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Client Alert

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Georgia Supreme Court Holds Federal Vaccine Act Does Not Preempt Design Defect Claim

On October 6, 2008 in American Home Products Corp. v. Ferrari, Ga., No. S07G1708, the Georgia Supreme Court unanimously ruled that federal vaccine law does not preempt all state law design defect claims involving vaccines approved by the U.S. Food and Drug Administration, but instead requires a case-by-case inquiry to determine whether the adverse side effects of a particular vaccine were unavoidable.

The plaintiffs alleged that their minor son suffered neurological damage after receiving a vaccine made with a mercury-based preservative, thimerosal. They sued both the manufacturer of the vaccine and the makers of thimerosal, claiming that the vaccine could have and should have been manufactured without a mercury-based preservative. The defendants argued that since the vaccine had been approved by the FDA, any vaccine related injuries were "unavoidable" and not subject to state tort claims.

The decision by Justice Carley involved interpretation of the express preemption clause in the 1986 National Childhood Vaccine Injury Compensation Act ("Vaccine Act"), which reads as follows:

> 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.
> 42 U.S.C. § 300aa-22(b)(1)

Acknowledging that the Vaccine Act meant to preempt some state law claims, the Georgia Supreme Court, nevertheless, concluded that Congress did not intend to bar all design claims for federally approved vaccines, but only those claims where the injurious side effects from the vaccine are unavoidable by means other than proper manufacturing and packaging. Consequently, the Court held that the Vaccine Act would not shield a manufacturer from liability if the injurious side effects could be avoided by a feasible alternative design. The Court held that this determination should be done on a case-by-case basis.

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The Georgia decision conflicts with the judgments of federal courts in Pennsylvania and Texas, and a state court in New York which held that the Vaccine Act preempts all design defect claims. The Georgia high court reasoned that those decisions erroneously construed comment k to Section 402A of the Restatement (Second) of Torts, which exempts from strict liability the seller of an unavoidably unsafe product. The Court noted that Congress used comment k as a model for Section 300aa-22(b)(1) of the Vaccine Act, but explained the majority of jurisdictions apply comment k in a limited fashion and use a case-by-case inquiry to determine whether a product is unavoidably unsafe. Accordingly, it concluded that its decision to limit preemption was more consistent with the majority approach to comment k.

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