Vaccine Liability in the Supreme Court: Forging a Social Compact

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Forging a Social Compact

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On February 22, 2011, the US Supreme Court decided Bruesewitz v Wyeth LLC, holding that the National Childhood Vaccine Injury Act of 1986 (NCVIA) preempts all design defect claims against vaccine manufacturers in which the plaintiff seeks compensation for injury or death caused by a vaccine’s adverse effects. The public health implications are profound because Congress designed the NCVIA to safeguard a social compact—ensuring access to vaccines by preventing the uncertainty of litigation, while also ensuring vaccine safety and effectiveness.

The Challenge of Vaccine Availability
Vaccines are unquestionably among modern public health’s greatest triumphs. In the United States alone, the incidence of vaccine-preventable diseases declined from more than 1 million cases per year at the start of the 20th century to only a few thousand cases per year by its close. Although vaccines remain a cornerstone of public health, they are far less profitable than most biologics, causing only a few manufacturers to produce them. The vaccine supply is threatened when the market is unpredictable and manufacturers face legal liability. Consequently, several major vaccine manufacturers ceased making vaccines in the 1980s. The public remains skeptical of vaccine safety, often without scientific foundation. At the same time, vaccines do injure some patients—although serious harm is extraordinarily rare—and a fundamental principle of the US legal system is that injuries caused by unsafe products should be compensated.

Vaccine policy makers thus face dueling concerns. Vaccines must be safe, effective, available, and publicly acceptable if their public health benefits are to be realized. Safety and effectiveness can be safeguarded primarily by premarket review, which has been in place for vaccines since 1944, as well as by postmarket surveillance. However, litigation can also pressure manufacturers to make vaccines safer and to withdraw vaccines from the market if these products cause inordinate adverse effects. Manufacturers need incentives for vaccine innovation, which requires sufficient certainty about future profitability. Uncertainty about future litigation costs can drive vaccine makers from the marketplace. The valuable public good of vaccination requires that manufacturers profit while the public feels confident about safety and effectiveness.

The Vaccine Injury Compensation Program
Congress balanced these divergent interests in the NCVIA, which created the Vaccine Injury Compensation Program (VICP)—a no-fault compensation system for individuals who sustain serious adverse events after vaccination. The system, funded by a small tax on vaccines, requires individuals alleging injury to file with the US Court of Federal Claims. A special master—a court-appointed officer with special expertise—reviews claims and decides on compensation. If the adverse event is listed in the VICP’s vaccine injury table (a so-called on-table injury) and occurs within a specified time after vaccine receipt, the vaccine is presumed to cause the injury.

On-table injuries are those that are well established and unlikely due to other causes (eg, anaphylaxis within 4 hours of vaccine administration). If the injury is not listed, the claimant has the higher burden of proving biological plausibility, a logical cause-and-effect relationship, and that the injury occurred within an acceptable time frame. If this burden is met, the federal government, not the vaccine maker, pays compensation. Claimants can file traditional products liability suits in court only after losing in the VICP system, and, even then, their ability to sue is limited. This system ensures that legitimate claims are quickly processed while simultaneously stabilizing the vaccine market by substituting a predictable tax for unpredictable litigation.

Bruesewitz v Wyeth LLC
In the early 1990s, the routine childhood immunization schedule called for 3 doses of the diphtheria, tetanus, and whole-cell pertussis (DTP) vaccine followed by an additional 2 doses of DTP or an alternate formulation using an acellular pertussis component (DTaP). At the time, DTaP
was not licensed for use in the first 3 rounds of immunization, although it was in 1996, and DTaP has since replaced DTP for all 5 rounds when given to young children. When Hannah Bruesewitz received her third round of DTP in April 1992, she received the older vaccine, which had a slightly worse safety record than the vaccine currently used. Within 1 day, she developed seizures and, subsequently, was diagnosed as having a seizure disorder and developmental delays.

The Bruesewitz family filed a claim with the VICP, but seizures were not an on-table injury and they could not provide sufficient evidence to meet the off-table burden of proof, so the Court of Federal Claims denied her claim. Her parents then sued in a Pennsylvania state court. Traditionally, products liability is based on 3 grounds: a dangerous manufacturing defect, failure to provide reasonable warnings, or the product’s design is unreasonably unsafe. The family argued the third ground—that the DTaP vaccine was a safer alternative design.

The NCVIA prohibits lawsuits “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.”1 The purpose was to preempt lawsuits except those for which the producer failed to follow appropriate manufacturing practices or misbranded the vaccine by failing to provide adequate safety information. (The NCVIA also provides a defense if manufacturers include all warnings required by the US Food and Drug Administration [FDA]).

The trial and appellate courts dismissed the case, and the Supreme Court affirmed, holding that NCVIA preempts suits for an unsafe design. Justice Scalia, writing for the court, found that the statute’s plain language preempted design defect suits. Scalia noted that the failure to list design defects alongside inadequate warnings and manufacturing defects demonstrates Congress’ intent to preempt state lawsuits.

Justice Breyer concurred, stressing that Congress deliberately balanced injury compensation with the imperative of a stable vaccine market. Congress, through vaccine licensure, intended the FDA to determine when a vaccine’s design is sufficiently safe—not lay juries hearing highly technical cases.1

**The Preemption Trilogy**

With *Bruesewitz*, the Supreme Court closed a trilogy of preemption cases. In *Riegel v Medtronic Inc*, the court ruled that products liability suits against medical device manufacturers were preempted by the FDA’s premarket review system.2 Shortly after came *Wyeth v Levine*, in which the court decided that state court suits were not preempted for pharmaceuticals.3 These cases create a confusing patchwork of preemption, with different results for medical devices, pharmaceuticals, and vaccines.

Preemption can often undermine public health by harming state regulation and litigation of hazardous products, such as tobacco and firearms. Yet in *Bruesewitz*, preemption serves the public’s health and safety. Thousands of NCVIA cases have been brought alleging vaccine-caused autism. Although no credible data support this association—and well-designed, adequately powered studies reject it—a different ruling in *Bruesewitz* could have unleashed a flood of unwarranted litigation, particularly related to unfounded autism claims. Although most cases would lose, lay juries could cause manufacturers significant litigation costs, exactly the sort of unpredictability the NCVIA was designed to prevent, and what resulted in producers discontinuing manufacture of pertussis vaccines in the 1980s.

The social compact forged by the NCVIA is sound policy that leaves many unsatisfied. Manufacturers surely prefer broader liability protection, while some plaintiffs feel the legal system has left them injured but uncompensated. The NCVIA represents a compromise that safeguards the public’s health. The Supreme Court was right to protect it.

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**REFERENCES**