In the Supreme Court of Pennsylvania

No. _____

PATSY LANCE, Administratrix for the Estate of
CATHERINE RUTH LANCE, Deceased,

Petitioner,

v.

WYETH, f/k/a
AMERICAN HOME PRODUCTS CORP; et al.

PETITION FOR ALLOWANCE OF APPEAL

On Petition for Allowance of Appeal from the Judgment of the Superior Court of Pennsylvania at No. 2905 EDA 2008, filed August 2, 2010, Affirming in Part and Reversing in Part the Judgment of the Court of Common Pleas of Philadelphia County, Pennsylvania, Civil Trial Division, November Term 2006, No. 926, entered September 19, 2008

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I. REFERENCE TO THE OPINIONS DELIVERED IN THE COURTS BELOW

The published and fully–precedential opinion that a three–judge panel of the Superior Court of Pennsylvania issued in this case on August 2, 2010 is attached as Exhibit A and is reported at *Lance* v. *Wyeth*, 4 A.3d 160 (Pa. Super. Ct. 2010).

The Superior Court's order denying Wyeth's motion for reargument or reconsideration dated October 1, 2010 is attached as Exhibit B.

The opinion that the Court of Common Pleas of Philadelphia County, Pennsylvania issued pursuant to Pennsylvania Rule of Appellate Procedure 1925(a) on January 7, 2010 is attached as Exhibit C.

And the summary judgment order that the Court of Common Pleas of Philadelphia County, Pennsylvania issued on September 19, 2008 is attached as Exhibit D.

II. THE ORDER IN QUESTION

The final paragraph of the Superior Court's opinion states:

> Order affirmed in part and reversed in part. Case remanded. Jurisdiction relinquished.

See Exhibit A at page 18, ¶33.

III. QUESTIONS PRESENTED

1. Did the Superior Court err in holding, in an acknowledged conflict with the U.S. Court of Appeals for the Third Circuit's prediction of Pennsylvania law, that Pennsylvania law would not recognize a claim against a prescription drug manufacturer for negligent failure to test to discover a prescription drug's actual harmful side–effects?

2. Did the Superior Court err in holding that Pennsylvania law would not recognize claims against a manufacturer of a prescription drug, which the federal Food and Drug Administration ultimately ordered withdrawn from the market as too dangerous for any potential users, for negligently marketing that drug and for negligently failing to withdraw that drug from the market?

IV. STATEMENT OF THE CASE

This case is one of three appeals that were argued in tandem before the same three–judge panel of the Superior Court of Pennsylvania in Philadelphia on June 22, 2010. The other two cases argued in conjunction with this case were *Cochran* v. *Wyeth*, 3 A.3d 673 (Pa. Super. Ct. 2010), *petition for alloc. filed*, No. 459 EAL 2010 (filed Aug. 19, 2010); and *Owens* v. *Wyeth*, No. 185 EDA 2009 (Aug. 2, 2010) (unpublished), *petition for alloc. filed*, No. 572 EAL 2010 (filed Oct. 12, 2010).

The questions presented for review herein are also presented for review in the Petition for Allowance of Appeal that has been filed in the *Owens* case. As a result, if this Court granted review either in this case or in the *Owens* case, this Court should hold the other case pending this Court's disposition of the case in which review has been granted.

The facts that give rise to this lawsuit are as follows. Catherine Lance was 35 years old and the mother of three sons when she died from complications related to treatment of her primary pulmonary hypertension (PPH), a commonly fatal condition caused by ingesting "Fen–phen" weight loss drugs, such as Pondimin and Redux, manufactured by Wyeth. R.17a, 127a.[1] Catherine ingested Redux from January through April 1997. R.17a. She was diagnosed with PPH on November 15, 2004. R.18a. Plaintiff Patsy Lance is Catherine's mother and the executrix of Catherine's estate. R.17a, 127a. When this case goes to trial, plaintiff's expert

[1] Cites herein to "R." followed by a page number refer to the Reproduced Record filed in the Superior Court. In accordance with Pennsylvania Rule of Appellate Procedure 1112(d), petitioner is filing one copy of that Reproduced Record in this Court together with this Petition for Allowance of Appeal.

witness will testify that Catherine Lance's use of Redux caused her PPH and resulted in her death. R.127a.

