Legal Backgrounder

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DOES FEDERAL VACCINE ACT PREEMPT STATE PRODUCT LIABILITY SUITS?

by

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Preemption continues to be the hot ticket item for product liability litigation involving drug products and medical devices. Within the realm of vaccine injury cases, however, practitioners may have believed that preemption was a relatively settled issue in favor of vaccine manufacturers after the passage of the National Childhood Vaccine Injury Compensation Act of 1986[1] (the "Vaccine Act"). Indeed, both state and federal courts in Pennsylvania, Texas and New York have interpreted the Vaccine Act as restricting product liability litigation.[2] Most recently, this includes the Court of Common Pleas of Pennsylvania in *Wright v. Aventis Pasteur, Inc., et al.*, 2008 WL 4144386 (C.P. Pa. Aug. 27, 2008). One state court, however, just months after the *Wright* decision, held otherwise. *American Home Products Corp. v. Ferrari*, 668 S.E.2d 236 (Ga. 2008).

The U.S. Supreme Court's recent decision in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), gives us pause to consider the preemptive effect of the Vaccine Act, an issue the vaccine manufacturer in *Ferrari* has asked the Supreme Court to consider by its filing of a petition for certiorari on March 5, 2009.[3] The competing interpretations of preemption protections of the Vaccine Act contained in the *Wright* and *Ferrari* decisions reveal that there is still room for a debate in childhood vaccine cases. The Third Circuit Court of Appeals has recently highlighted the debate by rejecting the *Ferrari* court's reading of the Vaccine Act as "[un]compelling", and holding that design defect claims are expressly preempted. *Bruesewitz v. Wyeth, et al*, 2009 WL 792468 (3d. Cir. 2009).

The Vaccine Act. Congress enacted the Vaccine Act to provide a "new system for compensating individuals who have been injured by vaccines routinely administered to children." *Wright*, at *4 (internal quotations and citations omitted). Section 300aa-22(b) of the Vaccine Act offers preemption (and thus no liability in a state court products liability suit) to vaccine manufacturers in certain circumstances:

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[1] 42 U.S.C. § 300aa-1 et seq.

[2] *See, e.g., Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 659 (S.D. Tex. 2004) (finding Vaccine Act preemption).

[3] *American Home Products v. Ferrari*, No. 08-1120.

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> (1) 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. (2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug and Cosmetic Act and Section 351 of the Public Health Service Act.

Thus, based on their interpretation of § 300aa-22(b)(1), the courts have generally held that the Vaccine Act serves to preempt product liability suits against manufacturers of FDA-approved vaccines. Under the Vaccine Act, any preempted lawsuit would then be administered through a federal no-fault system for compensating vaccine-related injuries or death using a lower standard of proof in specialized vaccine courts.

Role of thimerosal. Both the *Wright* and *Ferrari* courts analyzed the preemptive effect of the Vaccine Act in cases where plaintiffs claimed injury due to administration of vaccines containing thimerosal. Thimerosal is a mercury-containing compound which was used as a preservative in various vaccine strains until 1999, when the CDC and the American Academy of Pediatrics urged manufacturers to phase out its use. Although no reliable scientific evidence exists to show that use of thimerosal causes neurological damage or autism-related diseases[4], thimerosal and its alleged potential to cause autism in children remains a source of heated debate. On February 12, 2009, however, three Special Masters in the U.S. Court of Claims separately held there was insufficient scientific evidence to support the parents' contentions that the MMR (measles/mumps/rubella) vaccine was responsible for their childrens' neurological injuries. Despite the Special Masters' opinions, this debate will likely continue as the subject of future litigation.

***Presumption of preemption in* Wright**. The Pennsylvania Court of Common Pleas affirmed the trial court's grant of summary judgment on behalf of Aventis Pasteur, Merck, and Wyeth (the "Vaccine Defendants"), holding that "Plaintiffs' design defect claim and failure to warn claims against the Vaccine Defendants are preempted by the Vaccine Act . . . ." *Wright*, at *1.

In *Wright*, the plaintiffs alleged that the infant plaintiff suffered neurological damage, specifically, a condition within the "Autism Spectrum Disorder," following several injections of vaccines containing thimerosal. *Wright*, at *2. The plaintiffs sued the Vaccine Defendants asserting various theories of liability including a negligent failure to warn and design defect.

In their motions for summary judgment, the Vaccine Defendants argued that the Vaccine Act (1) operated to preempt the plaintiffs' design defect claims and (2) provided a presumption of proper warnings. In support of their motions, the Vaccine Defendants relied on the approvals and licenses granted by FDA for each of the subject vaccines, as well as submissions of the FDA-approved labeling, which disclosed that thimerosal was part of the vaccine's formula. *Wright*, at *3.

Plaintiffs countered that the Vaccine Defendants misread the Vaccine Act. Plaintiffs argued that

[4]Despite the CDC and AAP request for manufacturers to discontinue use of thimerosal, most scientific and regulatory bodies including CDC, AAP, American Medical Association ("AMA"), Food and Drug Administration ("FDA"), National Institutes of Health ("NIH"), and World Health Organization ("WHO") have all explicitly rejected the hypothesis that thimerosal is causally linked to neurological damage or autism.

preemption was generally disfavored in the law, and therefore the Vaccine Defendants would have to show (on a case-by-case basis) that the injuries were an "unavoidable" result of the vaccine before preemption would be available.

