

**DRUG & DEVICE
BULLETIN**



MARCH 31, 2009

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THIRD CIRCUIT: DESIGN DEFECT CLAIMS EXPRESSLY PREEMPTED UNDER VACCINE ACT

The Third Circuit Court of Appeals has held that all design defect claims—whether sounding in strict liability or negligence—are expressly preempted by the National Childhood Vaccine Injury Act. *Bruesewitz v. Wyeth*, No. 07-3794, slip op. (3d Cir. March 27, 2009).

The holding in *Bruesewitz* conflicts with a recent decision handed down by the Georgia Supreme Court in *American Home Products Corp. v. Ferrari*, 668 S.E.2d 236 (Ga. 2008), *petition for cert. filed*, 2009 WL 598046, *598046 (U.S. Mar. 05, 2009) (No. 08-1120). This split in authority could put yet another preemption issue before the U.S. Supreme Court.

In *Bruesewitz*, the plaintiff experienced seizures after receiving a DPT shot containing “whole-cell” pertussis vaccine. At issue was section 22(b)(1) of the Vaccine Act, which 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.” The Third Circuit concluded that section 22(b)(1), as well as section 22(a), contain *express* preemption clauses.

The plaintiffs argued that “avoidability” must be determined on a case-by-case basis—the very position embraced in *Ferrari* by the Georgia Supreme Court, which relied on a congressional discussion of parallel language in comment k to section 402A of the *Restatement (Second) of Torts*, exempting manufacturers of “unavoidably unsafe products” from strict liability. The Georgia court noted that most state jurisdictions have interpreted this language to require a case-by-case analysis.

The Third Circuit rejected this interpretation, finding it contrary to the structure of the Vaccine Act and noting that it would, in essence, bar no claims. “If we interpret the Vaccine Act to allow case-by-case analysis of whether particular vaccine side effects are avoidable, every design defect claim is subject to evaluation by a court.”

The court then addressed whether section 22(b)(1) preempts all design-defect claims or strict-liability design-defect claims only.

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Pharmaceutical & Medical Device

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Examining the legislative history, the court said that an Energy and Commerce Committee report from the 1980s supports the conclusion that the Vaccine Act preempts all design-defect claims, including those sounding in negligence.

The report (1) stressed the importance of vaccine development and availability (2) expressed concern about vaccine manufacturers leaving the marketplace, (3) noted that the new system would reduce and stabilize litigation costs while enabling manufacturers to estimate the costs associated with compensation, and (4) explicitly stated that it allowed civil litigation for warnings and manufacturing-defect claims only. Third Circuit Judge D. Brooks Smith, writing for the panel, noted that "[e]ach of the objectives extolled by the Commerce Report would be undermined if design defect claims were permitted under the statute."

If recent U.S. Supreme Court opinions are any indication, the fact that *Bruesewitz* involved *express* preemption—not implied preemption—may bode well for the industry if the Court elects to resolve the split in authority between the Third Circuit and Georgia's Supreme Court. *Riegel v. Medtronic, Inc.*, which involved express preemption under the Medical Device Amendments of 1976, was an 8-1 decision in favor of the federal preemption of state-law claims. *Wyeth v. Levine*, which involved implied preemption in a prescription drug failure-to-warn context, was a 6-3 decision against preemption.

DRUG SHIELD LAW UNDER ATTACK IN MICHIGAN LEGISLATURE

The Democratic-controlled Michigan House of Representatives has passed a trio of bills that would repeal Michigan's unique Drug Shield Law and even allow previously-barred lawsuits from as early as 1996. The effort to repeal the 13-year-old Michigan statute, which protects manufacturers from liability in cases involving FDA-approved prescription drugs, faces an uphill battle, however, in the Republican-controlled Michigan Senate.

This is not the first attempt to repeal the Drug Shield Law. Michigan Democrats have been rallying around efforts to repeal the law since as early as 2005, but these efforts have been unsuccessful in garnering enough support in the Senate. Undoubtedly, though, the current debate in the Michigan Legislature has been colored by *Wyeth v. Levine*, where the U.S. Supreme Court held earlier this month that federal law did not preempt a claim that Wyeth failed to adequately warn about the IV-push method of administering Phenergan.

In a press release issued on the heels of *Levine*, Senator Gretchen Whitmore (D-East Lansing) implored her senate colleagues to repeal the Drug Shield Law. "With today's announcement, the highest court in the nation—and others around the country—continue to discredit pharmaceutical companies' cries for limits on drug lawsuits in lieu of victims' rights," said Senator Whitmer.

Despite any momentum generated by *Levine* and the vote in the Michigan House, the *Detroit Free Press* reports that the issue is "not on a fast track" in the Senate.

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The debate over Michigan's Drug Shield Law suggests that the battle lines are being redrawn in the wake of *Levine*, with state legislatures likely to play an increasingly important role in determining the significance of FDA approval.

CANADIAN APPELLATE COURT OVERTURNS NATIONWIDE VIOXX CLASS ACTION

Commentators have said that no Canadian court has ever denied a motion to certify a class in a pharmaceutical or medical-device case and that manufacturers of these products have recently faced an ever-widening range of Canadian class actions. A decision issued March 30 by a unanimous panel of the Court of Appeal for Saskatchewan departs from this trend and distinguishes pharmaceutical cases as presenting individual issues not present in other class actions.

Concluding that the plaintiffs had failed to define issues common to the class or establish that a class action would be a preferable procedure, the court in *Wuttunee et al v. Merck Frost Canada Ltd. et al.*, 2009 SKCA 43 (Court of Appeal), quashed the lower court's order certifying a nationwide (except Quebec) consumer-fraud and product-liability class action for Vioxx.

The class included Vioxx purchasers or consumers who fell into one or more of eight subclasses and included those seeking restitution for alleged ineffectiveness, those seeking the difference in purchase price between Vioxx and less expensive NSAIDs and those claiming cardiovascular or gastrointestinal injuries.

In the lower court order under review, Judge Klebuc (now Chief Justice of Saskatchewan) had certified issues of general medical causation, defendant knowledge, product defect, failure to warn, misrepresentation, and punitive damages as common issues. Finding that the descriptions of these issues did nothing more than give "the impression of commonality, where commonality in fact does not exist," and that each presented "a myriad of questions, susceptible to different answers in relation to each of the risks or defects of Vioxx alleged" such that "all semblance of commonality is lost," the appeals court concluded that the proposed common issues were not, in fact, common to the class.

In sum, the appeals court held that class-wide resolution would be "unacceptably complex" and neither fair, efficient nor manageable.

Having found the class certification order improper on these grounds, the court chose not to address the propriety of multi-province or nationwide class actions. This ruling also does not have the effect of eliminating all certified Vioxx class actions in Canada because an Ontario-certified class (national other than Saskatchewan and Quebec) and a Quebec-only certified class action remain pending. The decision nevertheless provides significant precedent in support of efforts to oppose or narrow proposed pharmaceutical or medical-device class actions in Canada. ■