The medication Redux was a so–called Fen–phen medication sold to promote weight loss. "Fen–phen" refers to the use of fenfluramine in combination with phentermine. Wyeth was the sole supplier of fenfluramine in the United States, and Wyeth's trade name for fenfluramine was Pondimin. R.143a–44a. Fenfluramine (Pondimin) is 50% dexfenfluramine, which is the active ingredient of Pondimin.

Wyeth knew fenfluramine and dexfenfluramine caused PPH as early as 1993, and possessed additional evidence of that fact in March 1995, but Wyeth took no steps to investigate these disturbing findings. R.148a–50a, 162a–63a, 166a–67a, 171a–74a, 178a–83a. By mid–1995, Wyeth had also received numerous reports of valvular heart disease (VHD) in fenfluramine users, but deliberately chose not to investigate those cases, and did not follow up at all on those reports until the Mayo Clinic forced Wyeth's hand in April 1997. R.204a–349a. Even then, Wyeth intentionally deleted 17 of the 24 Mayo Clinic heart valve disease cases from its database and re–used the report numbers for other products, so that they would be untraceable by the FDA. R.359a–85a. Moreover, Wyeth failed to perform any studies of the potential harmful effects of fenfluramine and Fen–phen and failed to conform to FDA–mandated industry post–marketing surveillance standards.

In late 1995 and early 1996, Wyeth was in the process of seeking FDA approval for Redux, which contained only dexfenfluramine, the potent half of fenfluramine. Wyeth did not want a "black box" warning about PPH or VHD to be

attached to the Redux package label, and Wyeth was determined not to make public any bad information about Pondimin and Fen–phen during the approval process, since Pondimin and Redux were the same drug. R.389a–91a, 395a–96a, 401a–02a, 405a–34a, 436a–44a.

Wyeth was successful in getting Redux approved and marketed without the black box warning. The FDA advisory committee approved Redux by only one vote. One of the members who voted to approve, Dr. Illingworth, later testified that he would have voted against approval if he had been fully informed of the risks of the drug. R.448a.

As early as 1994 and 1995, Wyeth knew of far more reports of heart valve disease cases than it reported to the FDA. R.453a, 459a–64a. Wyeth also did not alert the medical community to these potential heart valve disease outcomes in long–term users. As a result, independent investigators made their discovery without the benefit of knowing about these other cases known only to Wyeth. Ultimately, Wyeth delayed public disclosure of the risk of heart valve disease caused by its fenfluramine until July 1997, less than two months before these drugs were taken off the market. R.477a–78a. Most tragically, Wyeth did nothing to investigate the possible association of fenfluramine and heart valve disease for two years after it knew about these reports in 1995.

Wyeth should have conducted an investigation in early 1995, and, if it had, it would have found then what was discovered in August 1997: that a significant portion of long–term Redux users developed serious heart valve disease. Had that

happened — had Wyeth acted as a reasonably prudent pharmaceutical company — Wyeth would never have completed its application for FDA approval of Redux, or at least Wyeth would have taken Redux off the market before January 1997, when the medication was first prescribed to Catherine Lance.

Eventually, Wyeth could no longer cover up the PPH/VHD epidemic. The truth percolated to the surface as outside researchers began publishing reports of VHD cases cropping up throughout the United States. Immediately thereafter, the FDA pressured Wyeth to issue a new black box warning for both PPH and VHD. R.477a. The FDA also demanded to see the sizable database of PPH/VHD cases that Wyeth had managed to keep hidden from the agency for several years. R.480a–507a. Faced with these mounting pressures, on September 15, 1997, Wyeth withdrew both Redux and Pondimin from the market. R.510a–11a.

Since then, the FDA added fenfluramine and dexfenfluramine to the list of unsafe products ineligible for compounding exemptions. In other words, the FDA determined that fenfluramine and dexfenfluramine are unsafe and unfit for their intended use regardless of warnings, and the FDA has made it illegal to compound these drugs, effectively preventing their use for any purpose whatsoever.

