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EXPERT ANALYSIS

Plaintiffs May Assert Negligent-Design Claims for Prescription Drugs, Pa. Supreme Court Holds

By Philip N. Yannella, Esq., Michael R. Carroll Esq., and Michelle C. Ventura, Esq.
Ballard Spahr

In a stunning decision with broad implications for pharmaceutical companies in Pennsylvania and elsewhere, the Supreme Court of Pennsylvania has held that plaintiffs may assert negligence claims against pharmaceutical companies relating to the design, testing, marketing and distribution of drugs regulated by the Food and Drug Administration.

The decision upends years of accepted law in Pennsylvania. While the state Supreme Court had not previously addressed the precise issue of a pharmaceutical company's alleged lack of care in the design and testing of a marketed drug, pharmaceutical companies generally have succeeded in securing the dismissal of such claims by relying on the learned-intermediary doctrine and the FDA's rigid approval process for prescription drugs.

This new decision will enable juries to second-guess FDA approval by concluding that an approved medicine is, or at least was, too dangerous to be marketed in the first place. If it stands, this case will alter the terrain of pharmaceutical litigation in Pennsylvania.

Lance v. Wyeth, Nos. 17 EAP 2011 and 18 EAP 2011, 2014 WL 260309 (Pa. Jan. 21, 2014), stemmed from two weight-loss drugs widely prescribed in the 1990s: Pondimin (fenfluramine) and Redux (dexfenfluramine). Wyeth stopped selling the drugs following reports that they were linked to valvular heart disease.

The plaintiff's daughter died from pulmonary hypertension years after taking one of the drugs. The plaintiff's central legal claim was one of negligence, alleging that the drug was "unreasonably dangerous," and that it therefore was unreasonable to market the drug or fail to remove it from the market sooner. Other claims included negligent design, research, development, sale and testing.

Wyeth argued, among other things, that Pennsylvania had refused to extend strict liability to prescription drug manufacturers, consistent with the approach of the Restatement (Second) of Torts, § 402A, Comment k. Specifically, Wyeth argued, consistent with Pennsylvania law, that prescription drugs are by necessity unavoidably unsafe but are not unreasonably dangerous or defective when accompanied by proper warnings and directions.

Wyeth interpreted Pennsylvania case law and Comment k as precluding negligent design claims against drug manufacturers, particularly given that no plaintiff ever could prove a reasonable alternative design.

Wyeth also argued that allowing the plaintiffs to bring only failure-to-warn and manufacturing defect claims struck the appropriate balance between compensating injured consumers and not discouraging the continued development of beneficial medicines. Indeed, Wyeth stressed that the FDA had approved its drugs, and the risk-benefit analysis underlying that approval was the FDA's exclusive province.

Lance ***stands as a significant expansion of pharmaceutical manufacturer liability in Pennsylvania.***

The Pennsylvania Supreme Court rejected what it characterized as Wyeth's attempts to "insulate" pharmaceutical companies from negligence claims. As the dissenting opinion makes clear, much of the court's reasoning relies on its questionable decision to frame the issue as one of limiting a recognized cause of action as opposed to one of recognizing a new cause of action.

In rejecting Wyeth's arguments, the court concluded that Comment k was inapplicable because it presumes that a medicine has some net benefit and therefore does not apply to a claim that a drug is too dangerous to be used by anyone. Additionally, the court acknowledged the FDA's limited resources and further concluded that absolute deference to a federal body based on its approval of a particular drug could have negative effects.

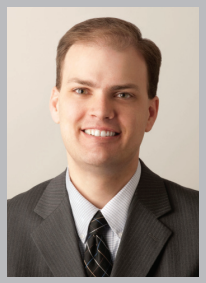
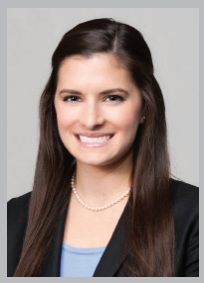
The court added that strict liability focuses on the product itself and not on the conduct of the manufacturer. Such companies are held to a high degree of care under Pennsylvania tort law and federal law, and they should not be excused from such duties categorically, the court said.

The opinion is less than clear regarding whether a plaintiff advancing a negligent design claim must demonstrate a reasonable alternative design, but the court emphasized that it has not previously required such proof as an "absolute prerequisite" to a design defect claim. In fact, the opinion suggests that a plaintiff may satisfy that requirement by referring to other existing treatments as a substitute for a drug "so dangerous it should not be used."

Interestingly, despite rendering a landmark decision recognizing a new cause of action, the court conceded, "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."

The court also raised significant doubt regarding the ability to assert a negligent-design claim (premised on the argument that a drug is too dangerous to be used by anyone) to a drug still on the market. Specifically, the court acknowledged that such an argument would be difficult to advance in a circumstance where a drug "maintained its FDA approval, it remained on the market and U.S. doctors continued to prescribe it."

Despite those concessions, *Lance* stands as a significant expansion of pharmaceutical manufacturer liability in Pennsylvania, particularly concerning withdrawn or recalled drugs, and it raises substantial preemption concerns in the process.

Philip N. Yannella (L), **Michael R. Carroll** (C) and **Michelle C. Ventura** (R) are attorneys at **Ballard Spahr** in Philadelphia. Yannella, a member of the firm's product liability group, has represented pharmaceutical companies in product liability, consumer fraud and commercial litigation matters throughout the country. Carroll focuses on complex commercial and product liability litigation, including the defense of class actions, and has substantial experience defending pharmaceutical and medical device companies. Ventura is an associate in the firm's litigation department.