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The Supreme Court Finds Design Defect Claims Preempted under the Vaccine Act

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Yesterday, in *Bruesewitz v. Wyeth*, No. 09-152, the United States Supreme Court held that the National Childhood Vaccine Injury Act of 1986 (the "Vaccine Act" or "Act"), 42 U.S.C. § 300aa-1 *et seq.*, preempts all design defect claims against vaccine manufacturers brought by plaintiffs seeking compensation for injury or death caused by a vaccine's side effects. The case is significant because it made clear that plaintiffs may not bring design defect claims against vaccine manufacturers under state law.

BACKGROUND

The *Bruesewitz* case arose from Plaintiffs-Petitioners Russell and Robalee Bruesewitz's claim that poor design of a diphtheria, tetanus, and pertussis ("DTP") vaccine by the manufacturer, Defendant-Respondent, Wyeth, Inc. ("Wyeth"), injured their daughter Hannah.

On April 1, 1992, when she was six months old, Hannah received her third injection of DTP, a vaccine designed to reduce pertussis (or "whooping cough") infections. Shortly thereafter, Hannah began experiencing persistent seizures that, Plaintiffs claimed, left her lethargic, developmentally stunted, and displaying autistic-like symptoms. Plaintiffs contended that Hannah's injuries could have been avoided had Wyeth used an alternative design called ACEL-IMUNE ("DTaP").

Plaintiffs submitted their case before the Vaccine Court, an Office of Special Masters created by Congress in the Act to adjudicate vaccine-related claims. The Vaccine Court found that Hannah's injuries, residual seizure disorder and encephalopathy, were not listed on the Act's Injury Table for DTP, and therefore denied Plaintiffs' claim for damages. Plaintiffs then sued Wyeth in Pennsylvania state court asserting claims for strict liability under theories of design and manufacturing defect, alleging that Defendant "negligently failed to produce a safer vaccine despite knowledge of the existence and feasibility of such safer alternatives" and "negligently failed to warn of the actual dangers associated with the particular batch [of] DPT." *Bruesewitz v. Wyeth, Inc.*, 508 F. Supp. 2d 430, 435 (E.D. Pa. 2007).

Shortly after removing the case to federal court based on diversity jurisdiction, Defendant moved for summary judgment on the grounds that the Vaccine Act preempts Plaintiffs' state law claims. Although the United States District Court for the Eastern District of Pennsylvania initially denied Defendant's motion without prejudice, the court granted Defendant's motion for summary judgment on all counts—which included negligence and design defect—after completion of discovery. After determining that Plaintiffs' negligence claim was a disguised defective design claim, the district court

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concluded that Plaintiffs' negligence and design defect claims were preempted pursuant to Section 22(b)(1) of the Act.

On appeal, the Third Circuit agreed, holding that Plaintiffs' design defect claims were expressly preempted by the plain language of the Act. The Court of Appeals rejected Plaintiffs' argument that Section 22(b)(1) shields manufacturers from design defect claims only when a vaccine's harmful side effects could not have been prevented through a safer design. Looking to "the language, structure, and purpose" of the Act, and using legislative history to aid its interpretation, the court concluded that Section 22(b)(1) in absolute terms protects vaccine manufacturers from all possible design defect claims.

At oral argument before the Supreme Court on October 12, 2010, Plaintiffs argued that Congress' intent in enacting the Act was not to preempt design defect claims against vaccine manufacturers for preventable vaccine-related injuries. Defendant Wyeth, on the other hand, argued that the Act was intended to preempt design defect claims, a reading supported by the "wave of tort litigation that threatened to drive manufacturers out of the business of providing the vaccine" at the time of its enactment. Finally, the United States, as amicus curiae, argued in its brief that the language, structure, purpose and history of Section 22 reveal that it preempts design defect claims against manufacturers.

SUMMARY OF THE DECISION

In its opinion, written by Justice Scalia and joined by Chief Justice Roberts and Justices Kennedy, Thomas, Breyer, and Alito, the Supreme Court held that the Act preempts all design defect claims against vaccine manufacturers brought by plaintiffs seeking compensation for injury or death caused by a vaccine's side effects.

The Court began its analysis with the text of Section 22(b)(1), which provides:

> 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.

"What the statute establishes as a complete defense must be unavoidability (given safe manufacture and warning) with respect to a particular design."

OPINION OF THE COURT

The Court reasoned that, if manufacturers could be held liable for failing to use a different design, the word "unavoidable" in the statute would become meaningless: "A side effect of a vaccine could *always* have been avoidable by use of a differently designed vaccine not containing the harmful element." Instead, the text of the statute suggests that a vaccine's design itself is not subject to question in a tort action. "What the statute establishes as a complete defense must be unavoidability (given safe manufacture and warning) *with respect to a particular design*."

The Court also noted that, under product liability law, there is a "classic and well known triumvirate of grounds for liability: defective manufacture, inadequate directions or warnings, and defective design." Of the three, the Act only mentions defective manufacture and inadequate warning, suggesting that the noticeable absence of design defect liability in the text was "by deliberate choice, not inadvertence."

Next, Justice Scalia's opinion for the majority rejected Plaintiffs' and the dissent's reliance on comment k to Restatement (Second) of Torts §402A to interpret the term

"unavoidable" from Section 22(b)(1).[1] It observed that cases interpreting comment k had attached special meaning to the phrase "unavoidably unsafe products," not the term "unavoidable" standing alone.