The *Wright* court recognized that § 22 of the Vaccine Act is an express preemption provision that "clearly indicates congressional intent to preempt state tort law standards and create legal protections that apply in any civil action brought against a vaccine manufacturer." *Wright*, at *5 (internal citations and quotations omitted). The court also examined other decisions that reviewed the plain language of the Vaccine Act, as well as its legislative history. Ultimately the defendants persuaded the court that preemption was preferred for any case involving an approved vaccine formulation. In concluding that Plaintiffs' design defect claims were preempted, the *Wright* court specifically rejected the case-by-case approach: "case-by-case determination of whether a vaccine was unavoidably unsafe would defeat the protection the [Vaccine] Act was intended to provide vaccine manufacturers." *Wright*, at 9 (quoting *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 302 (E.D. Pa. 2006)).

In order to defeat the presumption of preemption, the *Wright* court explained, Plaintiffs bore the burden to demonstrate that (1) the Vaccine Defendants "engaged in fraud or intentional and wrongful withholding of information from the FDA while seeking approval of the vaccine," (2) the Vaccine Defendants engaged in "intentional and wrongful withholding of information relating to the safety or efficacy of the vaccine after its approval," or (3) by "clear and convincing evidence" show that the Vaccine Defendants failed to exercise "due care notwithstanding its compliance with the applicable federal laws and regulations." *Wright*, at 12 (internal quotations omitted). None of these conditions were met, and thus the claims were preempted.[5]

The* Ferrari *court adopts a case-by-case approach. In stark contrast, the Supreme Court of Georgia affirmed the state Court of Appeals' finding that preemption did not apply without a case-by-case determination that the alleged injury was indeed "unavoidable." *Ferrari*, at 242.

The Ferraris contended in their suit against Wyeth and GlaxoSmithKline that their infant son, who had previously met all of his childhood milestones, stopped speaking at 18 months after receiving a vaccine, which contained thimerosal. The Ferraris' son was subsequently diagnosed with autism. *Ferrari*, at 237.

Despite the lack of scientific proof supporting their theory that thimerosal-containing vaccines caused autism, plaintiffs claimed that safer, non-thimerosal formulations of the vaccines could have been manufactured. *Ferrari*, at 237. Thus, plaintiffs argued, unless the defendants showed that the side effects were "unavoidable," preemption could not apply in this case.

The defendants argued that plaintiffs' interpretation of the Vaccine Act did not recognize the congressional intent to favor preemption in vaccine cases where there was no claim that the vaccine was manufactured or labeled out of compliance with governing regulations. *Ferrari*, at 235.

The Georgia Supreme Court ultimately held that the "Vaccine Act does not preempt all design defect claims, but instead provides that a vaccine manufacturer cannot be held liable for defective design if it is determined, on a case-by-case basis, that the injurious side effects of the particular vaccine were

[5]The *Wright* court noted multiple times that had the issue been raised by the parties, it would also have found plaintiff's claim to be impliedly preempted under the Food Drug and Cosmetics Act ("FDCA"). *Wright*, at n.1 ("[T]his court notes it would have also found Plaintiffs' failure to warn claims against . . . the Vaccine Defendants . . . impliedly preempted by the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*") (citing *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 523-38 (E.D. Pa. 2006) (finding the plaintiffs failure to warn claims impliedly preempted) and *Sykes v. Glaxo-SmithKline.* 484 F. Supp. 2d 289 (E.D. Pa. 2006) (finding the plaintiffs' failure to warn conflict preempted)).

unavoidable." *Ferrari*, at 237-38. The *Ferrari* court recognized the existence of the express preemption provision contained within § 22 of the Vaccine Act, but disagreed with previous courts' interpretations. Specifically, the Georgia Supreme Court read the Vaccine Act to first require a demonstration that the vaccine's side effects were "unavoidable," and that the presumption for preemption is *dis*favored where a different interpretation (i.e., case-by-case analysis) may exist. *Ferrari*, at 242.

The *Ferrari* decision made clear that the court was concerned that adopting a presumption favoring preemption could discourage vaccine manufacturers from exploring and creating safer alternatives. The *Ferrari* court reasoned that public policy recognized that manufacturers were in the best position to innovate and create safer alternative products, and that recognizing presumptive preemption would "have the perverse effect of granting complete tort immunity from design defect liability to an entire industry." *Ferrari*, at 243 (internal citations and quotations omitted).

Implications for the future. As mentioned previously, a petition for writ of certiorari was filed in the *Ferrari* case on March 5, 2009. The competing interpretations of statutory construction may interest the Supreme Court, making the petition one worth close monitoring. If the Court does grant review, it will be interesting to see whether manufacturers will fare better under the Vaccine Act's express preemption provisions than they did with arguments for implied preemption pursuant to FDCA. It is worth noting that, had the implied preemption argument been accepted, plaintiffs would have been foreclosed from compensation for their injuries, whereas the Vaccine Act was created to provide "an appealing alternative to the tort system." *Wright*, at 9. It remains to be seen whether this legislatively-created compensation system will affect future court decisions.

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