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Supreme Court Sides with Vaccine Manufacturers in Bruesewitz v. Wyeth LLC

February 23, 2011 by Kelly Savage

The Supreme Court, voting 6-2, ruled on Tuesday that the National Childhood Vaccine Act of 1986 (NCVIA or Act) bars state-law product liability claims against vaccine manufacturers. [*See Bruesewitz v. Wyeth LLC, FKA Wyeth, Inc.* .pdf]. The Act, designed to ensure a stable vaccine supply by limiting vaccine manufacturers' potential tort liability, created a special, company-financed, no-fault system that offers guaranteed payments to patients for injuries shown to be caused by a vaccine. The federal program has awarded more than $1.8 billion for vaccine injury claims in nearly 2,500 cases since 1989.

Design Defect Claims are Preempted under the Act

Writing for the majority, Justice Scalia noted that Congress intended to bar lawsuits against vaccine manufacturers based on so-called design defects. "Vaccine manufacturers fund from their sales an informal, efficient compensation program for vaccine injuries; in exchange they avoid costly tort litigation and the occasional disproportionate jury verdict. Congress enacted this deal to coax manufacturers back into the vaccine market."

The case involved a lawsuit over the injection of a diphtheria, tetanus, and pertussis (DPT) vaccine to six-month old Hannah Bruesewitz. After her parents' claims were rejected under the federal compensation system, Hannah's parents filed suit against the vaccine manufacturer in state court claiming their daughter developed a seizure disorder and experienced serious developmental delays from toxins in the vaccine. The parents argued that a safer alternative had been available but was not used.

The vaccine manufacturer removed the case to federal court and subsequently sought dismissal under the express preemption provision of the Act, which protects manufacturers from most state-law claims where there was an unavoidable injury and where the vaccine was both properly prepared and administered with the proper directions and warnings:

> 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.

Plaintiffs opposed dismissal, arguing that the DPT manufacturer knew there was a safer version of the vaccine that could have been used. They maintained that the vaccine maker should be liable despite the Act's express preemption provision because it chose not to produce the available safer vaccine, thereby rending the injury *avoidable*. The federal district court and later the Third Circuit Court of Appeals both ruled that the Act barred such claims.

In rejecting plaintiffs' claims and affirming the Third Circuit's decision, Justice Scalia wrote: "If a manufacturer could be held liable for failure to use a different design, the word 'unavoidable' would do no work. A side effect of a vaccine could *always* have been avoidable by use of a differently designed vaccine not containing the harmful element."

Justices Sotomayor and Ginsburg dissented. They maintain that the ruling "leaves a regulatory vacuum in which no one ensures that vaccine manufacturers adequately take account of scientific and technological advancements when designing or distributing their products." Justice Kagan took no part in the consideration or decision of the case.

Future Implications

The decision has broad ramifications for the vaccine manufacturers as well as the public. The Court's opinion effectively ends pending vaccine-related autism litigation. The decision also ensures the continuing viability of a stable vaccine market in the United States.

The Court's position may also bode well for generic drug manufacturers later this term in *Mensing*, since the Court acknowledged the economic realities of increasing tort liability on vaccine manufacturers when deciding these claims were preempted. These same economic realities apply equally to generic drug manufacturers.