Client Alert

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Lance v. Wyeth: A New Cause of Action in Pennsylvania?

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Issuing an opinion over two years after oral argument, the Pennsylvania Supreme Court ruled last week in *Lance v. Wyeth* that pharmaceutical companies can be held liable for negligence in the design and marketing of drugs. While the 4-2 majority opinion stated that Wyeth was asking for the court to impose "a new [restricted] duty regime" by ruling against such negligence claims, this decision actually expands the duty regime by allowing them.

BACKGROUND

In April 1996, the Food and Drug Administration ("FDA") approved Redux as a prescription weight-loss drug. The Redux packaging warned of an increased risk of pulmonary hypertension ("PPH"). By September 1997, Wyeth and the FDA announced that the drug would no longer be available in the United States following reports of an association between the medication and serious heart problems.

In the fall of 2006, Patsy Lance brought this case on behalf of her daughter, Catherine Lance, alleging that Catherine ingested Redux for several months in 1997. The complaint alleged that the drug caused Catherine to develop PPH, from which she died within a month after her diagnosis in 2004. Lance framed her claims as "Negligence—Unreasonable Marketing of a Dangerous Drug and Unreasonable Failure to Remove the Drug from the Market before January 1997." Lance disavowed any claim based upon inadequate labeling.

At the lower court level, Wyeth filed and won a motion for summary judgment, arguing that Lance failed to assert a cognizable cause of action. On appeal, the intermediate appellate court found that Lance should have been permitted to proceed with a claim of negligent design only. Wyeth and Lance cross-appealed to the Pennsylvania Supreme Court, "challenging, respectively…that pharmaceutical companies are not immune (under Pennsylvania law) from claims of negligent drug design, and that claims of negligent marketing, testing, and failure to withdraw are unviable."

THE SUPREME COURT'S DECISION

The majority of the Pennsylvania Supreme Court affirmed the intermediate court's ruling reinstating Lance's negligent design defect claim but reversed the part of the decision that disallowed other negligence-based theories, such as negligent marketing.

On appeal, Wyeth maintained that, under Pennsylvania precedent, claims against pharmaceutical companies were limited to manufacturing defects and inadequate warnings. But the Pennsylvania Supreme Court held that the case was a matter of first impression. The court noted that "products which a manufacturer or supplier knows or should know are too dangerous for any class of users are simply outside the purview" of previous decisions. Because the underlying decision was made at the summary judgment level, the court was required to accept as true that there was "a lack of due

care resulting in an untenably dangerous product being put into the marketplace."

The Pennsylvania Supreme Court recognized in *Lance* that previous decisions took "a blanket approach applying comment k of the Restatement (Second) of Torts § 402A to preclude strict-liability design defect claims for all prescription drugs."[1] The court held, however, that the adoption of comment k in the strict liability realm did not preclude a claim based on the negligent "design" of a prescription drug. According to the court, it is "plain enough that the comment [k] is premised on the assumption that all products within its scope carry some net benefit (relative to risks) for some class of consumers."

The court also disagreed "that comment k, a facet of the law of strict liability under the Restatement Second, readily translates into the negligence arena, particularly given the very distinct treatment of strict-liability versus negligence theory required under" Pennsylvania law. The court noted one of "the primary distinctions which has been vigorously maintained is that strict products liability is said to be concerned solely with the product itself. There is greater flexibility, however, with regard to traditional, fault-based liability – i.e., negligence – where the conduct of manufacturers and/or suppliers is squarely in issue."

Ultimately, the court saw Wyeth as "asking, in substance, that we should invoke policy justifications to scale back the existing duty of pharmaceutical companies to independently and vigilantly protect against unreasonable health risks which may be posed by products made for human consumption." The court suggested:

> A subtext of Wyeth's position…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. We do not discount the impact of litigation on the pharmaceutical industry, but we simply do not know enough about it to undertake any kind of reasoned comparison of the social policy effects of curtailing fault-based liability in Pennsylvania.

Maj. Op. at 36.

Despite the court's discussion of "scaling back" an "existing duty" and "curtailing fault-based liability," the opinion did not cite to a single decision allowing design-related negligence claims without providing an alternative feasible design. The court acknowledged that "proof of a reasonable alternative design is a typical device used to establish defect." But, the majority opinion also noted the lack of decisions from "this Court making an alternative safer design an absolute prerequisite to any and all design-based claims." The court held that a "company which is responsible for tendering into the market a drug which it knows or should know is so dangerous that it should not be taken by anyone can be said to have violated its duty of care either in design or marketing…In other words, in the negligence arena at least, the substantive allegations are more important than the labels."

In addressing Lance's negligent marketing claim, the court agreed with plaintiff that "the law of negligence establishes a duty, on the part of manufacturers, which can be viewed on a continuum" ranging from "a warning of dangers, through a stronger warning if justified by the known risks, through non-marketing or discontinuance of marketing" if the product

[1] RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965) relates to "unavoidably unsafe products" and states that "such a product, properly prepared and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous."

simply should not be used in light of its relative risks. Thus, the court held, to the degree Lance wished "to couch the lack of due care manifested in such circumstances as negligent marketing, this is consistent with her prerogative as master of her own claim."

DECISION'S SIGNIFICANCE

It is likely that this decision will lead to an increased number of complaints brought against pharmaceutical companies in Pennsylvania—especially in Philadelphia where plaintiffs already take advantage of the mass tort program. Indeed, the Pennsylvania Supreme Court implicitly acknowledged the possibility of increased lawsuits in its decision. It is also possible that this will be the start of a larger push by plaintiffs' attorneys in jurisdictions that have not yet addressed the question.

There are good arguments to limit the holding to situations in which the drug has already been taken off the market, but, on its face, the opinion does not do so. Moreover, it is important to remember that the *Lance* decision simply returned the case to the trial court level for further proceedings, and the ultimate outcome is unknown. In the interim, pharmaceutical manufacturers should expect additional litigation in Pennsylvania based on what is a novel theory of liability in the pharmaceutical arena.

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