Litigation Advisory

FEBRUARY 23, 2010

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Supreme Court Issues Latest in Series of Product Liability Preemption Opinions

During the past twenty years, the Supreme Court has issued a series of seemingly irreconcilable, sometimes unfathomable, opinions concerning federal preemption of state-law product liability suits involving various types of federally regulated products. The products involved in these cases—which have gone both ways on preemption—have included cigarettes,[1] medical devices,[2] motor boats,[3] automobiles,[4] pesticides,[5] prescription drugs,[6] and now, in *Bruesewitz v. Wyeth LLC*, No. 09-152 (Feb. 22, 2011), vaccines. Some of these cases involve "express preemption," where Congress has included in the text of a federal regulatory statute a preemption provision that bars, either explicitly or as a result of judicial interpretation, imposition of certain types of state tort liability upon product manufacturers. Other cases involve "implied preemption," where a statute does not contain a preemption provision, but congressional intent to preempt state tort liability is judicially inferred due to an implicit conflict with the objectives or operation of a federal regulatory scheme.

In *Bruesewitz*, the Court has held, in a 6-2 decision, that the National Childhood Vaccine Injury Act ("NCVIA"), 42 U.S.C. §§ 300aa-1 *et seq*., expressly "preempts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects." Slip. op. at 19. Justice Scalia authored the majority opinion, and was joined by Chief Justice Roberts and Justices Kennedy, Thomas, Breyer, and Alito. Justice Breyer also wrote a separate, concurring opinion. Justice Ginsburg, joined by Justice Sotomayor, dissented. Justice Kagan, who had served as U.S. Solicitor General, recused herself from the case.

As the majority opinion explains, NCVIA establishes a no-fault compensation program for individuals who suffer serious adverse side effects from FDA-approved childhood vaccines, such as the diphtheria, tetanus, and pertussis (DTP) vaccine blamed for the Bruesewitz child's disabilities and developmental delays. Slip op. at 3-5. Congress enacted the NCVIA as a substitute for tort litigation in order to maintain manufacturers' incentives for development and production of vaccines, to encourage parents to have their children vaccinated, and to provide relatively fast, informal adjudication of adverse side effects claims, in most cases, without the need to prove causation, or defective design, manufacture, or labeling. The compensation program is administered by the U.S. Court of Federal Claims. Compensation is funded through excise taxes on sale of vaccines, and is awarded according to a statutory Vaccine Injury Table. *Id.*

The majority opinion is basically a textual analysis of the NCVIA's preemption provision, which provides "significant tort-liability protections for vaccine

manufacturers" as the "*quid pro quo*" for the compensation awards available under the statute. Slip op. at 4. "The vaccine manufacturers fund from their sales an informal, efficient compensation program for vaccine injuries; in exchange they avoid costly tort litigation and the occasional disproportionate jury verdict." *Id.* at 15.

The preemption provision states that "[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.*" 42 U.S.C. § 300(aa)-22(b)(1) (emphasis added). The principal statutory interpretation issue in the case focused on the meaning of "unavoidable" side effects. The majority held that "[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." Thus, the Court held that the NCVIA preemption provision bars design defect-based liability claims, such as claims based on inclusion of an allegedly hazardous component, provided that a vaccine is properly manufactured and labeled. Slip op. at 7. A side-effect related suit alleging a manufacturing defect, or a suit alleging failure to comply with federally-imposed warning or labeling requirements, would not be precluded by the preemption provision. To support this interpretation, Justice Scalia pointed to the statute's structure and the manner in which FDA regulates vaccines, noting that in contrast to FDA-prescribed manufacturing methods and directions and warnings that must accompany a vaccine, "[d]esign defects . . . do not merit a single mention in the NCVIA or the FDA's regulations." *Id.* at 13. Justice Scalia further observed that

> [d]rug manufacturers often could trade a little less efficacy for a little more safety, but the safest design is not always the best one. Striking the right balance between safety and efficacy is especially difficult with respect to vaccines, which affect public as well as individual health. Yet the Act, which in every other respect micromanages manufacturers, is silent on how to evaluate competing designs.

Id.

Justice Sotomayor's dissenting opinion asserts that "the majority's interpretation does considerable violence to the statutory text, misconstrues the legislative history, and draws the wrong conclusions from the structure of the Vaccine Act and the broader federal scheme regulating vaccines." Slip op. at 13 (Sotomayor, J., dissenting). She asserts, for example, that the majority's "reading functionally excises 13 words from the statutory text, including the key term 'unavoidable.' " *Id.* In response to Justice Sotomayor's assertions that the NCVIA compensation program does "not spur innovation in precisely the same way as state-law tort systems," Justice Scalia, in his majority opinion, observes that "we have never suggested we would be skeptical of preemption unless the congressional substitute operated like the tort system." Slip op. at 16.

Although favorable to a specialized industry sector, the Court's opinion in *Bruesewitz*, like its other product liability preemption jurisprudence of the past two decades, offers little to predict the outcome of future product liability preemption cases. Two more of them will be decided this Term: *Williamson v. Mazda Motor of America, Inc.*, No. 08-1314 (argued Nov. 14, 2010) (automobile seat belt safety), and *Actavis, Inc. v. Demahy*, No. 09-1501 (to be argued Mar. 30, 2011) (generic prescription drugs). The continuing lesson to be gleaned from the Supreme Court's product liability preemption decisions is that federal preemption defenses based on a particular federal regulatory

scheme not only must be carefully crafted and argued, but also most probably will stand or fall on their own, with little guidance from Supreme Court preemption decisions addressing manufacture, design, labeling, and use of other categories of products.

A copy of the full slip opinion can be accessed **here**.

ABOUT THE AUTHOR

Larry Ebner leads the firm's national appellate litigation practice. For more than twenty years he has been extensively involved in devising and advocating federal preemption defenses in damages suits involving federally regulated products and services.

[1]*Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992).

[2]*Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

[3]*Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002).

[4]*Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861 (2000).

[5]*Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005).

[6]*Wyeth v. Levine*, 129 S. Ct. 1187 (2009).