BRUESEWITZ V. WYETH: EXPRESS PREEMPTION RETURNS TO THE FORE

February 23, 2011

To Our Clients and Friends:

On February 22, 2011, the Supreme Court of the United States issued its decision in the closely watched case, *Bruesewitz v. Wyeth*. In a 6-2 opinion written by Justice Scalia (Justice Kagan took no part in the decision), the Court held that the National Childhood Vaccine Injury Act of 1986 ("NCVIA") both preempts and bars design defect claims against vaccine manufacturers. Justice Breyer concurred separately, and Justices Sotomayor and Ginsburg dissented.

The case arose out of a lawsuit filed by the parents of Hannah Bruesewitz, who had unsuccessfully petitioned the federal Vaccine Court for compensation for their daughter's alleged injuries, which they contended were caused by a routine Diptheria, Tetanus and Pertussis ("DTP") vaccination administered in 1992. The Vaccine Court dismissed the claims for failure to establish causation. The plaintiffs rejected that judgment (which included an award of over $125,000 for fees and costs even though the claim was unsuccessful) and filed a products liability suit against Wyeth in Pennsylvania state court. Wyeth removed the suit to the federal district court, which granted summary judgment in Wyeth's favor, holding that Section 22(b)(1) of the NCVIA expressly preempts all design defect claims arising from a vaccine-related injury. The U.S. Court of Appeals for the Third Circuit affirmed. Yesterday, the U.S. Supreme Court agreed. Wyeth's position in the Supreme Court was supported by a host of heavy-hitting *amici*, including the U.S. government and expert medical societies like the American Academy of Pediatrics.

The majority opinion relied heavily on textual analysis of the NCVIA, which is an unusual and highly specific statute. Nonetheless, the case may well have broader implications, in that it indicates that the Court continues to be receptive to express preemption analysis (which applies, for example, to the Medical Device Amendments of the Food and Drug Act) even after its 2009 decision rejecting implied preemption in *Wyeth v. Levine*. Even more fundamentally, the majority evidenced discomfort with the prospect of juries operating under a patchwork of state laws, many with amorphous reasonable care standards, and disrupting the regulatory judgments of expert federal agencies. Justice Scalia wrote that the omission of a design defect claim under the NCVIA "reflects a sensible choice to leave complex judgments about vaccine design to the FDA and the National Vaccine Program rather than juries." The concurrence by Justice Breyer was even blunter: "petitioners'

interpretation of the Act would undermine its basic purposes by threatening to 'halt the future production and development of childhood vaccines in this country,' *i.e.*, by 'threaten[ing] a resurgence of the very problems which . . . caused Congress to intervene' by enacting this statute."

PREEMPTION UNDER THE NCVIA

By 1986, all but one manufacturer of childhood vaccines had dropped out of the U.S. market in the wake of an explosion in tort suits based on allegations of vaccine-related injuries. Public health officials were deeply concerned both about the widespread health implications of declining vaccination rates and the prospect of vaccine shortages. At the same time that suits were multiplying, however, many complaints arose that obtaining compensation for legitimate vaccine-inflicted injuries was too costly and difficult. Congress attempted to both address the stabilization of the vaccine market and facilitate compensation to injured parties through the enactment of the NCVIA.

Under the NCVIA, a person injured by a vaccine (or her guardian in the case of a minor) may file a petition for compensation in the United States Court of Federal Claims, naming the Secretary of Health and Human Services as the respondent. A special master then adjudicates the petition within 240 days, and the Court of Federal Claims reviews any objections and enters judgment within a similarly tight statutorily mandated timeline. The Act provides a Vaccine Injury Table, which lists the vaccines covered by the Act, describes the compensable side effects for each, and indicates how soon after vaccination such reactions are likely to manifest. So-called "on table" claims are *prima facie* entitled to compensation without proof of causation. A claimant may also recover for "off table" claims, but for those claims the petitioner must demonstrate causation. All claimants under the Act are excused from the usual tort requirements of showing that the vaccine was defectively manufactured, labeled or designed. Successful claimants receive compensation for medical, rehabilitation, counseling, special education and vocational training expenses, diminished earning capacity, pain and suffering and death. Even unsuccessful claims that are non-frivolous are entitled to attorney's fees. The awards are paid out of a fund created by an excise tax on each vaccine dose.

