



The “National Childhood Vaccine Injury Act” Immunizes Vaccine Manufacturers from State Design Defect Claims

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On February 22, 2010, the U.S. Supreme Court held in *Bruesewitz v. Wyeth*¹ that the National Childhood Vaccine Injury Act of 1986 (“NCVIA”) pre-empts state design defect common law claims against vaccine manufacturers for injury or death caused by a vaccine’s known and disclosed side effects. This vaccine pre-emption decision is consistent with the Court’s earlier decisions² for FDA-approved medical devices.

The National Childhood Vaccine Injury Act

The pertinent NCVIA section³ states “[n]o vaccine manufacturer shall be liable . . . for damages arising from a vaccine-related injury or death associated with the administration of a vaccine . . . if [it] resulted from side-effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.” A FDA vaccine’s license under the NCVIA provides the requisite manufacturing process, directions and warnings that must accompany the vaccine. If followed, vaccine makers are generally immunized from liability for failure to warn if they have complied with all regulatory requirements, disclosed all known side effects, and have provided instructions and warnings to the claimant or the claimant’s physician. The NCVIA allows a party alleging a vaccine-related injury to process a petition for compensation in the Court of Federal Claims. Awards from this Court are paid from a fund created by an excise tax on each vaccine dose.

The NCVIA Vaccine Injury Table (“Table”) lists the vaccines covered under the Act. Claimants who show that a listed injury arises at the indicated time are *prima facie* entitled to compensation without proving causation. If a claimant alleges injury from unlisted side effects, or for listed side effects that occur at times other than as indicated in the Table, the claimant must prove causation. Successful claimants receive compensation for: medical, rehabilitation, counseling, special education, and vocational training expenses; diminished earning capacity; pain and suffering; and \$250,000 for vaccine-related deaths. Attorney’s fees are awarded for successful cases and unsuccessful claims that are not frivolous.

The *Bruesewitz* Claim

Here, the *Bruesewitz* minor received her first diphtheria, tetanus, and pertussis (“DTP”) vaccine in 1991. As alleged, she experienced seizures after her 1992 DTP vaccination and was diagnosed with “residual seizure disorder” and “developmental delay.” In April 1995, this minor’s vaccine-injury petition was filed in the Court of Federal Claims, alleging residual seizure disorder and encephalopathy. Although denied on the merits, the court awarded her \$126,800 in attorney’s fees and costs. The minor rejected this ruling and in October 2005 filed a state common law design defective lawsuit in Pennsylvania alleging DTP vaccine-related disabilities. Defendant Wyeth removed the suit to federal court. The U.S. District Court granted Wyeth’s motion for summary judgment and held that Pennsylvania’s product liability design defect claim was pre-empted by the NCVIA. The U.S. Supreme Court affirmed.



Conclusion

Consistent with the federal law on prescription drugs and medical devices, the U.S. Supreme Court has confirmed in *Bruesewitz* that as long as an FDA-approved vaccine is properly manufactured and all applicable instructions and warnings are provided, all state common law design defect claims are pre-empted. A FDA-approved vaccine recipient's sole remedy for injuries associated with a vaccine's known but unavoidable side effects, therefore, is the NVCA claim procedures with the Court of Federal Claims.

Endnotes

- 1 Docket No. 09-152, 562 U.S. ____ (2011).
- 2 For example, *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).
- 3 42 U.S.C. § 300aa-22(b)(1).

For more information on the matters discussed in *Locke Lord's QuickStudy*, please contact the author:

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