SUPREME COURT OF PENNSYLVANIA

Lance v. Wyeth, Inc.

624 Pa. 231 (2014) (Pa. 2014) · No. 17 EAP 2011; 18 EAP 2011 · Decided January 21, 2014

SUMMARY

The Pennsylvania Supreme Court considered whether Pennsylvania products-liability law permits claims against a pharmaceutical manufacturer for negligent design, marketing, testing, or failure to withdraw an FDA-approved prescription drug, beyond claims based on impurities or inadequate warnings. The case involved Redux, an appetite suppressant alleged to have caused pulmonary hypertension and death, and addressed the relationship between negligence theories, strict liability, comment k to Restatement § 402A, and FDA regulation.

CASE DETAILS

COURT	Supreme Court of Pennsylvania
WRITING FOR THE COURT	Justice Saylor; Justice Baer; Justice Todd; Justice McCaffery; Justice Eakin; Chief Justice Castille
JURISDICTION	Pennsylvania
DECIDED	January 21, 2014
DOCKET	17 EAP 2011; 18 EAP 2011
DISPOSITION	other
PROCEDURAL POSTURE	Cross-appeals from a summary judgment order in a pharmaceutical products-liability action. The Philadelphia County Court of Common Pleas granted summary judgment for Wyeth; the Superior Court reversed in part, permitting a negligent-design-defect claim but rejecting negligent marketing, testing, and failure-to-withdraw theories.
STANDARD OF REVIEW	Plenary review of legal issues and summary judgment. Summary judgment is proper when there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law; facts and reasonable inferences are viewed in the light most favorable to the nonmoving party.
PRECEDENTIAL VALUE	Published precedential opinion of the Supreme Court of Pennsylvania
PARTIES	Wyeth, Patsy Lance v. Patsy Lance, Wyeth

TOPICS

products liability | negligence | duty of care | personal injury | appellate procedure

PRACTICE AREAS

products liability | pharmaceutical litigation | negligence | personal injury | appellate procedure

QUESTIONS PRESENTED

1. Whether Pennsylvania law immunizes pharmaceutical manufacturers from negligence liability for introducing or continuing to market a prescription drug that the manufacturer knew or should have known was too dangerous for anyone to use.
2. Whether Pennsylvania's adoption of Restatement (Second) of Torts § 402A comment k, which limits strict liability for unavoidably unsafe products, also bars negligence-based design, marketing, or failure-to-withdraw claims.
3. Whether the plaintiff waived a negligent-design or related negligence theory by styling her claim as negligent marketing and failure to withdraw.
4. Whether the learned-intermediary doctrine insulates a pharmaceutical manufacturer from liability where the alleged danger is so severe that no warning would make the drug appropriate for any patient.

HOLDINGS

1. Under Pennsylvania law, a pharmaceutical company violates its duty of care if it introduces a drug into the marketplace or continues to market it with actual or constructive knowledge that the drug is too harmful to be used by anyone. Pennsylvania law does not immunize pharmaceutical companies from fault-based liability for such conduct.
2. Comment k's protection against strict liability for unavoidably unsafe products does not categorically bar negligence claims involving prescription drugs.
3. A manufacturer or supplier has a duty to cease further distribution of a product when it knows or reasonably should know that the product is too dangerous to be used by anyone.
4. The learned-intermediary doctrine does not diminish a pharmaceutical manufacturer's duties or insulate it from liability where the alleged product is so dangerous that no warning would be sufficient and no physician, if appropriately informed, would prescribe it.
5. The plaintiff did not waive the theory because Wyeth itself sought a categorical rule barring all pharmaceutical-products-liability theories other than impurities and warnings, thereby providing a fair opportunity to address the scope of the proposed preclusion.