"[T]he Act, which in every other respect micromanages manufacturers, is silent on how to evaluate competing designs."

OPINION OF THE COURT

Refuting the claim that its interpretation renders part of the statute superfluous, the Court stated: "[T]he rule against giving a portion of text an interpretation which renders it superfluous does not prescribe that a passage which could have been more terse does not mean what it says." The majority also rejected Plaintiffs' and the dissent's own textual interpretation, which created a "useless appendage" of the "even though" clause.

Furthermore, the structure of the Act as well as the regulation of vaccines in general reinforces what the text of the statute suggests, the Court concluded. It contrasted the Food and Drug Administration's ("FDA") extensive regulations of a vaccine's manufacturing process with the complete absence of a single mention of design defects in the Act or the FDA's regulations: "Yet the Act, which in every other respect micromanages manufacturers, is silent on how to evaluate competing designs."

The Court bolstered its conclusion by emphasizing the mandates contained in the Act—federal agency improvement of vaccine design and the federal compensation program—as alternate means for achieving the same results intended by design defect torts: (1) prompting the development of improved designs and (2) providing compensation for inflicted injuries. The Court concluded that the Act's *quid pro quo* structure, which allows vaccine manufacturers to fund an efficient compensation program for vaccine injuries in exchange for avoiding costly tort litigation and the occasional disproportionate jury verdict, further supports the preemption of design defect liability.

Finally, Justice Scalia's opinion countered the dissent's reliance upon legislative history, observing that the dissent ignored unhelpful statements in the legislative history, and relied upon post-enactment legislative history, which is not a legitimate tool of statutory construction.

"Given these broad general purposes [of Congress as revealed through legislative documents], to read the preemption clause as preserving design-defect suits seems anomalous."

JUSTICE BREYER, concurring

In his concurring opinion, Justice Breyer looked beyond the "purely textual argument" and drew from legislative history and congressional reports, the statute's "basic purpose as revealed by that history," and views of the expert federal administrative agency alongside relevant medical and scientific association perspectives to reinforce the Court's conclusion. Justice Breyer observed: "Given these broad general purposes [of Congress as revealed through legislative documents], to read the preemption clause as preserving design-defect suits seems anomalous."

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[1] A 1986 House Committee Report stated that Section 22(b)(1) "sets forth the principle contained in Comment k of Section 402A of the Restatement of Torts (Second)" and in 1986, at the time of the Act's enactment, some state and federal courts had interpreted comment k to mean that "a product is 'unavoidably unsafe' when, given proper manufacture and labeling, no feasible alternative design would reduce the safety risks without compromising the product's cost and utility." Plaintiffs and the dissent argued that given Congress' intent to codify the principle contained in comment k, Congress must have intended Section 22(b)(1) to require a "specific inquiry" to determine whether a "feasible alternative design existed that would have eliminated the adverse side effects of the vaccine without compromising its cost and utility."

"[The majority opinion] imposes its own bare policy preference over the considered judgment of Congress."

JUSTICE SOTOMAYOR, dissenting

The dissenting opinion, authored by Justice Sotomayor and joined in by Justice Ginsburg, accused the majority of "impos[ing] its own bare policy preference over the considered judgment of Congress." Justice Sotomayor contended that the plain text and structure of the Vaccine Act preempts some—but not all—design defect claims. According to Justice Sotomayor: "Given that the 'even though' clause requires the absence of manufacturing and labeling defects, the 'if' clause's reference to 'side effects that were unavoidable' must refer to side effects caused by something other than manufacturing and labeling defects . . . [t]he only remaining kind of product defect . . . design defect." Thus, a vaccine manufacturer may only invoke the exemption from liability if it establishes that the side effects resulting from a vaccine's design was "unavoidable," and the vaccine was properly prepared and accompanied by proper directions and warnings, the dissent reasoned. Justice Sotomayor also invoked congressional documents accompanying the Act to interpret "unavoidable" as a term of art, incorporating comment k of Restatement (Second) of Torts §402A.

In addition, the dissenting opinion sought to rebut the majority's contention that there would always be an alternative design without the harmful element by arguing that side effects would be unavoidable "only where there is no feasible alternative design that would eliminate the side effect of the vaccine without compromising its cost and utility." Congress did not need to preserve design defect claims expressly in Section 22(b)(1), Justice Sotomayor argued, because state law is preserved under the default rule under the Act and therefore state law design defect claims are already preserved. The dissenting opinion charged that the majority decision "leaves a regulatory vacuum in which no one—neither the FDA nor any other federal agency, nor state and federal juries—ensures that vaccine manufacturers adequately take account of scientific and technological advancements."

Justice Kagan took no part in the consideration or decision of this case.

IMPLICATIONS

In *Bruesewitz,* the Court held in no uncertain terms that all design defect claims against vaccine manufacturers brought by plaintiffs seeking compensation for injury or death caused by a vaccine's side effects are preempted. The Court's holding reiterates the importance of a statute's text in demonstrating Congress' intent to preempt state law claims. It also demonstrates that the Court will analyze the overall nature and purpose of the statutory scheme in question in deciding whether to find for preemption. Although the *Bruesewitz* decision will directly protect vaccine manufacturers from design defect claims, the Court's holding likely will be limited to this context and does not appear likely to have a broader impact on claim preemption jurisprudence.

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