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Pennsylvania Considers Changes to Drug Products Liability Law

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Howard Bashman


Pa. Supreme Court Justice Max Baer

In questioning during oral argument Tuesday in Philadelphia, a state Supreme Court justice characterized the drugmaker Wyeth as asserting that there is enough protection for persons harmed by prescription drugs in federal regulation of the release of drugs onto the market, and limiting plaintiffs to lawsuits for drugmakers' alleged failures to adequately warn of risks.

Plaintiffs are arguing in a case that could change the landscape of pharmaceutical products liability law in Pennsylvania that drugmakers can be sued for the negligent design defect of their drugs.

Questioning the plaintiffs' lawyer, Justice Max Baer also said that Wyeth asserts that Pennsylvania would chill the manufacturing of prescription drugs if pharmaceutical companies can be sued for the negligent design defect of their drugs. He asked the lawyer to address why that may not be so.

The plaintiffs lawyer said in response that prescription drugs are inherently dangerous products. The lawyer added that it is insufficient for drugmakers to have FDA approval and still put allegedly defective drugs out on the market. Drug companies must reduce the inherent dangerousness of their products as much as possible, argued Howard Bashman, appellate counsel in the case of *Lance v. Wyeth* and a Willow Grove, Pa., solo practitioner. Bashman is a columnist on appellate issues for *The Legal* .

There is no other area of law where such immunity is available for negligence, Bashman said.

The state Superior Court panel of President Judge Correale F. Stevens and Judges Cheryl Lynn Allen and Susan Peikes Gantman ruled that a claim for negligent design defect of prescription drugs is cognizable under Pennsylvania law. But the panel also ruled that claims of alleged negligent marketing and failure to withdraw an allegedly dangerous drug from the market are not cognizable.

Design defect claims sounding in strict liability have been barred in Pennsylvania, but design defect claims sounding in negligence focus on the conduct of defendants, rather than the product in question, and should be allowed in Pennsylvania, the plaintiffs argued in court papers.

But Wyeth argued in its appellate brief that the Supreme Court "has established a tort regime that attempts to balance the need for compensating injured plaintiffs against the need to ensure the public continued access to

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affordable and beneficial prescription drugs. The court has struck this balance by appropriately focusing the inquiry on whether the risk information conveyed to prescribing physicians was sufficient to permit them to conduct an individualized risk-benefit analysis."

If a drug is properly manufactured, drugmakers only face liability if they alter that risk-benefit analysis by providing inadequate warnings of the drug's risks by "'nullifying'" adequate warnings through a swarm of marketing or by other means, Wyeth argued in court papers.

In the case of Bashman's client, Catherine R. Lance died from primary pulmonary hypertension because, according to the plaintiffs' court papers, she had taken Wyeth's weight loss drug Redux for three months in 1997. Redux was removed from the market Sept. 15, 1997, and later the FDA banned the compounding of diet-drug ingredients fenfluramine and dexfenfluramine, according to the plaintiffs' brief.

Lance's case is being brought by her mother and administratrix of her estate, Patsy Lance.

Wyeth was allegedly negligent for making a drug "whose benefits fail to outweigh its risks as to any class of patients," the plaintiffs' brief said.

However, Wyeth, now wholly owned by Pfizer, argued that Pennsylvania has recognized that prescription drugs carry a risk of harm and are "'unavoidably unsafe'" through its adoption of Comment K to *Restatement (Second) of Torts* 402A.

In light of the adoption of Comment K, the only cause of action that can be made over a prescription drug is negligent failure to warn, said Robert C. Heim, Wyeth's counsel from Dechert.

Baer, who was by far the active questioner during the oral argument, also commented that the negligent design defect theory would not exist in Pennsylvania unless the court construes the theory to not require plaintiffs to prove an alternative design.

"It's self-evident that there is no reasonable alternative design" for prescription drugs, Baer said.

Heim said that plaintiffs cannot make out a claim for negligent design defect unless they can show an alternative design. However, Heim argued that the practicalities of proving an alternative design are not possible in the realm of pharmaceutical drugs because the redesign of a prescription product would result in a different compound with a different risk profile, Heim said.

Drug companies can revise their warning labels through an FDA process, but drug companies cannot redesign their drugs without starting the testing and regulatory approval process over from start, Heim said.

The plaintiffs argued in court papers that "regardless of whether a feasible alternate design must be alleged in an ordinary case involving a product or medication that possesses some beneficial uses, this case involves a medication that the FDA has deemed to be offered for sale to any potential class of patients."

Chief Justice Ronald D. Castille commented that plaintiffs might only be able to make out a negligent design defect claim once drugs were recalled and the FDA's position on the drugs was known.

Heim argued that Lance died of primary pulmonary hypertension, which was a risk from the use of Redux warned of in the drug's label. The drug was withdrawn from the market because of the increased risk of valvular heart disease to its users, not because of the increase risk of PPH, Heim said.

Eakin asked if Lance could only prove a design defect in Redux regarding the actual medical condition that caused her death.

Bashman said it is a hurdle that his client will have to overcome, but he said it is an issue that can be litigated in trial court.

Both sides also argued that their opponents have waived parts of their case.

Wyeth argued that Lance did not brief and argue the negligent design defect claim in the trial court or the Superior Court, while Lance argued Wyeth failed to argue in the Superior Court that Lance waived her effort to reinstate her negligent design defect theory.

Lance is also represented by Linda C. Love and Michael L. Williams, of Williams Love O'Leary & Powers in Portland, Ore.

Wyeth is also represented by Judy L. Leone and Will W. Sachse of Dechert.

The oral arguments were held in Old City Hall at the Independence National Historic Park in honor of Constitution Week and under agreement between the court and the Pennsylvania Cable Network to implement television coverage of the Supreme Court's oral arguments. The Supreme Court last sat in the space 209 years ago, Castille said.

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