



U.S. Supreme Court Decision In Bruesewitz V. Wyeth A Win For Public Health

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(BUSINESS WIRE)--Today, in a 6-2 decision, the U.S. Supreme Court affirmed the ruling of the U.S. Court of Appeals for the Third Circuit in favor of Pfizer's subsidiary Wyeth, in *Bruesewitz v. Wyeth*. The Third Circuit determined that the National Childhood Vaccine Injury Act prevents civil suits against manufacturers of FDA-approved childhood vaccines based on a claim that a particular vaccine should have been designed differently.

"Vaccines are one of modern medicine's greatest success stories," said Pfizer Executive Vice President and General Counsel Amy Schulman. "Their nearly universal administration to children is responsible for the elimination of polio and smallpox in the United States, and the near-elimination and containment of other childhood diseases. The Vaccine Act that Congress enacted nearly 25 years ago appropriately places the responsibility for determining the optimal design of life-saving childhood vaccines in the hands of expert federal agencies, not a patchwork of state tort systems. We are pleased that the U.S. Supreme Court affirmed the ruling of the Third Circuit."

The opinion of the Court, written by Justice Antonin Scalia, stated that "[The Vaccine Act] reflects a sensible choice to leave complex epidemiological judgments about vaccine design to the FDA and the National Vaccine Program rather than juries."

In amicus briefs supporting Wyeth's position, many expert medical and scientific groups, as well as the U.S. government, expressed their view that upholding the preeminence of expert federal agencies, including the U.S. Department of Health and Human Services (HHS), would benefit public health by protecting the supply of childhood vaccines.

In a concurring opinion, Justice Stephen Breyer articulated that HHS's view on this matter holds significant weight because of the importance of this case to childhood health. Justice Breyer stated that "HHS's position is particularly persuasive here because expert public health organizations support its views and the matter concerns a medical and scientific question of great importance: how best to save the lives of children."

While serious injuries from vaccines are rare, those who suffer from such injuries have a source of compensation from the vaccine compensation program, which is run by the federal government. Under the Vaccine Act, compensation may be awarded without showing any fault or defect in the administered vaccine. Today's decision leaves intact the right of individuals allegedly harmed by childhood vaccines to sue in state or federal court based on the alleged improper manufacture or inadequate labeling of a vaccine.

"We have great sympathy for the Bruesewitzes," Ms. Schulman continued. "We recognize, however, that the Vaccine Act provides for full consideration of the liability issues through the National Vaccine Injury Compensation Program. Here the Vaccine Court concluded that the petitioners failed to prove their child's condition was caused by vaccination."

In its amicus brief, the American Academy of Pediatrics and 21 other physician and public health organizations noted that a Court ruling against Wyeth could "precipitate the same crisis that Congress sought to avert in passing the Vaccine Act: 'the very real possibility of vaccine shortages, and, in turn increasing numbers of unimmunized children, and, perhaps, a resurgence of preventable diseases.'"

In its amicus brief, the U.S. Government wrote that the Vaccine Act has resulted in "a robust federal framework that encourages the development of even safer vaccines and that provides compensation where Congress deemed it appropriate."

To read the Court's decision, please visit: [\files\pressrelease_assets\pdf\09-152.pdf](#).

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