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THE PREEMPTIVE SCOPE OF THE VACCINE ACT: MUST UNAVOIDABLE DAMAGES BE DETERMINED ON A CASE-BY-CASE BASIS?

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On January 11, 2011, the Superior Court of Pennsylvania decided *Wright v. Aventis Pasteur, et al.*, 2001 Pa. Super. 9 (2011) in which it determined as a matter of first impression that the National Childhood Vaccine Act (Vaccine Act) does not preempt any design defect claim based on state law, but rather requires case-by-case inquiry to determine whether a particular vaccine's side effects are unavoidable.

In a complaint filed in the Court of Common Pleas on May 29, 2003, plaintiffs alleged that their son suffered from autism, or autism-related symptoms as a result of exposure to multiple vaccines containing thimerosal (that contains ethyl mercury). Plaintiffs alleged negligent design defect and failure to warn claims. Relying on the 3rd Circuit's decision in *Bruesewitz v. Wyeth*, 561 F.3d 233 (3d Cir. 2009), *cert. granted*, --- U.S.---, 130 S.Ct. 1734, 176 L.Ed.2d 211 (2010), the vaccine defendants asserted that plaintiffs' claims were preempted under the Vaccine Act, that the circuit had interpreted to preempt all strict liability and negligent design defect claims, and that the plaintiffs failed to overcome the presumption of proper warnings necessary to pursue their failure to warn claims. Noting that Pennsylvania "appellate courts are not obligated to follow the 3rd Circuit on issues of federal law," the superior court rejected the circuit's opinion regarding preemption of state law negligent design defect claims yet recognized that the U.S. Supreme Court has granted certiorari in *Bruesewitz* and "may address the issue before us."

The debate centers on the legislative history of the preemptive scope of § 300aa-22(b)(1) of the Vaccine Act which states that no vaccine manufacturer shall be liable for damages that were "'*unavoidable*' even though the vaccine was properly prepared and was accompanied by proper directions and warnings." Relying on the 1986 report of the House Committee on Energy and Commerce, the 3rd Circuit concluded that the Vaccine Act preempts *all* design defect claims which were approved by the FDA. As Judge Shogan stated in dissent in *Wright*, "use of a case-by-case approach is unnecessary because an FDA-approved design includes the side effects of that vaccine, and, [t]herefore, by statutory definition, [makes] the unavoidably unsafe product subject to … immunity." *Wright*, *supra*, 2011 Pa.Super. 9 at *31 (Shogan, J., dissenting).

The 1986 Act, however, did not include a funding source for the compensation system, or Vaccine Court, it created to compensate victims of vaccine-related injuries. The 1987 report of the House Committee on the Budget which proposed legislation to fund the compensation system the following year stated that "there should be no misunderstanding that the Act sought to decide as matter of law whether vaccines were unavoidably unsafe or not. This question is left to the courts to determine in accordance with applicable law." *Wright*, *supra*, 2011 Pa.Super. 9 at *25 (citing U.S.C.C.A.N. at 2313-2365). The superior court found the intent espoused in the 1987 report as a plausible interpretation of congressional intent which compelled it to accept the interpretation which disfavored preemption. The court therefore found that a determination of whether the vaccine was "unavoidably unsafe" must be made on a case-by-case basis.

Ironically, swirling behind the superior court's decision is the recent editorial in the *British Medical Journal, BMJ 2011; 342:c7452* that the 1998 study by Dr. Andrew Wakefield linking autism to childhood vaccines was fraudulent. The *Journal*, which previously published the investigation, concluded that medical histories of all 12 of the patients whose cases formed the basis of the study had been misrepresented or altered. The superior court, however, did not consider any expert evidence on causation, it simply remanded the case to the trial court "to determine whether the injury causing side effects were unavoidable" and, as such, whether plaintiffs' negligent design defect claims are preempted under the Act. Whether the case ever reaches trial will be determined in large part by the Supreme Court's decision in *Bruesewitz*. Argument was held before the Supreme Court last October and a decision is expected in the spring.