuits when it interpreted the express preemptive provisions in the Public Health Cigarette Smoking Act of 1969 to bar not only conflicting state "laws," "rules," and standards," but state tort lawsuits as well. Similarly, the Court emphasized the regulatory function of state tort lawsuits in *Riegel v. Medtronic*, 522 U.S. 312 (2008), when it found preemption of state tort law claims involving Class III medical devices. However, the Court has also emphasized the regulatory function of tort lawsuits even where it has rejected a preemption argument, finding generally the tort system to be a complementary form of regulation. *See, e.g.*, Wyeth v. Levine, 129 S. Ct. 1187 (2009) (finding that the Federal Food Drug and Cosmetic Act did not preempt a state tort (continued...)

this point of view, the conclusion reached in *Bruesewitz* fits neatly with the Court's past preemption decisions. Arguably, the Court in *Cipollone v. Liggett*, 505 U.S. 504 (1992) began to emphasize the regulatory nature that tort lawsuits serve over the parallel regulatory/compensatory effects of tort lawsuits.[82] Under this continued emphasis of the regulatory paradigm, it is not surprising that Justice Scalia in *Bruesewitz* found the "imposition of tort liability" to impede the Vaccine Act's regulatory goals of improving vaccine designs, because such an imposition could drive manufacturers away and threaten the supply of vaccines, "much as state positive enactments might impose unreasonable burdens on manufacturers to the public good."[83]

Lastly, the *Bruesewitz* decision does not address other issues with the Vaccine Act that have been the subject of some academic discussion. These include (1) the lack of a clear evidentiary standard for scrutinizing the admissibility of scientific evidence,[84] and (2) the lack of a clear understanding of the level of proof necessary to show causation.[85] These issues, which pertain to causation, have become more critical because "most claims are in fact for off-[T]able injuries … [whereas] in the early years of the program … ninety percent of the cases were covered [injuries]," in which case causation was presumed.[86] These commentators observe that there has been inconsistency in Special Masters' decisions due to a lack of clarity on these particular issues. For example, under the Vaccine Act, Congress charged the U.S. Court of Federal Claims with promulgating "flexible and informal standards of admissibility of evidence," to govern the Vaccine Act litigation, which are known as the Vaccine Rules.[87] As a result, Special Masters enjoy a great deal of discretion to admit and weigh evidence because the Federal Rules of Evidence do not apply. The Vaccine Rules specifically state that Special Masters "will not be bound by common law or statutory rules of evidence."[88] While it has been noted that the admissibility of evidence has become very similar to the tort system in that Special Masters purport to be following the standards set forth in *Daubert v. Merrell Dow Pharmaceuticals*,[89] they have "openly expressed frustration with the lack of uniform standards by which they reach entitlement

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lawsuit based upon the manufacturer's failure-to-warn, in part, because the tort system acts as a "complementary form of drug regulation"); Williamson v. Mazda, 131 S. Ct. 1131 (2011) (finding no preemption of wrongful death claims because such lawsuits do not conflict with the federal regulatory objective of auto safety).

[82] Wells, *supra* note 81, at 807.

[83] Wells, *supra* note 81, at 816. *See also* James M. Beck, *The Food, Drug, and Cosmetic Act: Searching for Crossroads of Safety and Innovation: Federal Preemption in FDA-Regulated Product Liability Litigation*, 32 Hamline L. Rev. 657 (2009) (arguing that the Court's decisions in *Cipollone v. Liggett Group* and *Geier v. Am. Honda Motor Co.* where it found express and implied preemption, respectively, eliminated any "doctrinal impediments" to preemption and cleared the way for FDA-regulated drug and medical device manufacturers to assert that FDA regulation had a preemptive effect).

[84] Brandon Boxler, *What to do with Daubert: How to Bring Standards of Reliable Scientific Evidence to the National Vaccine Injury Compensation Program*, 52 Wm. & Mary L. Rev. 1319 (March 2011).

[85] Betsy J. Grey, *The Plague of Causation in the National Childhood Vaccine Injury Act*, 48 Harv. J. on Legis. 343 (Summer 2011).

[86] Robert L. Rabin, *The Vaccine No-Fault Act: An Overview*, 8 Ind. Health L. Rev. 267 (2011). The drafters of the Compensation Program may not have anticipated this change in dynamic, that is, the increase of off-Table injury claims compared to covered injury claims, because they intended the Vaccine Injury Table to be the centerpiece of the program. As a result, it is possible that less attention was paid to providing clear guidelines to the Vaccine Court on how to resolve off-Table injury claims. Grey, *supra* note 85, at 346.

