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Drugmakers May Face Liability For Design Defects in Pa. Court

Drug companies may face products liability claims in Pennsylvania for defectively designed drugs, the state Supreme Court has ruled on a 4-2 vote in a case stemming from the fatal use of a diet drug made by a Pfizer subsidiary that was later taken off the market.

The majority rejected the argument that manufacturing defects and inadequate warnings are the only viable products liability claims against pharmaceutical companies, and allowed claims to go forward alleging the drug company negligently designed and marketed the diet pill. The court issued its 47-page majority opinion in *Lance v. Wyeth* on Wednesday.

The case, which was set to determine whether a plaintiff could sue pharmaceutical drug companies on theories that the companies were negligent in testing, marketing and designing their prescription drug products, was argued before the high court in September 2011.

Writing the majority opinion, Justice Thomas G. Saylor ruled that a drugmaker's reliance on federal regulations and the "learned intermediary doctrine," which places duties to warn of the risks on the doctors, was not sufficient to limit a plaintiff's access to civil recovery. That issue, Saylor said, would best be taken up by the General Assembly.

"A subtext of Wyeth's positions ... is that the likelihood that a pharmaceutical company would actually tender an essentially worthless and dangerous drug into commerce is so minimal, and the burden of responding to meritless claims so great, that it is not sound to preserve an avenue for redress even for legitimate claims,"

Saylor said. "We are asked to curtail an avenue of traditional, fault-based tort liability as an all-or-nothing proposition. Based on the presentation and record before us, however, we are unable to see with reasonable clarity the results of such decision and to say with reasonable certainty that the change will serve the best interest of society. ... Accordingly, we are not in a position to make a responsible, substantive change in the law."

Saylor was joined by Justices Max Baer, Debra M. Todd and Seamus P. McCaffery.

Justice J. Michael Eakin offered a dissenting opinion, contending that the plaintiff's arguments had not been preserved and were not properly before the Supreme Court. Chief Justice Ronald D. Castille joined the dissent.

"We are disappointed in today's ruling, which is procedural in nature and is not a decision on the merits of the case which the plaintiff still must prove," Pfizer said in an emailed statement. "The company is prepared to defend against the plaintiff's claims when the case returns to a lower court for further proceedings. Novel design-defect claims have never been previously recognized in Pennsylvania law, and we are considering all our legal options."

According to Howard Bashman, one of the attorneys representing the plaintiff, the ruling will not only impact products liability law in Pennsylvania, but in other jurisdictions as well.

"Not only does this confirm the existence of these claims in Pennsylvania law, but it may lay the groundwork in other states to consider the availability of claims like these," he said. "Not very many state appellate courts have yet had the occasion to consider the availability of negligent design and negligent marketing claims against an available drug."

According to court papers, plaintiff Patsy Lance is the administratrix for the estate of her deceased daughter, Catherine Lance. Catherine Lance took Wyeth diet drug Redux from January to April 1997, court papers said. Catherine Lance died from complications related to primary pulmonary hypertension. Redux was withdrawn from the market in September 1997.

Patsy Lance alleged in court papers that Wyeth, now owned by Pfizer, delayed public disclosure of the risk of heart valve disease caused by its diet drugs, including Redux, in long-term users. Redux only contained dexfenfluramine, the potent half of fenfluramine, which made up part of the diet drug cocktail Fen-Phen. Fenfluramine and dexfenfluramine are now both illegal to compound, court papers filed by plaintiffs said.

The plaintiff contended, according to court papers, that the U.S. Food and Drug Administration's removal of the drug indicated that no risk-benefit balancing test could have indicated that Redux should have ever been available to any class of patients.

Wyeth argued that state law only recognizes theories based on adverse effects of prescription drugs, and the court should only allow recovery for manufacturing defect and inadequate warning claims, Saylor said.

Citing the state Supreme Court's 1984 decision in *Baldino v. Castagna* and 1996 decision in *Hahn v. Richter*, Wyeth also argued for a need to allow reasonable limitations on liability against pharmaceutical companies so that the continued availability and development of beneficial yet possibly risky medication is not deterred.

Wyeth further argued that because no drug can have a safer alternative design, as a redesign would result in a different compound, negligent design theories could not be applied to prescription drugs, Saylor said.

Saylor, however, said that Wyeth's argument was "in tension with the nature of common-law lawmaking."

"Although the company does not articulate its position in such terms, Wyeth is asking, for policy reasons, that we should insulate pharmaceutical companies from liability even for a patent lack of due care so deleterious as to create an untenable threat to human health," he said.

Noting the advantages that the FDA process affords to drug manufacturers, Saylor said that the creation of a design-defect immunity for drugmakers is an issue that should be brought before the General Assembly.

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(Copies of the 56-page opinion in Lance v. Wyeth, PICS No. 14-0080, are available from The Legal Intelligencer. Please call the Pennsylvania Instant Case Service at 800-276-PICS to order or for information.)
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