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Justices Take Up Case on Negligent Design Drug Claim

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The state Supreme Court has taken up a case that gives it 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 to grant allocatur in *Lance v. Wyeth* last week has the potential to change the landscape of prescription drug liability in Pennsylvania.

Currently, lawyers say that the only cognizable claims that plaintiffs can make in Pennsylvania are those that say drug manufacturers were negligent in failing to warn the plaintiffs' prescribers of the risks of using their products, or that drugmakers are strictly liable for manufacturing defects.

According to the order granting allocatur, the justices are prepared to consider the validity of a claim for negligent design defect of a prescription drug.

Another issue in the case is whether Pennsylvania law should recognize a claim against prescription drug manufacturers for alleged negligence in failing to test drugs for harmful side effects.

The case also presents the issue of whether state drug law would allow plaintiffs to sue on the theory that drugmakers can be negligent in marketing a drug and failing to withdraw the drug from the market if the federal Food and Drug Administration ultimately orders that drug be withdrawn because it is too dangerous for anyone to use it.

The court granted plaintiff Patsy Lance's and drugmaker Wyeth's cross-petitions for allowance of appeal.

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.

Among other arguments, Wyeth, now owned by Pfizer, argues that plaintiffs in a design defect case must plead and prove a feasible alternative design.

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 Redux was withdrawn from the market September 1997.

Patsy Lance alleges in court papers that Wyeth 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 another diet drug, Fen-Phen. Fenfluramine and dexfenfluramine are now both illegal to compound, court papers filed by plaintiffs said.

Testing

The plaintiff argued that the Superior Court's decision to reject negligent testing as a cause of action is in conflict with the 1973 prediction by the 3rd U.S. Circuit Court of Appeals in *Hoffman v. Sterling Drug Inc.* that Pennsylvania would allow a claim for negligent failure to test to be asserted against a prescription drug manufacturer.

The plaintiff also argued that all six judges, on an equally divided en banc Superior Court panel, said in *Leibowitz v. Ortho Pharmaceutical Corp.* that a drugmaker can't escape liability by "'merely ignoring existing reports of side-effects or dangers in the use of its product.'"

Barring the theory of negligent failure to test may make sense in the context of a prescription drug that has a benefit that outweighs "its actual but undisclosed dangers," but the theory is cognizable in the case of a drug like Redux in which the medication's risks outweighs the benefits "as to all possible classes of plaintiffs," the plaintiff said in her brief.

"What makes this case and other cases involving these Fen-Phen drugs different from the typical, run-of-the-mill prescription drug failure to warn cases is that these medications have subsequently been entirely banned from the market by the FDA," Lance argued in court papers. "In other words, there is no risk-benefit balancing test that can be performed with respect to Redux that would allow anyone to conclude that this medication should be, or ever should have been, available to any class of patients, as demonstrated by the FDA's decision completely banning this drug from the market."

Pfizer argues that the Supreme Court's decision in *Hahn* and in other cases recognized a failure to warn as the only cognizable claim against the seller of "properly manufactured drug." But Lance argues that *Hahn* barred strict liability claims against drugmakers, not other negligence claims besides failure to warn claims.

Design

The Superior Court panel concluded the *Restatement (Second) of Torts* , Section 395, which regards a negligent design of products, does not provide special protection for prescription drugs, *The Legal* previously reported.

Citing an Idaho Supreme Court decision from 1987 and a California appeals court decision from 1994, the court said that "a negligent design defect claim is considered to be distinct from a strict liability design defect claim."

Pfizer's first argument against the negligent design defect theory is procedural. The company said in its brief that the specific issue was not presented in the trial court of the intermediate appellate court, including in the plaintiff's statement of issues, the plaintiff's briefing in opposition to the defense motion for summary judgment and in the plaintiff's statement of questions presented to the Superior Court.

Secondly, on a different view of the law than espoused by the Superior Court, Pfizer looked to Comment K of the *Restatement (Second) of Torts* , Section 402A, rather than Section 395, arguing that Comment K gives special treatment to prescription drugs. The Supreme Court's adoption of Comment K "reflects a policy judgment by this court that prescription drugs, as a category, are 'unavoidably unsafe,'" Pfizer said in its brief. "Put simply, prescription drugs are different from other products — drugs inevitably carry some risk accompanying the benefits they provide, which is why they require a physician's prescription."

Lance argued that Comment K requires that the prescription drugs are "'properly prepared and marketed, and proper warning is given.'"

Thirdly, Pfizer said the new cause of action does not require plaintiffs to provide the existence of a feasible alternative design or show the necessary deference to the FDA about the safety of prescription drugs.

"The Superior Court's decision potentially greatly expands liability against prescription drug manufacturers," Pfizer argued in its brief. "In fact, plaintiff's failure to put forth any 'feasible alternative design' makes clear that her 'negligent design defect' cause of action is nothing more than a disguised claim that Redux should never have been approved by the FDA, or should have been withdrawn sooner than it was — a claim even the Superior Court recognized that is not cognizable under Pennsylvania law."

Howard Bashman, the appellate counsel for the plaintiff and a Willow Grove, Pa., solo practitioner, said "the defendants have been arguing the only type of negligent claim they can be liable for is negligent failure to warn. It's our position that's not what Pennsylvania law says."

Bashman said that they were encouraged recently by a Superior Court decision in *Wright v. Aventis Pasteur* that a negligent design defect claim could be sustained against the manufacturers of vaccines. The court found that some design defect claims that arise from unavoidable vaccine side effects are pre-empted by federal law.

That ruling would seem to allow recognition of negligent design defect claims for prescription drug manufacturers, Bashman said. Bashman writes an appellate law column for *The Legal* .

Pfizer counsel Robert C. Heim, of Dechert, said that "we were very happy that the court decided to take this because the Superior Court had seemed to be creating a whole new cause of action that had never been argued or briefed to the Superior Court and which has never been a part of Pennsylvania law: this theory of negligent design defect in a prescription drug."

Co-counsel for Lance are Linda C. Love and Michael L. Williams of Williams Love O'Leary & Powers in Portland, Ore.

Co-counsel for Pfizer are Judy L. Leone and Will W. Sachse of Dechert.

Two other cases, *Owens v. Wyeth* and *Cochran v. Wyeth* , decided by the same Superior Court panel and also presenting issues of first impression, are still pending in front of the Supreme Court. •