The Product Liability Preemption Problem: No Clear Directive from the Supreme Court

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The product liability preemption debate is once again taking center stage inside the United States Supreme Court. But rather than providing clarity on an issue that was similarly addressed during the 2008-2009 Term, the Court seems intent on not providing any bright-line rules, instead sending litigators scrambling to attempt to distinguish their arguments on a case-by-case basis, depending upon what side of the issue they find themselves.

The trilogy of cases involving preemption of product liability claims begins with a 6-2 February 22, 2011, decision in *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068 (2011), ruling that the family of an infant who allegedly suffered a severe reaction to a vaccine could not sue the drug manufacturer for failing to update the vaccine with a newer, safer version. Behind the decision was the National Childhood Vaccine Injury Act of 1986, a law granting drug companies immunity from lawsuits involving injuries or deaths related to vaccinations. The law was enacted to thwart the exodus of drug manufacturers from the vaccine market in the wake of wide-ranging lawsuits seeking millions of dollars on behalf of those who suffered severe reactions from vaccines. The law aimed for a balance by simultaneously protecting vaccine manufacturers, while also creating a compensation fund for those suffering from a vaccine's negative effects.

While Justices Sonia Sotomayor and Ruth Bader Ginsburg decried the ruling, asserting that the decision "leaves a regulatory vacuum in which no one ensures that vaccine manufacturers adequately take account of scientific and technological advances when designing and distributing their products," the majority rejected this broad public policy argument and instead, parsed the language of the statute to find in favor of preemption. At issue was why Congress did not specifically state that "defective design" claims were preempted from potential lawsuits, while the statute was clear in identifying product liability claims resting on theories of defective manufacture and inadequate warnings as preempted. The Act says that vaccine manufacturers are not liable "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*." (emphasis added). In interpreting the statute, Justice Antonin Scalia concluded that the inclusion of design defect wording would have been redundant since "the design of the vaccine is a given, not subject to question in a tort action." Further, Justice Scalia looked carefully at the word "unavoidable," noting that if there was a proper manufacture and warning, any remaining side effects, including those resulting from a design defect, are deemed unavoidable. Otherwise, he continued, if a manufacturer could be liable for not using a different design, the word "unavoidable" would serve no purpose since side effects could always be avoided by coming up with a different design. A confusing extrapolation, apparently prompting Justice Scalia to further state that Congress intended to leave the defective design wording out "by deliberate choice, not inadvertence." One can debate whether this demonstrates a result-oriented reading of the statute.

The very next day, February 23, 2011, the Supreme Court *rejected* a preemption argument in favor of plaintiffs suing car manufacturer Mazda for not installing a lap-and-shoulder belt on a rear seat of their minivan, and instead installing a simple lap belt – which plaintiffs maintained led to the demise of their daughter as the result of a head-on collision. While the Federal Motor Vehicle Safety Standard 208 (FMVSS 208), enacted in 1989, allows auto manufacturers to choose which types of seat belts to install on rear inner and aisle seats (those situated along the center axis of the vehicle), the Court held that this provision does not preempt state tort actions seeking to impose liability on those manufacturers who choose to install simple lap belts. While the decision at first blush appears to possibly overrule the Court's 2000 decision in *Geier v. American Honda Motor Co*., 529 U.S. 861, holding that a regulatory decision expressly giving manufacturers a choice was preemptive, Justice Stephen Breyer distinguished the scenario in this case, *Williamson v. Mazda Motor of America, Inc.*, 131 S. Ct. 1131 (2011).

The Court reaffirmed the *Geier* decision, explaining that the Department of Transportation had indicated that the choice there, allowing manufacturers to choose which type of permissible restraint system to install (including airbags and seat belts), was a "significant regulatory objective," while the choice in *Williamson* was not. In keeping with its acute analysis of legislative history, the Court again went into great detail about the reasoning surrounding the DOT's directives and made the close and narrow ruling largely on the basis of agency intent. Simply put, DOT and other government officials saw manufacturer choice as a major factor in its 1984 regulation, yet did not regard choice so highly in its revamped FMVSS 208 in 1989. The DOT promulgated its 1984 regulation with the aim of avoiding public backlash against airbags while also giving manufacturers time to improve airbag safety. The Court explained that the DOT was not as concerned about consumer acceptance in 1989, but worried more about cost effectiveness – a concern that could not override state tort law.

The third case, *Pliva, Inc. v. Mensing*, 131 S. Ct. 817 (2010), currently hangs in the balance. It is a consolidated case set to determine whether federal drug labeling law preempts state tort claims when a generic drug approved by the U.S. Food and Drug Administration is inadequately labeled. While the Court ruled in 2009 in *Wyeth v. Levine*, 129 S. Ct. 1187, that federal law did not preempt state tort claims against *brand-name* manufacturers for failure to warn, the Court is now being asked whether the same applies to generic manufacturers. At oral argument, the Court focused on whether generic manufacturers have the same abilities and requirements to effect changes to their own drug labels as brand-name manufacturers. The Fifth and Eighth Circuits have already ruled in these consolidated cases that the generic manufacturers do have the same opportunities as brand-names and should thus be required to comply with both federal drug labeling and state tort standards of care.

One additional case, out of the Southern District of New York, is worthy of mention as well. In *In re Jackson, et al. v. General Motors Corporation, et al.*, 2011 WL 989601 (S.D.N.Y. February 16, 2011), the court came down on the side of preemption, ruling that tort claims arising out of exposure to

diesel exhaust fumes are preempted by the Clean Air Act (CAA). In *Jackson*, the court dismissed negligence and product liability/failure to warn claims brought by the bus drivers, shifters and mechanics employed by the New York City Transit Authority. District Judge Paul A. Crotty held that the CAA's sweeping preemption provision that no state "shall adopt or attempt to enforce any standard relating to the control of emissions" included state common law tort actions. Judge Crotty held that not only does Section 209(a) of the CAA prohibit states from promulgating their own emissions standards, but it also precludes common law tort actions based on emissions exposure. After all, state tort law actions that question whether defendants complied with emissions standards promulgated under the CAA "is an example of a state attempting to enforce the CAA, and is therefore subject to preemption." Judge Crotty was careful to distinguish his decision from the Supreme Court's in *Wyeth v. Levine*, 555 U.S. 555 (2009), holding that state law failure to warn claims were not preempted by Food and Drug Administration regulations because such claims would not "obstruct the federal regulation of drug labeling." Allowing such claims that certain vehicles did not meet the emissions standards of the CAA, however, would fly in the face of the plain wording and purpose of the statute – that "vehicle manufacturers not be subject to 50 sets of requirements relating to emission controls which would unduly burden interstate commerce." Interestingly, Judge Crotty pointed out that this decision did not leave plaintiffs without recourse. His decision noted that plaintiffs' exposure to diesel exhaust fumes could have been the result of improper ventilation, which would be a proper basis for a negligence claim. Judge Crotty noted that while the CAA preempts common law tort claims relating to emissions controls, it would not preempt claims relating to ventilation.

This array of cases in both the nation's highest court and in one federal trial court is indicative of the long-standing, ongoing preemption debate. Manufacturers and their lawyers continue to oftentimes be left to read the proverbial tea leaves regarding this issue, using the conflicting and, at times, counter-intuitive case law as their guide.