Patsy Lance, as administratrix of the estate of Catherine Lance, filed this lawsuit on November 13, 2006. R.1a, 12a. In the complaint, plaintiff affirmatively disclaimed any intention to assert a negligent failure–to–warn claim against Wyeth. R.19a–20a. Instead, the complaint makes clear that plaintiff's claims against Wyeth assert negligence in bringing Redux to the market, negligent failure to withdraw

Redux from the market sooner, negligent failure to test, and negligent design defect. R.17a–19a, 45a–47a, 134a–35a.

Wyeth filed a motion for summary judgment asserting that plaintiff's claims against Wyeth were not cognizable under Pennsylvania law. R.70a–79a. Plaintiff filed a timely response in opposition (R.125a–40a), and then Wyeth filed a reply brief (R.512a–19a). On September 19, 2008, the trial court entered an order granting Wyeth's motion for summary judgment. R.8a; Exhibit D hereto.

Thereafter, on October 10, 2008, plaintiff filed a timely notice of appeal. R.8a, 526a. After the trial court ordered plaintiff to file a "Statement of Errors Complained of on Appeal" pursuant to Pennsylvania Rule of Appellate Procedure 1925(b) (R.8a), and after plaintiff filed a timely Rule 1925(b) statement in response to that order, the trial court issued its opinion explaining the basis for its summary judgment order on January 7, 2010. *See* Exhibit C hereto.

After briefing and oral argument, a three–judge panel of the Superior Court issued a published, precedential opinion on August 2, 2010 affirming the trial court in part and reversing the trial court in part. *See* Exhibit A hereto. With respect to plaintiff's claims that Wyeth had negligently marketed Redux and had negligently failed to withdraw Redux from the market sooner, the Superior Court ruled that Pennsylvania law would not recognize either of those claims. *See* Exhibit A at page 8, ¶15; *id.* at page 15, ¶26. The Superior Court next turned to plaintiff's claim that Wyeth had negligently failed to test Redux, thereby failing to ascertain that medication's actual risks before bringing it to market. Although the Superior

Court's opinion correctly acknowledged that the U.S. Court of Appeals for the Third Circuit, in *Hoffman* v. *Sterling Drug, Inc.*, 485 F.2d 132, 140–41 (3d Cir. 1973), had predicted that Pennsylvania law would allow a claim for negligent failure to test to be asserted against a prescription drug manufacturer, *see* Exhibit A at page 16, ¶28, the Superior Court ruled that no such claim exists under Pennsylvania law, *see* Exhibit A at page 17, ¶30. Lastly, the Superior Court recognized that Pennsylvania law allows plaintiff to assert a claim for negligent design defect against the manufacturer of a dangerous prescription drug. *See* Exhibit A at pages 11–12, ¶20.

Because this case presents important questions of first impression concerning what type of claims sounding in negligence a person injured or killed as the result of ingesting an unsafe prescription drug may assert against the manufacturer of that medication, plaintiff has filed this timely Petition for Allowance of Appeal seeking this Court's review and resolution of the questions presented herein.

V. THE PETITION FOR ALLOWANCE OF APPEAL SHOULD BE GRANTED

A. Review Should Be Granted To Resolve A Conflict Between The Pa. Superior Court And 3d U.S. Circuit Court of Appeals Concerning Whether Pa. Law Would Recognize A Claim For Negligent Failure To Test A Prescription Drug

As the Superior Court's opinion in this case correctly recognizes, *see* Exhibit A at page 16, ¶28, in *Hoffman* v. *Sterling Drug, Inc.*, 485 F.2d 132, 140–41 (3d Cir. 1973), the U.S. Court of Appeals for the Third Circuit examined what sort of negligence claims may be brought against a drug manufacturer under Pennsylvania law, and the Third Circuit recognized a claim for the negligent, inadequate testing of the drug in addition to a negligent failure to warn claim. Indeed, Westlaw's Keycite report for the Third Circuit's ruling in *Hoffman* states that the Superior Court's decision in this case "Declined to Follow" the Third Circuit's ruling in *Hoffman*. Thus, Westlaw — one of the leading objective sources for legal research — confirms the conflict between the Superior Court's ruling in this case and the Third Circuit's ruling in *Hoffman*.

