ALERTS AND UPDATES

In Pennsylvania Products Liability Decisions, Pharmaceutical Manufacturers May Lose a Little, but Gain a Lot

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In a trio of recent Pennsylvania Superior Court decisions involving the diet drug Redux, plaintiffs' lawyers may have gained a new cause of action against pharmaceutical manufacturers, but not before the reaffirmance of the learned intermediary defense and the rejection of a plaintiff's unique challenge to that defense.

In *Lance v. Wyeth*,[1] considering an issue of first impression, the court held a claim for negligent design defect is a proper cause of action in Pennsylvania in a pharmaceutical products liability case. In *Lance*, the plaintiff's decedent took Wyeth's diet drug Redux, and subsequently developed primary pulmonary hypertension (PPH). The plaintiff brought suit, alleging three causes of action sounding in negligence—unreasonable marketing of a dangerous drug, failure to remove Redux from the market and breach of the standard of care in designing Redux. The trial court granted the defendant's motion for summary judgment on all three claims. The Superior Court reversed in part and affirmed in part.

The Superior Court held the first two claims did not state a cognizable cause of action under Pennsylvania law, but found the last claim did. The court determined it was not its place to create a common-law claim for failure to withdraw a drug from the market and deferred to the U.S. Food and Drug Administration for any such determination. As to the unreasonable marketing claim, the court found it akin to negligent failure-to-test, and Pennsylvania does not recognize any such claim as an independent tort. The court found the negligent design claim was cognizable, and although Pennsylvania's adoption of comment k of the Restatement (Second) of Torts section 402A limits strict liability claims to manufacturing defect claims and failure-to-warn claims, "a negligent design defect claim is considered to be distinct from, and not subsumed within, a strict liability design defect claim." Consequently, the court reversed summary judgment on the negligent design defect claim.

In the other two cases, *Cochran v. Wyeth*[2] and *Owens v. Wyeth*,[3] the trial court granted the defendant's motion for summary judgment, and the Superior Court affirmed, finding the plaintiffs could not prove their injuries were proximately caused by the diet drug. In both cases, applying the learned intermediary doctrine, the court held the drug manufacturer's duty to warn runs to the physician only. To prove proximate causation, a plaintiff would have to show that the drug caused the plaintiff's injury and that a stronger warning from the manufacturer would have led the physician not to prescribe the drug to the plaintiff-patient.

In *Owens*, the prescribing doctor testified that even if there had been a stronger warning of the injury alleged, he still would have prescribed the drug. The court found summary judgment appropriate because, "to create a jury question, the evidence introduced must be of sufficient weight to establish. . . some reasonable likelihood that an adequate warning would have prevented the plaintiff from receiving the drug."

In *Cochran*, the prescribing doctor testified that he would not have prescribed Redux to the plaintiff had he been warned that Redux may cause valvular heart disease (VHD). The plaintiff, however, was diagnosed with PPH, not VHD. The trial court granted summary judgment because Wyeth's failure to warn of the risk of VHD was not and could not have been a proximate cause of her PPH. The Superior Court affirmed, adopting the policies of other jurisdictions that have concluded a plaintiff cannot establish proximate causation where the nondisclosed risk never materialized into an injury.

Analysis

Pharmaceutical defendants may want to consider a new approach when seeking the dismissal of a negligent design claim. Under *Lance*, summary judgment based on a failure to state a cognizable claim for negligent design is no longer sustainable in Pennsylvania. Instead, defendants may wish to establish that a plaintiff's evidence falls short of showing that the design of a drug resulted from the absence of a manufacturer's due care.

However, claims for negligent failure to withdraw a drug from the market or negligent failure-to-test are not viable causes of action in Pennsylvania and may continue to be ripe for summary judgment. In failure-to-warn cases, if a drug maker is able to show that the prescribing physician would not have altered his or her prescribing decision even with a stronger warning, there would be no proximate causation and the case would be subject to dismissal. Lastly, as the Superior Court concluded in *Cochran*, the failure to warn by a drug company remains for the injury claimed by the plaintiff—and not some other undiagnosed and unrealized injury.

For Further Information

If you have questions about this *Alert* or would like more information, please contact Alan Klein, Sharon L. Caffrey, Karen Shichman Crawford, any other member of the Products Liability and Toxic Torts Practice Group or the attorney in the firm with whom you are regularly in contact.

Notes

1. *Lance v. Wyeth, Inc.*, 2010 PA Super 137 (Pa. Super. Ct. 2010).
2. *Cochran v. Wyeth, Inc.*, 2010 PA Super 131 (Pa. Super. Ct. 2010).
3. *Owens v. Wyeth, Inc.*, 2010 Pa. Super. LEXIS 2095 (Pa. Super. Ct. July 26, 2010).