



Court Urged to Uphold Preemption of Design Defect Suits Involving Vaccines

WASHINGTON, July 30 -- [The Washington Legal Foundation](#) issued the following news release:

The [Washington Legal Foundation](#) (WLF) this week urged the U. S. Supreme Court to hold that federal law expressly preempts state-law products liability suits that challenge the design of widely administered childhood vaccines, which the Food and Drug Administration (FDA) has already determined to be safe and effective.

In a brief filed in *Bruesewitz v. Wyeth, Inc.*, WLF argued that Congress mandated such preemption when it adopted the National Childhood Vaccine Injury Act of 1986 (the Vaccine Act), which established a national, comprehensive, no-fault compensation program for vaccine-related injuries. WLF argued that state-court judgments against a vaccine manufacturer based on a determination that the vaccine was defectively designed would wholly undermine the Vaccine Act, which was intended to safeguard a robust childhood vaccine market.

"WLF agrees with the courts below and the great majority of federal appeals courts that have upheld Congress's express intent to preempt such design defect suits as spelled out in a federal statute, 42 U.S.C. S 300aa- 22(b)(1)," said WLF Senior Litigator Cory Andrews after filing WLF's brief. "The plaintiffs' contrary argument ignores both the unique and vital role vaccines have historically played in safeguarding the public health, as well as the national health emergency that resulted in the 1980s from the very patchwork of state tort liability that the plaintiffs now seek to revive."

The case arises in connection with a lawsuit filed by Russell and Robalee Bruesewitz, who had unsuccessfully petitioned the federal Vaccine Court to compensate their daughter's alleged injuries, which they claimed were caused by a routine Diphtheria, Tetanus, and Pertussis (DTP) vaccination administered in 1992. The Vaccine Court dismissed with prejudice the Bruesewitzes' claims for failure to establish any causal link between the administered DTP vaccine and their daughter's alleged injuries. Rather than appeal their dismissal to the Court of Federal Claims, the Bruesewitzes rejected the judgment of the Vaccine Court and filed a products liability suit against Wyeth, the vaccine's manufacturer.

The district court granted judgment for Wyeth, holding that Section 22(b)(1) of the Vaccine Act expressly preempts all design defect claims arising from a vaccinerelated injury. Section 22(b)(1) provides that "[n]o vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death ... if the injury or death resulted from side effects that were unavoidable." The U.S. Court of Appeals for the Third Circuit affirmed that decision. The Supreme Court has agreed to review the Third Circuit's decision.

In a brief urging that the appeals court be affirmed, WLF argued that the Vaccine Act was passed in the midst of a national crisis of out-of-control costs and vaccine shortages caused by an explosion in state tort litigation against vaccine manufacturers. By providing a comprehensive, no-

fault compensation regime to address vaccine-related injuries, Congress sought to protect vaccine manufacturers from the same kind of burdensome litigation that previously drove so many vaccine manufacturers from the market. Allowing a disappointed vaccine claimant who lost in Vaccine Court to then seek compensation for design defects via civil tort litigation would exacerbate, not ameliorate, the costly burden of litigation that initially prompted Congress to pass the Vaccine Act, WLF argued.

The position advanced by WLF does not leave injured vaccine recipients without remedies. For example, they are still free to pursue other, non-preempted claims against the manufacturer, such as a claim that the vaccine was manufactured negligently (i.e., not in conformance with the FDA-approved design), or that the manufacturer failed to accompany the vaccine with proper directions and warnings. Alternatively, they can pursue remedies against others who may be responsible for their injuries, such as the administering physician.

WLF is a public interest law and policy center with supporters in all 50 States. WLF devotes a substantial portion of its resources to defending free enterprise, individual rights, and a limited and accountable government.

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