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This Week's Double Feature

Georgia High Court Finds the National Childhood Vaccination Injury Compensation Act of 1986, 42 U.S.C. § 300aa-1 et seq. Does Not Preempt State Products Liability Actions

By Jeremy W. Gregory, Balch & Bingham LLP

On October 6, 2008, the Georgia Supreme Court issued an opinion finding that The National Childhood Vaccination Injury Compensation Act of 1986, 42 U.S.C. §§ 300aa-1 et seq. (the "Vaccination Act") does not preempt state design defect claims. *Ferrari v. American Home Products Corp.*, 2008 Ga. LEXIS 833, *18 (2008) (Ferrari II). The Vaccine Act provides in pertinent part: "No vaccine manufacturer shall be liable in a civil action for damages arising from 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).

The plaintiffs' asserted strict liability and negligence claims, alleging their son suffered neurological damage caused by multi-dose vials of vaccines containing the preservative thimerosal that were manufactured by defendants. *Ferrari v. American Homes Products Corp.*, 286 Ga. App. 305, 305, 650 S.E.2d 584, 586-587 (2007) (*Ferrari I*). The trial court granted partial summary judgment in favor of the defendants, finding the plaintiffs' design defect claims were preempted by the Vaccine Act. *Id.*

The plaintiffs appealed, arguing 1) design defect cases are barred by the Vaccine Act only if side effects are determined to be unavoidable on a case-by-case basis, and 2) in this case, their son's injuries could have been prevented if Defendants used mercury-free preservatives, or manufactured single dose vials. *Ferrari I*, 286 Ga. App. at 208. Defendants argued that any vaccine-related injury should be deemed unavoidable under the Vaccine Act, so long as the vaccine was properly prepared and accompanied by proper warnings. *Id.* The Georgia Court of Appeals agreed with the plaintiffs and found that *Bates v. Dow Agrosciences*, 544 U.S. 431, 125 S. Ct. 1788, 161 L. Ed. 2d 687 (2005), required it to "accept a reading [of the Vaccine Act] that disfavors preemption." *Ferrari I*, 286 Ga. App. at 312.

The Supreme Court of Georgia granted certiorari and affirmed, albeit on different grounds. The Georgia Supreme Court found based on the text of the statute and an analysis of congressional intent, that the Vaccine Act "clearly does not preempt all design defect claims against vaccine manufacturers, but rather provides that such a manufacturer cannot be held liable for defective design if it is determined, *on a case-by-case basis*, that a particular vaccine was unavoidably unsafe." *Ferrari II*, 2008 Ga. LEXIS 833, *18 (emphasis added).

Before *Ferrari II*, every court addressing the issue of vaccine design defect preemption found the Vaccine Act provides blanket preemption of any state-law defective design claims. See *Bruesewitz v. Wyeth, Inc.*, 508 F. Supp. 2d 430 (E.D. PA 2007); *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289 (E.D. PA 2007); *Blackmon v. American Home Products Corp.*, 328 F. Supp. 2d 659 (S.D. TX 2004); *Miltrano v. Lederle Laboratories*, 769 N.Y.S.2d 839 (2003). *Bruesewitz*, *Sykes*, *Blackmon*, and *Miltrano* expressly considered, and rejected, the case-by-case analysis now adopted by Georgia. *Bruesewitz*, 508 F. Supp. 2d (“allowing case-by-case inquiries into whether a particular vaccine is unavoidably unsafe would do nothing to protect vaccine manufacturers from suit from design defects, since such an inquiry would require a finder of fact to consider the manufacturer’s design against a purported safer alternative”); *Sykes*, 484 F. Supp. 2d at 301 (“the purposes of the Vaccine Act would not be served if defective design claims could be tried before juries”); *Blackmon*, 328 F. Supp. 2d at 665. (“to permit juries in each state to pass judgment on the design of childhood vaccines could interfere with the federal government’s efforts to establish a uniform national standard for childhood vaccines”); *Miltrano*, 769 N.Y.S.2d at 845 (“Congress did not intend that the national vaccine policy be determined by the vagaries of a jury’s determination on a case-by-case basis”).

The immediate implications of the *Ferrari II* decision are significant. Manufacturers of vaccines can be subject to strict liability and negligence claims despite the Vaccine Act. *Ferrari II*, 2008 Ga. LEXIS 833, *21. The Georgia Supreme Court appears to intend that whether an “injury or death resulted from side effects that are unavoidable” will be determined on a case-by-case basis as a question of fact. *Id.* at *10. This holding may practically eliminate preemption of vaccine-related claims.

Other states may follow Georgia’s example, but at this early stage it is impossible to determine whether this decision is an anomaly or an emerging trend. Until the United States Supreme Court provides a definitive answer, the cost of defending a vaccine-related design defect in Georgia has increased significantly.

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