

# Update

Spring 2009

## United States Supreme Court Holds That FDA Approval of Warning Label Does Not Preempt State Law Failure-to-Warn Claims

In *Wyeth v. Levine*, 129 S. Ct. 1187 (March 4, 2009), the plaintiff intravenously injected a drug manufactured by the defendant into her arm and experienced complications arising from the injection that eventually led to the amputation of her arm. The plaintiff filed an action against the drug manufacturer in Vermont state court claiming it failed to include a warning label describing the possible arterial injuries that could occur from direct intravenous injection of the drug.

The drug manufacturer filed a motion for summary judgment arguing that, because its warning label was approved by the Food and Drug Administration ("FDA"), any Vermont state regulations deeming the label insufficient were preempted. The Vermont trial court denied the defendant's motion for summary judgment based on preemption, and the jury found in favor of the plaintiff.

The Supreme Court of Vermont affirmed the ruling on appeal, holding that the requirements under the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 307 *et seq.*, "create a floor, not a ceiling, for state regulation." The court reasoned that states are free to create more stringent labeling requirements than provided by federal law.

The United States Supreme Court affirmed the Supreme Court of Vermont holding that federal law did not preempt the plaintiff's state law claim that the manufacturer's labeling of the drug failed to warn of the dangers of its intravenous

administration. The Court rejected the defendant's argument that by unilaterally changing its labeling of the drug, it would have violated federal labeling regulations. Rather, the Court asserted that the manufacturer bears ultimate responsibility for the content of its labels at all times. The Court then rejected the defendant's argument that requiring it to comply with any state law duty to provide a stronger warning would interfere with Congress's purpose of entrusting the FDA with drug labeling decisions. The Court noted that the history of the FDCA does not support the argument that Congress intended to preempt state law prescription drug failure-to-warn claims.

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### Inside this Update

United States Supreme Court Holds That FDA Approval of Warning Label Does Not Preempt State Law Failure-to-Warn Claims

Pa. Superior Court Rejects Constitutional Challenge to Statutory Limit on Asbestos Liability

Pa. Superior Court Reverses Grant of Summary Judgment In Favor of Forklift Manufacturer

Third Circuit Court Holds Strict Liability Does Not Apply to a Refurbisher

E.D. Pa. Court Rules That Expert Witness Is Necessary to Sustain Claim of Defect in Surgical Robot

## Pa. Superior Court Rejects Constitutional Challenge to Statutory Limit on Asbestos Liability

In *Johnson v. American Standard*, 2009 Pa. Super. 22 (Feb. 6, 2009), a deeply divided en banc panel of the Superior Court ruled that three plaintiffs did not have standing to challenge a statute limiting the liability of successor corporations in asbestos litigation.

At issue was the validity of 15 Pa.C.S. § 1929.1, which limits asbestos-related liability of Pennsylvania corporations when that liability arises from a merger or consolidation. The statute caps the successor corporation's asbestos-related liability at the fair market value of the prior company, as of the time of the merger or consolidation.

The plaintiffs did not dispute that the defendant, Crown Cork & Seal Co., was protected under the statute. Crown Cork had paid hundreds of millions of dollars in asbestos-related claims arising from the activities of Mundet Cork, a company it purchased in 1963 and sold 90 days later. Rather, the plaintiffs argued the statute violated the Commerce Clause and the Equal Protection Clause of the U.S. Constitution, as well as the Equal Protection Clause and other provisions of Pennsylvania's constitution.

Writing for the four-judge majority, Judge Lally-Green concluded that the plaintiffs did not have standing because they did not fall within the zone of interest intended to be protected by the constitutional provisions on which their claims were based.

With respect to the plaintiffs' dormant Commerce Clause challenge, the Superior Court adopted the analysis of the trial court, finding that plaintiffs were not adversely affected because they could recover all of their damages from the remaining defendants through settlement or otherwise. Accordingly, the court held that the plaintiffs failed to demonstrate how any alleged violation of the dormant Commerce Clause had a tangible effect on their interests.

The court concluded that, for the same reasons, the plaintiffs lacked standing to raise claims that the statute violates the Equal Protection Clause or was enacted in an unconstitutional manner.

## Pa. Superior Court Reverses Grant of Summary Judgment In Favor of Forklift Manufacturer

In *Kiak v. Crown Equipment Corporation*, 2009 Pa. Super. 32 (Feb. 17, 2009), the Superior Court reversed a grant of summary judgment in favor of a forklift manufacturer, holding that federal Occupational Safety and Health Administration (OSHA) regulations did not preempt the plaintiff's product liability claim.

