Products Liability Law Daily Wrap Up, DESIGN AND MANUFACTURING DEFECTS—DRUGS—Pa. Sup. Ct.:Responsibility of drug companies to maintain safety not limited: manufacturers liable for negligent design, (Jan. 23, 2014)

By Patricia K. Ruiz, J.D.

The Pennsylvania Supreme Court reversed in part an order of the Superior Court granting summary judgment to a manufacturer of an appetite suppressant drug alleged to cause serious coronary impairments. In its decision, the court noted that—despite arguments that a drug manufacturer only can be liable for drug impurities and deficient labeling and that compliance with Food and Drug Administration (FDA) regulation forecloses the possibility of negligence—there is no basis for scaling back the responsibility of pharmaceutical companies for ensuring the safety of its drugs for human consumption (*Lance v. Wyeth*, January 21, 2014, Saylor, T).

Background. Catherine Lance, the daughter of Patsy Lance, took the drug Redux for several months, which Patsy alleged caused Catherine to develop pulmonary hypertension (PPH). Within a month following her diagnosis in 2004, Catherine died. Patsy sued Wyeth, formerly known as American Home Products Corporation, the manufacturer and supplier of Redux, and its pharmaceutical cousin, Pondimin.

Pondimin consists of fenfluramine, which contains dexfenfluramine, an appetite suppressant. Pondomin was paired with phentermine, an amphetamine used to negate some of the undesirable side effects of fenfluramine. Redux, which was purified dexfenfluramine, was created to stimulate the anorectic effect of Pondimin without the drug pairing. It was approved by the FDA in 1996, containing a prominent warning of the increased risk of PPH on its packaging. By mid-1997, reports surfaced of a connection between dexfenfluramine and serious coronary impairments, leading Wyeth and the FDA to take Pondimin and Redux out of distribution in the U.S.

Manufacturer liability. In her complaint, Patsy alleged negligence, citing unreasonable marketing of a dangerous drug and unreasonable failure to remove the drug from the market before January 1997. She claimed that Wyeth owed a duty to Catherine not to introduce an unreasonably dangerous drug into the market, and that Wyeth "failed to exercise ordinary care in the design, research, development, manufacture, sale, testing," and/or distribution of Redux. However, Patsy did not allege inadequate labeling.

Negligent design defect. Wyeth moved for summary judgment arguing that under the products liability law of Pennsylvania, the only theories for which a manufacturer can be liable are drug impurities and deficient warnings, neither of which Patsy argued. Further, Wyeth argued that courts have refused to impose tort liability for negligent design defects because recognizing a design defect claim would require evidence of an alternative safer design. Wyeth asserted this was impossible for drugs because an alternative design "would result in a completely different compound with different properties and its own unique benefits and risks."

Analysis. Reviewing the lower court's grant of of summary judgment, the Pennsylvania Supreme Court looked at the facts in the light most favorable to Patsy, accepting that Wyeth manufactured and distributed Redux with actual or constructive knowledge that the risks outweighed the benefits of the drug. As such, the court also accepted that Wyeth failed to share relevant information with the FDA and that information did not reach prescribing physicians. Despite Wyeth's arguments regarding the limits of liability for drug manufacturers, the authority cited by Wyeth did not encompass a scenario in which lack of due care resulted in the dissemination of an "effectively useless and dangerous" drug.

In addition, the Pennsylvania Supreme Court refused to expand the responsibilities of medical professionals in order to scale back the duties of pharmaceutical companies "to independently and vigilantly protect against unreasonable health risks" posed by drugs meant for human consumption. The court also noted that Wyeth's argument that its compliance with FDA regulation warrants departure from Pennsylvania tort law failed because there existed in the current case "a demonstrated lack of due care in the face of an existing duty."

Justice Eakin dissented, and was joined by Chief Justice Castille.

The case numbers are 17 EAP 2011, 18 EAP 2011.

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Companies: Wyeth, formerly known as American Home Products Corporation

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