This Court serves as the supreme arbiter of Pennsylvania law, and when a conflict arises between the Superior Court and the Third Circuit over whether Pennsylvania law would recognize a certain type of claim against a prescription drug manufacturer, only this Court can definitively resolve that conflict. As matters now stand, plaintiffs who can obtain federal court jurisdiction over their personal injury claim arising under Pennsylvania law against the manufacturer of a dangerous prescription drug can assert a cause of action for negligent failure to test,

while plaintiffs who must sue in the state courts of Pennsylvania cannot. This has resulted in an arbitrary and inequitable state of affairs that only this Court may resolve by means of granting review in this case.

The Superior Court's resolution of this issue conflicts not only with the Third Circuit's decision in *Hoffman*, but it also conflicts with the unanimous views expressed by all of the judges serving on an equally divided en banc panel of the Superior Court in *Leibowitz* v. *Ortho Pharmaceutical Corp.*, 307 A.2d 449 (Pa. Super. Ct. 1973) (en banc). Although that case failed to produce a majority opinion, all six judges who participated in that decision recognized the existence of such a duty to test under Pennsylvania law. *See id.* at 459 (opinion in support of affirmance) ("By this opinion, we wish to make it clear that a drug manufacturer may not escape liability by merely ignoring existing reports of side–effects or dangers in the use of its product. Neither may a drug company fail to conduct tests and research to obtain such information."); *id.* at 464 (opinion in support of reversal) ("The law required that defendant be bound to act in accordance with not only the knowledge it did actually possess but the knowledge it could have and should have possessed in 1964. The plaintiff's complaints in trespass and assumpsit expressly alleged that defendant did in 1964 market a drug without adequate testing. The body of knowledge subsequently obtained from testing conducted subsequent to 1964 by governmental agencies, other manufacturers, or by the defendant, was relevant . . . .") (internal citations omitted).

The substance of plaintiff's claim for negligent failure to test asserts that had Wyeth adequately tested the medication in advance of bringing it to market, Wyeth would have concluded (as the FDA later concluded) that Redux's risks outweighed its benefits as to all possible classes of users of that medication. That conclusion explains why the FDA ultimately required Wyeth to withdraw Redux from the market and is why, even today, pharmacists are prohibited from compounding or selling to patients the active ingredients in that medication for any purpose whatsoever.

In holding that Pennsylvania law would not recognize a separate claim for negligent failure to test for the dangers inherent in a prescription drug, the Superior Court reasoned that a prescription drug manufacturer that had negligently failed to test for the dangerous propensities of a prescription drug would instead face liability for its negligence in failing to test by means of a claim for negligent failure to warn of the drug's actual dangers — dangers that would have been discovered had adequate testing occurred. This sort of reasoning very well might make sense in a case, unlike this one, involving a prescription drug whose benefits outweigh its actual but undisclosed dangers as to some potential class of patients.

But in this case, by contrast, the FDA's subsequent decision — made once the FDA became fully aware of all of Redux's actual harmful risks — that Redux could not be offered for sale by Wyeth to anyone because the medication's risks outweighed its benefits as to all possible classes of patients demonstrates that

Redux was never capable of being safely offered for sale to the public irrespective of warnings. In light of the FDA's ultimate decision to ban Redux from the market, the only sort of warning that could have adequately conveyed Redux's actual risks was a warning in the nature of "Do not purchase or ingest this drug for any purpose whatsoever." In the real world, of course, products that are incapable of being safely used by anyone are not sold with a warning advising "Don't purchase or use this product under any circumstances whatsoever." Rather, such products are simply not offered for sale.

Thus, where a manufacturer's negligent failure to adequately test for the dangers inherent in a prescription drug results in the manufacturer's failure to discover that the prescription drug is too unsafe to be offered to sale to anyone, the hypothetical availability of a claim for negligent failure to warn does not adequately substitute for the ability to assert a claim for negligent failure to test. Because this is that very sort of case, this Court should grant review to consider whether plaintiff may assert a negligent failure to test claim under Pennsylvania law as the result of having been injured by ingesting a drug that the FDA later determined was too unsafe to be offered for sale to anyone.