KEY QUOTATIONS

> *"Under Pennsylvania law, pharmaceutical companies violate their duty of care if they introduce a drug into the marketplace, or continue a previous tender, with actual or constructive knowledge that the drug is too harmful to be used by anyone."* (461-62)

> *“We are convinced that a manufacturer or supplier has a duty to cease further distribution of a product at such point as it may know, or may reasonably be charged with knowledge that the commodity is too dangerous to be used by anyone.”* (460)

> *“In other words, in the negligence arena at least, the substantive allegations are more important than the labels.”* (458)

FACTUAL BACKGROUND

Wyeth manufactured and supplied the prescription appetite suppressant Redux, which was approved by the FDA in 1996 and carried a warning concerning pulmonary hypertension. Catherine Lance ingested Redux for several months in 1997 and was diagnosed with pulmonary hypertension in 2004; she died within a month of the diagnosis. Her administratrix alleged that Wyeth knew or should have known that Redux's risks outweighed its benefits for all potential users, yet introduced or continued to market the drug.

PROCEDURAL HISTORY

Patsy Lance, as administratrix of her daughter's estate, sued Wyeth alleging that Redux caused pulmonary hypertension and that Wyeth negligently marketed the drug and failed to remove it from the market. The Court of Common Pleas granted Wyeth summary judgment on the ground that Pennsylvania law limited pharmaceutical-products liability to impurities and inadequate warnings. The Superior Court held that a negligent design-defect claim could proceed but rejected other negligence theories. The Supreme Court of Pennsylvania affirmed in part and reversed in part.

DISPOSITION

other

REMAND INSTRUCTIONS

The Superior Court's order was affirmed in part and reversed in part. The opinion permitted the plaintiff to pursue a negligence claim based on the alleged marketing, design, or continued distribution of Redux despite knowledge that it was too dangerous for anyone to use. The opinion left evidentiary issues for further proceedings.

CASES CITED

- In re Diet Drugs, 582 F.3d 524 (3d Cir. 2009)
- In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Products Liability Litigation, 553 F. Supp. 2d 442 (E.D. Pa. 2008)
- Hahn v. Richter, 543 Pa. 558, 673 A.2d 888 (1996)
- Lance v. Wyeth, 4 A.3d 160 (Pa. Super. Ct. 2010)
- Summers v. Certainteed Corp., 606 Pa. 294, 997 A.2d 1152 (2010)
- Incollingo v. Ewing, 444 Pa. 263, 282 A.2d 206 (1971)
- Baldino v. Castagna, 505 Pa. 239, 478 A.2d 807 (1984)

- Coyle v. Richardson-Merrell, Inc., 526 Pa. 208, 584 A.2d 1383 (1991)
- Phillips v. Cricket Lighters, 576 Pa. 644, 841 A.2d 1000 (2003)
- Wright v. Aventis Pasteur, Inc., 14 A.3d 850 (Pa. Super. Ct. 2011) (en banc)
- Wyeth v. Levine, 555 U.S. 555, 129 S. Ct. 1187 (2009)
- Azzarello v. Black Bros. Co., 480 Pa. 547, 391 A.2d 1020 (1978)
- Seebold v. Prison Health Services, Inc., 618 Pa. 682, 57 A.3d 1232 (2012)
- Oliver v. City of Pittsburgh, 608 Pa. 386, 11 A.3d 960 (2011)
- Cafazzo v. Central Medical Health Services, Inc., 542 Pa. 526, 668 A.2d 521 (1995)
- Grundberg v. Upjohn Co., 813 P.2d 89 (Utah 1991)
- Freeman v. Hoffman-La Roche, Inc., 260 Neb. 552, 618 N.W.2d 827 (2000)
- Toner v. Lederle Laboratories, 112 Idaho 328, 732 P.2d 297 (1987)
- Duchess v. Langston Corp., 564 Pa. 529, 769 A.2d 1131 (2001)
- Berrier v. Simplicity Manufacturing, Inc., 598 Pa. 594, 959 A.2d 900 (2008)
- Bruesewitz v. Wyeth LLC, 562 U.S. 223, 131 S. Ct. 1068 (2011)