The plaintiff sought to recover for injuries which occurred when a forklift, operated by a coworker, pinned the plaintiff between two boxes and nearly amputated his foot. The plaintiff asserted a claim for strict product liability, alleging that the back-up travel alarm on the forklift was defectively designed because it would not sound when the forklift throttle was disengaged and the forklift was coasting backwards.

The trial court found that the case was controlled by *Arnoldy v. Forklift, LP*, 927 A.2d 257 (Pa. Super. 2007), and the law of federal preemption, and granted summary judgment in favor of the defendant manufacturer. In *Arnoldy*, the Superior Court held that OSHA regulations preempted plaintiff's claims based on allegations that the forklift manufacturer failed to install additional safety devices necessary to make the forklift safe. The court held that, under federal regulations, the duty to select appropriate safety devices rests with the user of the forklift and not the manufacturer. Thus, permitting a state products liability tort law claim would have improperly shifted the burden to the manufacturer.

On appeal, the Superior Court found that the facts in *Kiak* differed markedly from those in *Arnoldy*, where the plaintiff's claims were premised on the failure of a manufacturer to install an available safety device. Because the plaintiff in *Kiak* contended that the safety device selected by his employer was defective, the court was not confronted with a direct conflict between state tort law and the applicable OSHA regulations. Accordingly, the court reversed and remanded the case for trial.

### Third Circuit Court Holds Strict Liability Does Not Apply to a Refurbisher

In *Meadows v. Anchor Longwall and Rebuild, Inc.*, 2009 WL 74399 (3d Cir. 2009), the plaintiff appealed the district court's grant of summary judgment in a strict liability action involving a shut-off valve fitting that came loose from a valve assembly and struck the plaintiff in the eye. The plaintiff worked for a mining company that hired a contractor to repair longwall shields in a mine. The contractor subcontracted with the defendant whom the plaintiff alleges was responsible for repairing the shields that caused his injury.

*Under the Restatement (Second) of Torts § 402A*, which has been adopted in Pennsylvania, a seller of a defective product is subject to liability for physical harm caused to the ultimate user. The defendant filed a motion for summary judgment on the strict liability claim which the district court granted on the basis that the defendant did not sell or supply a product but, rather, provided a service which is not subject to strict liability claims.

On appeal, the plaintiff argued that the defendant did not engage solely in servicing the longwall shield because in repairing and refurbishing the shields, it "redesigned" the hydraulic system and "sold" the designed system back to the mining company. The defendant countered that it did not design the faulty valve that caused the plaintiff's injury but merely attached the component to the shield unaltered from the way it was received from the manufacturer.

The Third Circuit noted that service providers are excluded from strict liability. The Court affirmed the district court's summary judgment ruling noting that adopting the plaintiff's theory that by refurbishing and repairing the longwall shield, the defendant "redesigned," manufactured and sold a product to the mining company, would effectively swallow the distinction between sellers of products and those that simply provide a service for products after manufacturing.

### E.D. Pa Court Rules That Expert Witness Is Necessary to Sustain Claim of Defect in Surgical Robot

In *Mracek v. Bryn Mawr Hosp.*, 2009 WL 637380 (E.D.Pa. March 11, 2009), the plaintiff brought an action for damages in connection with a prostatectomy performed with an operative robot that was manufactured by the defendant. The manufacturer filed a motion for summary judgment asserting that the plaintiff failed to submit an expert report critical of the robot and therefore failed to meet his burden of proof with respect to his theory of strict liability.

The court noted that in order to bring a products liability claim in Pennsylvania, a plaintiff must demonstrate that: (1) the product was defective; (2) the defect existed while the product was in the control of the manufacturer, and (3) the defect was the proximate cause of the plaintiff's injuries. Citing *Oddi v Ford Motor Co.*, 234 F.3d 136, 159 (3d Cir. 2000), the court observed that expert testimony is not required to meet this standard when the matter under consideration is simple and the asserted defect is obvious enough to be ascertainable by the average juror without speculation.

The plaintiff contended that an expert report was not necessary since the surgeon who performed the operation was willing to testify that the defect of the surgical robot was obvious because all of its component parts shut down after repeatedly flashing "error" messages and it was unable to be restarted once the surgery commenced. The robot manufacturer claimed that the average juror did not have the requisite background to adjudicate and reach a conclusion as to whether the machine was defective, and the lack of expert testimony would only lead to jury speculation.

The court noted that the surgeon did not offer his opinion as a robot expert, and the plaintiff did not assert that the surgeon was an expert on the topic. The court granted the manufacturer's motion for summary judgment and held that the robot was a complex machine and a juror would require the assistance of expert testimony in order to reasonably determine whether the robot had a defect.

*Product Liability Update* is a publication of Thorp Reed & Armstrong's Product Liability Group, and is edited by Kimberly A. Brown, Esq.

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