

P R O D U C T L I A B I L I T Y

A L E R T

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2011DESIGN DEFECT CLAIMS AGAINST VACCINE
MANUFACTURERS ARE PREEMPTED BY FEDERAL LAW

By Tracey Dolin Waldmann

On February 22, 2011, in *Bruesewitz v. Wyeth, Inc.*, the U.S. Supreme Court held in a 7–2 decision that the National Childhood Vaccine Injury Act of 1986 (“Vaccine Act”) preempts all design defect claims brought against vaccine manufacturers. The case is not only a victory for supporters of federal preemption, but signals that the Court is willing to find “express preemption” in a federal statute that many criticize as not expressly preempting state law claims. This willingness, however, is not likely a harbinger of expansion of the federal preemption doctrine, but rather, evidence of the Court’s consideration of factors other than the words of the statute, such as the effect of rampant lawsuits on a particular industry, and strong public policy considerations.

Express preemption occurs when a federal statute contains a clause that expressly preempts state law, such as “this Act expressly preempts state law claims.” In such cases, the preemption is clear and the only issue may be the scope of the preemption. After the Supreme Court’s 2009 decision in *Wyeth v. Levine*, in which the Court ruled that approval of a drug’s label by the U.S. Food and Drug Administration (“FDA”) did not preempt state law claims for insufficient drug safety warnings, it seemed that the Court was taking a narrow view of federal preemption, at least in the pharmaceutical industry. Since there is no express preemption provision of failure to warn claims in the Federal Food, Drug and Cosmetic Act (“FDCA”), Wyeth argued in *Levine* that it would have been impossible for it to comply with state law labeling requirements without violating FDA requirements. The Supreme Court rejected Wyeth’s “impossibility” or “conflict” preemption argument and stated that “[i]f Congress thought state-law suits posed an obstacle to its objective, it surely would have enacted an express pre-emption provision at some point during the FDCA’s 70-year history.” It seemed from this statement that in order for federal law to preempt state law, at least with regard to failure to warn claims in the pharmaceutical industry, an express statement of preemption in the federal statute was needed.

In *Bruesewitz*, Wyeth relied on express preemption and argued that the Vaccine Act expressly preempted the plain-

tiffs’ state design defect claims. The difficulty Wyeth faced was that the Vaccine Act does not state in absolute terms that it preempts all design defect claims. However, the Court determined Congress’s intent to expressly preempt state law design defect claims through statutory interpretation as well as reliance on outside sources.

At issue in *Bruesewitz* was whether protections under the Vaccine Act for vaccine manufacturers included immunity from state law design defect claims for “unavoidable” adverse side effects. Section 300aa-22(b)(1) of the Vaccine Act states “[n]o vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death ... 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 parties offered different interpretations for the word “unavoidable.” The interpretation favored by the vaccine manufacturers was that if the injury is caused by a vaccine, the injury is deemed unavoidable (assuming the vaccine contained no manufacturing defects and had proper warnings), and therefore, the Vaccine Act preempts state claims. The interpretation favored by claimants required a case-by-case analysis by a fact finder to determine whether the injury was unavoidable thereby permitting state tort design defect claims.

Justice Scalia, writing for the majority, and Justice Sotomayor, writing for the dissent (joined by Justice Ginsberg), sparred over the interpretation of the word “unavoidable” as well as the grammatical significance of the words “if” and “even though” in the statute. Although the majority maintained that it relied solely on its statutory interpretation, as Justice Breyer states in his concurring opinion, “the textual question considered alone is a close one.” What seemed to sway the Court in favor of preemption was the history surrounding the Vaccine Act. The majority opinion begins with the history of the Vaccine Act and describes the dramatic increase in lawsuits in the mid-1980s against vaccine manufacturers. The Court states that the lawsuits

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destabilized the vaccine market and led two of the three manufacturers of the diphtheria, tetanus, and pertussis (“DTP”) vaccine to withdraw from the market, as well as a vaccine shortage in 1984. The Court also noted that prior to the passage of the Vaccine Act, plaintiffs bringing state tort claims were not being adequately compensated. The Vaccine Act was passed in 1986 to strike a balance between compensating those injured by vaccines and the viability of the vaccine industry. The Vaccine Act created a no-fault compensation program — Vaccine Court — in which the claimant must seek relief before filing suit. The claimant, however, has the option of accepting the Vaccine Court’s judgment or rejecting it and seeking relief in state court. The vaccine manufacturers received protections under the Vaccine Act such as: immunity from liability for failure to warn if they complied with all regulatory warnings; and immunity from liability for punitive damages absent failure to comply with regulatory requirements, fraud, intentional wrongdoing, or illegal activity.

A key consideration in this case was the evidence that a flood of lawsuits would negatively affect the industry and jeopardize the supply of childhood vaccines. The threat of a flood of lawsuits is not mere conjecture. Vaccine manufacturers likely would have faced a large number of lawsuits based on claims from families of autistic children claiming a link between a formerly used mercury based preservative in vaccines and autism, despite studies finding no link.

No doubt the *Bruesewitz* case presents some unique factors such as a national interest in vaccinating children against

preventable diseases, and an alternative system of no-fault compensation. Nevertheless, it does suggest that the Supreme Court may not take a hard stance in requiring an unequivocal, or absolute, express preemption provision before finding state law claims preempted. Other factors such as public policy considerations, and importance of maintaining a viable industry to provide vaccines or prescription drugs, may convince the Court that federal preemption was Congress’s intent. ♦

This document is a basic summary of legal issues. It should not be relied upon as an authoritative statement of the law. You should obtain detailed legal advice before taking legal action.

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