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Justices Turn Down New Theory on Failure to Warn in Pharma Case

Amaris Elliott-Engel | Contact | All Articles
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Judge Cheryl Lynn Allen

The state Supreme Court has declined to consider a novel theory that a plaintiff may show that a drugmaker failed to warn of all the harmful risks from its drug, rather than directly showing that the drugmaker failed to warn of the specific harm that ultimately caused the plaintiff's injury.

When the Superior Court considered *Cochran v. Wyeth* , the front-line appellate court treated it as an apparent case of first impression, and affirmed the current scope of the failure-to-warn theory.

The Supreme Court denied plaintiff Nancy Cochran's petition for allowance of appeal April 18.

Superior Court Judge Cheryl Lynn Allen, writing last year for the unanimous panel in *Cochran* , said that a plaintiff cannot prove proximate causation if "the non-disclosed risk did not materialize in physical injury."

Cochran is one of a trio of diet-drug cases advancing theories of first impression that could affect the landscape of drug products liability law in Pennsylvania.

The Supreme Court did decide last month to take up *Lance v. Wyeth* , which gives the court the chance to consider whether plaintiffs may sue pharmaceutical drug companies on theories that the companies were negligent in testing, marketing and designing their prescription drug products.

The Supreme Court's decision on granting a petition for allowance of appeal in the third case, *Owens v. Wyeth* , has been held in reserve pending the outcome in *Lance* , according to an April 11 court docket.

Howard Bashman, the appellate counsel for the plaintiff and a Willow Grove, Pa., solo practitioner, said, with the justices' order regarding *Cochran* , that the Superior Court's decision remains the law of Pennsylvania. But denying review is not equivalent to a ruling on the merits of the plaintiff's theory or the Superior Court's holding, he said.

The same proximate cause issue in *Cochran* also is at issue in *Owens* . And like *Lance* , *Owens* raises issues of first impression regarding negligent marketing and withdrawing drugs from the market.

The court may not have been interested in taking up the proximate cause issue in *Cochran* because lawyers say that it might not affect very many other cases.

The *Cochran* case involves an "unusual factual scenario presented by the type of diet drug in that case," and it is not a factual scenario that regularly arises, Bashman said. Wyeth argued in its briefing that the question in *Cochran* may not affect many other cases regardless of how it was resolved, Bashman said.

Bashman writes an appellate law column for *The Legal* .

The same panel of Allen, President Judge Correale F. Stevens and Judge Susan Peikes Gantman decided all three cases.

Nancy Cochran, who took diet drug Redux from November 1996 to August 1997, alleged that the warnings about Redux were inadequate regarding the risk of valvular heart disease (VHD), *The Legal* previously reported. Cochran, however, developed primary pulmonary hypertension (PPH), not VHD, and her treating physician, Dr. Stephen Anthay, had warned Cochran about the risk of PPH from ingesting Redux. Anthay, however, testified he would not have prescribed the drug if he had known about the risk of VHD associated with Redux. Tereshko granted summary judgment in favor of Wyeth.

Wyeth, now owned by Pfizer, argued that even if its warning about VHD was inadequate, Cochran could not prove the proximate causation prong of the failure-to-warn tort because the alleged failure to warn of VHD was not the proximate causation of Cochran's alleged injury, *The Legal* previously reported.

"The company is pleased with the Pennsylvania Supreme Court's order that allows the trial court's summary judgment ruling in Wyeth's favor to stand," Pfizer said in a statement. "The trial court found the Redux label adequately warned plaintiff's doctor of the risk of PPH, which plaintiff claimed to have sustained, and that the adequacy of the warning concerning a potential injury not suffered by the plaintiff was not relevant for purposes of establishing proximate cause for plaintiff's claims. The plaintiff has now exhausted all recourses for appeal in Pennsylvania."

Allen concluded that, if Wyeth had a duty to disclose the risk of VHD, the breach of that duty was not the proximate cause of Cochran's PPH, even though her treating physician would otherwise not have prescribed Redux to her, *The Legal* previously reported.

Without any on-point Pennsylvania case law, the court looked on its own to cases regarding the plaintiff's burden of proving proximate causation when suing physicians for allegedly not disclosing the risks of medical procedures when obtaining the informed consent of their patients, *The Legal* previously reported.

The court, citing cases from the U.S. Circuit Court of Appeals for the District of Columbia and the Maine Supreme Court, said that it found persuasive that plaintiffs cannot establish proximate causation if the non-disclosed risks from their physicians did not materialize in injuries.

Drawing a parallel between the tort of informed consent and the tort of failure to warn, the court said that "in these circumstances, the relationship between the legal wrong (the failure to disclose the risk of VHD) and the injury (PPH) is not directly correlative and is too remote for proximate causation. Therefore, as a matter of law, there is no proximate, causal connection between Wyeth's failure to disclose the risk of VHD and appellant's specific injury," Allen wrote.

Cochran's attorneys, however, argued in her appellate brief that another court, the U.S. District Court for the Western District of North Carolina, has ruled the opposite way on the very issue of first impression in *Cochran* . That court found that a plaintiff who took the Fen-Phen diet drug Pondimin could rely on the allegedly inadequate warnings about VHD even though the plaintiff was injured by PPH, Cochran argued in her brief.

The plaintiff also argued in her brief that Pennsylvania's informed consent claim sounds in battery, rather than negligence, and the Superior Court's ruling was an import "into Pennsylvania law from the 'informed consent' law of other states [that] is directly contrary to the far more relaxed proximate cause approach that applies to 'informed consent' claims arising under Pennsylvania law."

In *Lance* , the Superior Court panel held that plaintiffs can make a negligent design defect claim. But the three-judge panel declined to impose upon drugmakers a common law duty to recall drugs or to let plaintiffs pursue theories of a negligent failure to test or negligence in marketing. •