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Justices' Pharma Ruling Could Open New Avenue for Recovery

MAX MITCHELL
Of the Legal staff

Although not all attorneys agree, many plaintiffs lawyers are taking the recent state Supreme Court decision that allowed a plaintiff's defective-design claims to go forward against a Pfizer subsidiary as a major victory in the pharmaceutical litigation arena.

Last week, the justices issued their decision in Lance v. Wyeth, which affirmed the state Superior Court's holding to allow a plaintiff to pursue a negligence claim against the drugmaker for putting an allegedly defective drug on the market. The court on a 4-2 vote issued the ruling Jan. 22 with Justice Thomas G. Saylor writing the majority opinion.

According to several attorneys who spoke with The Legal, the decision essentially greenlights a new avenue of recovery against drugmakers and also weakens the plaintiff's dependence on the prescribing physician to successfully bring a case.

"This opinion is absolutely right," said attorney Rosemary Pinto of Feldman & Pinto. "The failure-to-warn theory should not be the only theory. If this drug is dangerous and shouldn't have been on the market, there's no reason people should be limited to the failure-to-warn theory."

Shanin Specter of Kline & Specter said the opinion was a "monumental" decision on par with some of the most important decisions of the last 50 years, and validates the negligent design-defect theory for products that are too risky for the marketplace.

"The Lance decision is a common-sense approach, long in coming, but now adopted by the Pennsylvania Supreme Court," he said. "It's a really important day in Pennsylvania for consumers of pharmaceuticals, which is all of us."

Mass torts attorney Claudine Homolash said the decision is a win for plaintiffs.

"It allows plaintiffs to bring a design-related negligence action for a company's lack of due care for allowing a untenably dangerous product to be introduced into the market," she said in an email. "Many times we learn during the course of discovery that the company knew all along that the product was simply not safe and ignored the known adverse effects, making profits its key focus. Hopefully this decision will curb some of this misconduct in the pharmaceutical industry."

Some defense attorneys who spoke with The Legal, however, said that Lance was a limited decision, which hinged on procedural concerns and was bound by the unique history of the case.

According to court papers, plaintiff Patsy Lance is the administratrix for the estate of her deceased daughter, Catherine Lance. Catherine Lance took the 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, however, 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.

While the common pleas court granted Wyeth's summary judgment motion, the state Superior Court reversed, and Wyeth appealed to the Supreme Court.

According to defense attorney Joseph E. O'Neil of Lavin O'Neil Ricci Cedrone & DiSipio, because of the procedural history, and particularly the summary judgment, the court was bound by the assumption that the plaintiff's allegations were true, and therefore the case was too fact-specific to have a sweeping effect.

"In my own view, it will have limited impact on pharmaceutical cases in Pennsylvania," he said. "Justice Saylor goes out of his way to repeatedly, in footnotes and the body of the opinion to stress the facts that in this case, we have to presume the plaintiff's allegations are true. That's where the court was issuing its opinion."

Defense attorney John F. Brenner of Pepper Hamilton agreed that the decision was very fact-specific, but said he found that the holding was striking and deviated from the longstanding idea that design-defect claims cannot be applied to pharmaceutical drugs, as it takes the regulatory considerations out of the hands of the FDA and places them in the hands of a jury.

"As we all know, lawyers are clever and creative and I could see plaintiffs attorneys using this as a new avenue for liability in prescription drug cases," he said. "I'm confident that creative lawyers will use this to say it's not constrained to its facts at all, and that it's a new cause of action they can apply to a lot of different scenarios."

Brenner said he wouldn't be surprised if the claims were used against drugs that were still on the market, which he said could create wide-ranging policy problems.

"If someone proves to a jury that drug X shouldn't be on the market at all, does that mean that the manufacturer needs to remove that drug from all 50 states?" he asked. "Is that fair to a person in California [using the drug], that a jury in Pennsylvania found the drug was so unsafe?"

Learned Intermediary Doctrine

According to several plaintiffs attorneys who spoke with The Legal, plaintiffs who bring similar defective-design claims may be able to avoid the hurdle of the learned intermediary doctrine. The doctrine, attorneys said, placed much of the liability on the shoulders of the prescribing doctors after the pharmaceutical companies provided warnings to the doctors regarding the risks associated with the products. As a result of the doctrine, plaintiffs were dependent on the testimony of the prescribing doctors, which proved problematic even for meritorious claims.

According to Pinto, cases involving drugs with long latency periods, in particular Fen-Phen, were problematic, as some of the prescribing doctors have retired and are unable to be reached and have died.

"It becomes difficult to get the testimony potentially required under the learned intermediary doctrine," she said. "For those cases where the plaintiff would have been potentially out of court due to the unfortunate circumstances, that will no longer occur."

Attorney Howard Bashman, who represented Lance during the appeals, said he anticipated that the decision will be used by plaintiffs to chip away at the learned intermediary doctrine in the more customary negligent failure-to-warn cases as well.

"The rationale for the learned intermediary doctrine has become more questionable," he said. "I anticipate that people in negligent warning and failure-to-warn cases will undoubtedly be trying to draw on the majority opinion's language."

The ruling, according to Specter, brings pharmaceutical products liability litigation in line with other products liability cases.

"These cases should always have been approached in the way the court has now ordered, and that is that a pharmaceutical is like any other product, and the manufacturer has to appropriately warn and they have to not put it on the market if it's unsafe," Specter said. "If that's the law for a car, or a consumer product, or a widget, it ought to be true for a pharmaceutical and now it is."

O'Neil, however, said that the ruling will not diminish the learned intermediary doctrine because the facts in the Lance case differed from the majority of pharmaceutical cases and because the summary judgment mandated that the high

court accept the plaintiff's allegations about the allegedly inherently dangerous drug as fact.

"If you start with that premise, which was not proven but the court had to presume ... how could the learned intermediary be applied to that?" he asked.

Attorneys agreed that the high court's decision will, at the very least, strengthen numerous pharmaceutical cases that are pending in the state. Plaintiffs have for years been making negligent design claims in their complaints, several attorneys said, and this decision will now validate those claims.

While some attorneys said that it will not likely cause any increase in litigation, Brenner, and others, said that the decision does create the possibility of new claims.

"It does have the capacity to bring new claims that might not otherwise have been brought," he said.