Client Alert.

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Another Liability Shield for Vaccine Manufacturers:
U.S. Supreme Court Rules that Design Defect Claims Against Vaccine Manufacturers Are Preempted

By Erin Bosman and Julie Park

On February 22, the Supreme Court issued its decision in *Bruesewitz v. Wyeth*, 562 U.S. __ (2011). The Court's 6-2 opinion, written by Justice Scalia (Justice Kagan took no part in the decision), held that design defect claims against vaccine manufacturers are preempted by the National Childhood Vaccine Injury Act of 1986 ("NCVIA" or "Act").

NATIONAL CHILDHOOD VACCINE INJURY ACT OF 1986

The NCVIA was enacted in response to increasing tort claims against vaccine manufacturers, their inability to obtain liability insurance, and the attendant fear of a vaccine shortage if manufacturers decided to exit the market. The Act created a no-fault system of compensation for claimants who demonstrate that they have suffered an adverse side effect from a vaccine. In return, vaccine manufacturers are significantly shielded from tort liability. A claimant is only permitted to file suit after seeking relief through the compensation system. In addition, manufacturers are generally not liable for failure-to-warn claims if they are in regulatory compliance. The immunity relevant to this case (42 U.S.C. § 300aa-22(b)(2)) limits liability for a vaccine's unavoidable side effects:

> 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.

BACKGROUND

The claimant, Hannah Bruesewitz, was injured after receiving a diphtheria, tetanus, and pertussis ("DTP") vaccine as an infant in 1992. After her claim for compensation was denied, she and her family filed suit in Pennsylvania state court, alleging that her injuries were caused by the vaccine's defective design. Wyeth, the successor-in-interest to the vaccine manufacturer, removed to federal court, where Wyeth's motion for summary judgment was granted on the grounds that the design defect claim was preempted. The Third Circuit affirmed.

THE COURT'S PREEMPTION ANALYSIS

The Court conducted a textual analysis of the statutory language and determined that, because a vaccine's side effect "could *always* have been avoidable by use of a differently designed vaccine," the design of the vaccine is not open to attack by tort claims, which are therefore preempted. Only the remaining two of the "known triumvirate of grounds" for product liability cases—defective manufacture and inadequate warnings—are explicitly mentioned and subject to tort claims. The majority rejected any notion that the term "unavoidable" refers to comment *k* of the Restatement (Second) of Torts § 402A, and therefore rejected that a case-specific showing must be made that a product is "quite incapable of being made safer for [its] intended use."

The Court further reasoned that the regulatory scheme governing vaccines supported the Court's textual analysis of the statute, in that the manufacturing process and labeling of vaccines are pervasively regulated by the FDA. "Material noncompliance with any . . . FDA regulation[] could cost the manufacturer its regulatory-compliance defense." In contrast, "the Act, which in every other respect micromanages manufacturers, is silent on how to evaluate competing designs," offering strong support for the proposition that manufacturers cannot be held liable for design defects.

The Court also found that the Act effectively achieves the two benefits of design-defect torts: (1) promoting the improvement of product designs, and (2) compensating injuries. Moreover, allowing design-defect claims, which "are the most speculative and difficult type of products liability claim to litigate," would defeat the Act's purpose of encouraging manufacturers to enter or remain in the vaccine market.

IMPLICATIONS OF *BRUESEWITZ*

Of the "triumvirate" of product liability claims—design defect, manufacturing defect, and failure to warn—failure-to-warn claims were already preempted by the Act (assuming regulatory compliance). Under *Bruesewitz*, design defect claims are also preempted, leaving vaccine manufacturers open only to liability for manufacturing defect claims. Although the decision was narrowly tailored to vaccines and vaccine manufacturers, the Court makes a number of statements that may be extended to other fields. In particular, the Court suggests that "more than 90" federal regulations can constitute pervasive regulation, and that a regulatory compliance defense can be defeated only by "[m]aterial noncompliance" with federal regulations. These suggestions could conceivably be used to a defendant's advantage in product liability lawsuits involving highly regulated products, such as prescription drugs, or where statutory compliance is raised as a defense.

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