Scope of Prescription Drug Tort Lawsuits to Be Tested

Appeals Ct. to Mull Negligent Marketing Cause of Action

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By Amaris Elliott-Engel
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Two diet drug cases on appeal to the state Superior Court are expected to provide a test of the scope of claims that plaintiffs may make against drug manufacturers under Pennsylvania's products liability law.

The key questions before the frontline appeals court include:

• Can a plaintiff sue a drugmaker for alleged negligent marketing and failure to withdraw an allegedly dangerous drug from the market in a standalone claim?

• In the effort to establish proximate causation between a plaintiff's injury and a drugmaker's product, does a plaintiff have to show in a failure-to-warn claim that a drugmaker failed to warn of the specific harm that ultimately caused the plaintiff's injury rather than failing to warn of all the harmful risks from its drug?

In a recent opinion, a Philadelphia judge said he was rejecting a plaintiff's "novel claim" that a plaintiff can sue a drug manufacturer for negligent marketing and that a plaintiff is not required to prove a drug manufacturer's failure to adequately warn of the risks of its product as a part of such a claim.

Philadelphia Common Pleas Judge Allan L. Tereshko said Wyeth, now owned by Pfizer, argues in *Lance v. Wyeth* that, since Pennsylvania adopted the learned intermediary doctrine for prescription drug cases in the 1971 *Incollingo v. Ewing* case, there have been no reported decisions premising a drugmaker's liability on a theory of negligent marketing. There are no other grounds to sue a drugmaker for negligence besides alleging negligence in making a drug or a negligent failure to warn a plaintiff's physician of the risks of using a drug, Tereshko said.

Wyeth also said the plaintiff either must allege harm due to "'an impurity'" in making the drug, or failure to adequately warn of the known or suspected risks of ingesting the drug, the judge wrote.

Plaintiff Patsy Lance, an Ohio resident who is administratrix for the estate of Catherine Ruth Lance, is appealing Tereshko's order granting summary judgment Sept. 19, 2008, in favor of Wyeth. Catherine Lance used the diet drug Redux from January to April 1997, and the plaintiff alleged that Lance was diagnosed with primary pulmonary hypertension, or PPH, seven years after taking Redux and that Lance's use of Redux caused her PPH. Lance died in December 2004, according to Tereshko's Jan. 7 opinion explaining his reasoning to the appellate court.

The plaintiff did not make any claim that the Redux FDA-approved warnings were inadequate, or that Wyeth failed to adequately warn about the risk of Redux beyond failing to remove Redux from the market, Tereshko wrote.

The judge then wrote that no Pennsylvania court has recognized a claim for negligently putting an FDA-approved prescription drug on the market, or failing to withdraw the drug from the market. The marketing practices of a drug manufacturer are not irrelevant in plaintiffs' lawsuits, Tereshko said, but the marketing practices are a factor in determining the reasonableness of a drugmaker's warnings accompanying their drugs.

"Pennsylvania's recognition of the learned intermediary doctrine nullifies this novel claim by plaintiff that this prescription drug was unreasonably dangerous and unfit to be prescribed to anyone," Tereshko wrote. "In acknowledging the inherent risks that come along with the benefits of prescription drugs, Pennsylvania law holds that drugs 'properly tested, labeled with appropriate warnings, approved by the Food and Drug Administration, and marketed properly under federal regulation' are reasonably safe products as a matter of law ... The learned intermediary doctrine provides further protection from the dangerous propensities of prescription drugs by requiring drug manufacturers to supply adequate warnings to the physicians."

Attorneys for plaintiffs seeking to sue Wyeth for allegedly negligently marketing diet drugs and failing to withdraw them from the market say in court papers that such claims can be made out under state law.

In an appellate brief in *Owens v. Wyeth*, the plaintiffs said that Wyeth is reading Pennsylvania case law incorrectly by arguing that the only claim available to a plaintiff injured by a prescription drug is a claim for negligently failing to warn a plaintiff's physicians. The plaintiffs said the 1973 state Superior Court decision in *Leibowitz v. Ortho Pharmaceutical Corp.* and the state Supreme Court's decisions in *Incollingo* and *Baldino v. Castagna* acknowledge the validity of "plaintiff's negligent marketing theory of liability against a drug manufacturer."

"Plaintiffs have extensively searched Pennsylvania case law and have found no case holding that the *only basis* for a

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negligence claim against a drug manufacturer is failure to warn, and any such holding would of course be contrary to the precedent ... [Plaintiffs] have found no case requiring them to prove inadequate warning as an element of any other negligence claim, such as negligent marketing or negligent failure to withdraw from the market," the brief said.

Owens, another diet drug case, also raises an issue of first impression regarding proximate causation, according to the plaintiffs' appellate brief in the case.

Plaintiffs Marie Owens and her husband, Fred Owens, are alleging that Marie Owens' PPH was caused by her use from November 1995 to April 1996 and from January to June 1997 of Pondimin, a Fen-Phen medication. Tereshko granted summary judgment in favor of Wyeth Dec. 17, 2008, on the Owens' claims.

The plaintiffs said that summary judgment should have been denied because Wyeth failed to adequately warn medical professionals of the risk of valvular heart disease from using Pondimin, according to court papers. Owens, however, was diagnosed with PPH, not valvular heart disease.

Wyeth argued that Owens did not establish proximate causation between her injury and her use of Pondimin because she failed to contest that Wyeth inadequately warned of the risk of PPH from the use of Pondimin, court papers said.

Despite Tereshko's decision to grant summary judgment on the grounds that Owens did not establish that the warning on the particular harm she suffered was inadequate, the plaintiffs continue to argue on appeal that Owens has a cognizable claim.

A drugmaker must fully warn prescribing physicians of all the harmful risks from its drugs, the Owens brief said. "Whether the drug manufacturer has breached that duty, and whether the breach was the proximate and factual cause of a given patient's injury, does not depend on what injury the patient suffered in cases where, as here, a jury could reasonably find from the doctor's testimony that he would not have prescribed the drug to the plaintiff had the doctor received from the drug's manufacturer an accurate and complete warning of all of the drug's harmful side-effects," the brief said.

Neither case is scheduled for oral argument. The Superior Court denied plaintiffs' application to consolidate appeals, but the cases will be listed, along with *Cochran v. Wyeth*, before the same panel to decide the merits of the appeals.

Plaintiffs' counsel in both *Owens* and *Lance* are Linda C. Love of Williams Love O'Leary & Powers in Portland, Ore., and Howard J. Bashman, a Willow Grove, Pa., solo practitioner. Tobi Millrood of Pogust Braslow & Millrood in Conshohocken, Pa., also is plaintiffs' counsel in *Owens*. Kenneth M. Rothweiler and Frederic Eisenberg of Eisenberg Rothweiler Winkler Eisenberg & Jeck in Philadelphia also are plaintiff's counsel in *Lance*.

Defense counsel in *Owens* includes Tracy G. Weiss, Henry F. Reichner, Barbara R. Binis and Michael T. Scott of Reed Smith in Philadelphia and Amy Rohe of Arnold & Porter in Washington, D.C. Defense counsel in *Lance* include Reichner, Scott and Binis and Ira S. Lefton of Reed Smith in Philadelphia.

Plaintiffs' counsel and a Wyeth spokesman could not be reached for comment. •