The NCVIA offers significant protections for vaccine manufacturers. It requires claimants to seek relief through the NCVIA program before filing suit. Failure to warn claims are eliminated, as long as the manufacturer has complied with regulatory requirements, and punitive damages generally are not available. Most significantly with respect to the claims in the *Bruesewitz* case, the NCVIA expressly eliminates liability for a vaccine's unavoidable adverse 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.

After extensive parsing of the phrase beginning "if the injury or death . . . ," yesterday's decision easily concluded that this language expressly preempts any state-law design defect claims. As the Court held, "[p]rovided that there was proper manufacture and warning, any remaining side effects, including those resulting from design defects, are deemed to have been unavoidable."

The majority rejected the dissent's contention, based on comment k to the Restatement (Second) of Torts §402A, that the vaccine manufacturer is protected against liability only if there is no alternative feasible vaccine design that would be safer. Justice Scalia tartly pointed out that "[i]f a manufacturer could be held liable for failure to use a different design, the word 'unavoidable' would do no work. A side effect of a vaccine could *always* have been avoidable by use of a differently designed vaccine not containing the harmful element."

The majority also determined that the legislative history of the NCVIA provided further support that state-law design defect claims are preempted (despite a preamble to this section of the opinion stating that "[s]ince our interpretation of §300aa-22(b)(1) is the only interpretation supported by the text and structure of the NCVIA, even those of us who believe legislative history is a legitimate tool of statutory interpretation have no need to resort to it"). Justice Breyer found the textual question a closer one, but looking to other sources "including legislative history, statutory purpose, and the views of the federal administrative agency, here supported by expert medical opinion" found ample additional basis for the conclusion that state-law design defect claims with respect to vaccines are preempted.

POTENTIAL BROADER IMPLICATIONS OF THE DECISION

At its most basic level, the Supreme Court's holding decisively bars state law claims for allegedly defectively designed vaccines. This is a significant victory for vaccine manufacturers that should lift any potential shadow of tort suits alleging a connection between allegedly defectively designed childhood vaccines and autism. However discredited (indeed disgraced) the scientific basis for such claims, their definitive elimination must bring vaccine manufacturers a sigh of relief.

But the decision has potentially broader implications. First, the Supreme Court has confirmed that where express preemption clauses appear in statutes, the Court will have no difficulty in giving such language full effect. A defendant with an express preemption argument is in a different, and frankly far more favorable, position than one that must rely on implied preemption alone, as the Court confirmed in the *Williamson v. Mazda* decision issued just today. Although the Court indicated that it is especially willing to preempt product liability claims where claimants had access to a substitute federal scheme of compensation, it is notable that the *Bruesewitz* claim was rejected by the Vaccine Court and that all vaccine design defect claims – whether brought under state or federal law – are barred.

Perhaps the most notable division between the majority and the dissent, however, was not with respect to textual analysis of the NCVIA but with respect to the role of juries and the tort system. The dissent plainly believes that the state tort system plays an important role in spurring innovation, but the majority was just as plainly uncomfortable with the concept that "complex epidemiological judgments about vaccine design" should be removed from the province of years-long monitoring by an expert federal agency and instead entrusted to laypeople with a highly limited exposure to the data. Noting that "[d]rug manufacturers could often trade a little less efficacy for a little more safety but the safest design is not always the best one," the Court touched on a sensitive trade-off in product design that is not limited to vaccine design or even the pharmaceutical industry. What that means for defendants in cases before this Supreme Court in years to come remains to be seen.

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