[87] 42 U.S.C. §300aa-12(d)(2).

[88] Vaccine R. Fed. Cl. 8(b)(1), *available at* http://www.uscfc.uscourts.gov/sites/default/files/11.07.15finalversionofvaccinerules.pdf.

[89] Rabin, *supra* note 86, at 271.

decisions."[90] The result appears to be "case-by-case jurisprudence that is void of any cohesive explanation of what it takes to prevail within the Vaccine Program."[91] Similarly, the applicable legal standards governing causal proof in off-Table cases arguably "is a story of mixed signals from the Federal Circuit, ranging from only a minimal showing of medical opinion and circumstantial temporal evidence to mirroring the more stringent standards developed in traditional toxic tort cases."[92] While the *Bruesewitz* decision provides a definitive understanding that design defect claims are precluded from being brought in state court, a lack of resolution on these causation issues may give continued rise to inconsistent case law, thereby creating unpredictability in Vaccine Act litigation for both claimants and vaccine manufacturers.

Congressional Legislation

No legislation has been introduced on this issue in the 112th Congress, though some measures were introduced in the 111th Congress. These and other similar bills have been introduced repeatedly in the past; however, none of them would have directly affected the outcome of the *Bruesewitz* case, nor overturned the Court's decision. In the 111th Congress, these bills were (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 have amended the statute of limitations for filing a petition with the Vaccine Court. Specifically, these bills would have extended 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."[93] The bills would have also allowed petitions to be filed notwithstanding a previous dismissal for an untimely filing. H.R. 2459 would have also addressed 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 attorneys' fees.

Congress has conducted oversight hearings on the Compensation Program, among concerns that the program was not meeting its original goals of providing expeditious and fair compensation to individuals who may have suffered harm from vaccinations.[94] The practical effect the *Bruesewitz*

[90] Boxler, *supra* note 84, at 1340.

[91] *Id*. at 1341. For example, in *Curcuas v. Sec'y of HHS*, 26 Cl. Ct. 537 (1992), the Court of Federal Claims affirmed a Special Master's finding that the DPT vaccine cannot—and-did not—cause chronic encephalopathies because he found an Institute of Medicine Report (IOM) was more persuasive than the conflicting expert testimony of Dr. Mark Geier. In contrast, one year later in *Estep ex rel. Estep v. Sec'y of HHS*, 28 Fed. Cl. 664, 668-69, the Court of Federal Claims affirmed a decision by the same Special Master who had reached a conclusion opposite from *Curcuas*, finding Dr. Geier's testimony to prove more persuasive than the IOM report.

[92] Grey, *supra* note 85, at 379. For example, the Federal Circuit rejected a stringent five-prong test for establishing causation in the off-Table injury claims and "re-imposed on petitioners a three-part evidentiary test: (1) medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccine and injury." *Althen v. Sec'y of HHS (Althen III)*, 418 F.3d 1274 (Fed. Cir. 2005). Despite this standard, a recent decision by the Federal Circuit, *Moberly ex rel. Moberly v. Sec'y of HHS*, 592 F.3d 1315 (Fed. Cir. 2010), has suggested that "the relaxed presumptions applicable to Table injuries may not satisfy causal proof for non-Table claims and that traditional tort standards should apply." *Id*. at 1332.

[93] 111th Congress, H.R. 2459, Section 7; H.R. 4096, Section 2 (2009).

[94] *Compensating Vaccine Injuries: Are Reforms Needed? Before Subcomm. On Criminal Justice, Drug Policy, and* (continued...)

decision may have on the autism proceedings could renew Congress's interest in evaluating the Compensation Program. If Congress finds that it wishes to give claimants, such as the 5,000 claimants mentioned above, the ability to pursue design defect claims in state courts, then it may choose to revisit the specific language at issue to clarify if the Vaccine Act precludes design defect claims. 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.[95] 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."[96] Furthermore, Congress could choose to amend the act to clarify the level of causation needed to be shown in order to provide more stability to the system.

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[95] 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 (name redac ted).

[96] 111th Congress, H.R. 1346, Medical Devices Safety Act; S. 540, Medical Devices Safety Act (2009).