U.S. Supreme Court Upholds Federal Preemption In Childhood Vaccine Liability Case

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Late last month, the U.S. Supreme Court ruled on a significant federal preemption case concerning an individual's right to sue a vaccine manufacturer for injury that is alleged to have resulted from a defect in a vaccine's design. The 6-2 decision (Justice Kagan recused herself) in Bruesewitz v. Wyeth held that a provision within the National Childhood Vaccine Injury Act of 1986 (NCVIA) preempts all design-defect tort claims against vaccine manufacturers brought by plaintiffs seeking compensation for injury or death caused by vaccine side effects. The NCVIA was originally enacted to establish a no-fault compensation program that serves as an alternative to the traditional tort system for resolving vaccine injury claims.

In 1995, the parents of Hannah Bruesewitz claimed that their daughter became disabled after receiving a vaccine manufactured by Lederle Laboratories (now owned by Wyeth). In response, they filed a vaccine-injury petition in the U.S. Court of Federal Claims, which the NCVIA designated to decide which vaccine injury claims should be compensated. After the Bruesewitz's claim was denied, the parents sued Lederle in Pennsylvania state court alleging that Lederle was subject to strict liability and liability for negligent product design under Pennsylvania common law. The case was removed to the U.S. Third Circuit Court of Appeals, which sided with Wyeth on its summary judgment motion and held that the state law claim was preempted by the NCVIA.

The Supreme Court affirmed the Third Circuit decision based on a textual analysis of the NCVIA preemption provision, which reads:

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, 1998, 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.

The Court considered the preemption provision's applicability to the three common grounds for liability under product liability law — defective manufacture, inadequate directions or warnings, and defective design. The Court noted that the preemption provision explicitly refers to the manufacturing process ("properly prepared") and "directions and warnings," yet it excludes design defects. The Court determined that this was an intentional omission by the NCVIA drafters based upon the Court's reading of the NCVIA and related FDA regulations on vaccines. Specifically, the NCVIA and FDA regulations both extensively address vaccine manufacturing and the proper use of warnings, yet neither source mentions vaccine design defects. According to the Court, this omission "strongly suggests" that design defects are not a basis for liability.

The Court further stated that if a vaccine manufacturer could be held liable for failing to use a

different design, as the petitioners argued, the word “unavoidable” within the preemption provision would be wrongly rendered meaningless because a side effect from a vaccine can always be avoided with a different design that excludes the harmful element. Thus, the Court held that where a vaccine is properly manufactured and accompanied by adequate warnings, any remaining adverse effects — including those that result from design defects — are unavoidable and not subject to liability.

The Court’s opinion acknowledged that design-defect torts can prompt the development of improved design and provide compensation for injuries; however, the Court also noted that the NCVIA already provides sufficient means for achieving both of these objectives. For example, the opinion, in addition to discussing the compensation program, highlighted provisions within the NCVIA that mandate vaccine research and testing, and require manufacturers and health-care providers to report adverse side effects and monitor vaccine safety through a collaboration with managed-care organizations.