Sedgwick LLP

Supreme Court Sides With Vaccine Manufacturers; State-Law Design Defect Claims Preempted

Pharmaceutical Law Update

March 2011

By: Kelly Savage Day

The U.S. Supreme Court, in a 6-2 decision, ruled that the National Childhood Vaccine Act of 1986 (NCVIA) preempts state-law design defect claims against vaccine manufacturers. [*See* *Bruesewitz v. Wyeth LLC, FKA Wyeth, Inc.*] The NCVIA, designed to ensure a stable vaccine supply, establishes a special, company-financed, no-fault system that guarantees payments to patients for injuries caused by a vaccine, but, in exchange, provides significant tort liability protection to the vaccine manufacturer. In considering the NCVIA's preemptive effect, Justice Antonin Scalia, writing for the majority, found that the NCVIA itself "suggests that the design of the vaccine is a given, not subject to question in [a] tort action" and, therefore, Congress must have intended to bar lawsuits against vaccine manufacturers based on so-called design defects.

Bruesewitz v. Wyeth LLC, FKA Wyeth, Inc.

In *Bruesewitz*, the plaintiff, Hannah Bruesewitz, alleged that she suffered seizures and developmental delay as a result of the injection of a diphtheria, tetanus and pertussis (DPT) vaccine when she was only 6 months old. After her claim filed under the federal compensation system was rejected, Hannah's parents filed suit against the vaccine manufacturer in state court alleging their daughter's injuries were caused by toxins in the vaccine – and 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 NCVIA, which protects manufacturers from state-law claims for injuries or death if they resulted from side effects that were unavoidable and the vaccine was properly prepared and accompanied with proper warnings. Specifically, the NCVIA states:

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.

The 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 NCVIA'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 NCVIA barred such claims.

In rejecting the plaintiffs' claims and affirming the Third Circuit Court of Appeals' decision, Justice Scalia stated: "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 Sonia Sotomayor and Ruth Bader 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 Elena Kagan took no part in the consideration or decision of the case.

Future Implications

The decision has broad ramifications for vaccine manufacturers as well as the public. The Supreme Court's opinion effectively ends pending vaccine-related autism litigation – the great bulk of which is premised on a so-called "design defect." 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 when the Court considers whether the Federal Food, Drug and Cosmetic Act preempts failure-to-warn claims against generic manufacturers in *PLIVA, Inc., et. Al, v. Mensing*, later this term, as the same economic realities of

increasing tort liability that influenced the Court's decision in *Bruesewitz* apply equally to generic drug manufacturers.

Related Practices:

Appellate

Drug & Medical Device

Products Liability