Given this Court's role as the supreme arbiter of Pennsylvania law, and given the inadequacy of a claim for negligent failure to warn in a case where the prescription drug in question is in fact too unsafe to be offered for sale to anyone, this Court should grant allowance of appeal to resolve the conflict between the Third Circuit's ruling in *Hoffman* and the Superior Court's ruling in this case over

whether Pennsylvania law would recognize a negligent failure to test claim against the manufacturer of a dangerous prescription drug.

B. This Court Should Also Grant Review To Determine Whether Pennsylvania Law Recognizes Claims For Negligently Marketing And Negligently Failing To Withdraw From The Market A Dangerous Prescription Drug

Wyeth argued, and the trial court agreed, that the only negligence claim that Pennsylvania law recognizes against the manufacturer of a prescription drug for injuries caused by the ingestion of its product is a claim for negligent failure to warn. The Superior Court correctly rejected this argument, holding that Pennsylvania law also recognizes a claim for negligent design defect against the manufacturer of a prescription drug. *See* Exhibit A at pages 11–12, ¶20.

Although the Superior Court correctly interpreted Pennsylvania law as allowing a claim for negligent design defect against the manufacturer of a dangerous prescription drug, the Superior Court committed an error of law in holding that Pennsylvania law does not recognize claims for negligently marketing and negligently failing to withdraw from the market a dangerous prescription drug. Because the types of negligence claims that a plaintiff injured as the result of ingesting a dangerous prescription drug can bring against the manufacturer of the medication is a question of great importance under Pennsylvania law, this Court should grant this petition for allowance of appeal to decide the second question presented.

To be sure, in *Hahn* v. *Richter*, 543 Pa. 558, 673 A.2d 888 (1996), this Court ruled that a plaintiff cannot assert strict liability claims against the manufacturer of a prescription drug. This petition for allowance of appeal does not challenge the Court's actual holding in *Hahn*. Rather, this petition for allowance of appeal challenges the lower courts' overly broad understanding and application of *Hahn*'s holding to preclude any claims sounding in negligence against prescription drug manufacturers other than claims for negligent failure to warn or negligent design defect. Because the claims that the plaintiff seeks to assert against Wyeth in this case sound in negligence and not in strict liability, this Court's actual holding in *Hahn* does not bar those claims.

In determining what type of negligence claims may be asserted against a prescription drug manufacturer for personal injuries resulting from prescription drugs, this Court, in *Incollingo* v. *Ewing*, 444 Pa. 263, 282 A.2d 206 (1971), obtained guidance from comment k of Restatement (Second) of Torts §402A. *See Incollingo*, 444 Pa. at 287–88, 282 A.2d at 219–20; *see also Hahn*, 543 Pa. at 560 & n.2, 673 A.2d at 889–90 & n.2 (relying on and favorably quoting comment k of Restatement (Second) of Torts §402A).

Comment k to Restatement (Second) of Torts §402A concludes as follows:

> The seller of [prescription drugs], *again with the qualification that they are properly* prepared and *marketed*, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts §402A comment k (emphasis added).

As the above–quoted portion of comment k makes clear, the manufacturer of an unavoidably unsafe product such as a prescription drug has the duty not only to provide proper warnings, but also to properly market the medication. And comment k treats those two matters as *separate* obligations and duties, for whose breach independent claims sounding in negligence may be brought.

Plaintiff's claim for negligent failure to withdraw Redux from the market alleges that it was Wyeth's negligent failure to adequately evaluate the reports it was receiving of health problems being caused by Redux that resulted in Redux's remaining available on the market when Catherine Lance was prescribed that medication.

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. 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.

With regard to the FDA, the Supreme Court of the United States last year issued its ruling in *Wyeth* v. *Levine*, 129 S. Ct. 1187 (2009), vastly curtailing the instances when federal law will preempt state law personal injury claims sounding

in negligence against prescription drug manufacturers. Recognizing claims under Pennsylvania law for negligently marketing and negligently failure to withdraw from the market dangerous prescription drugs will furnish an important state law incentive to protect the interests and health of consumers in accessing only those medications whose benefits outweigh their risks as to at least some potential class of patients. Moreover, this case does not implicate the question of deference to the FDA, because once the FDA became fully informed about Redux's actual risks, the FDA convinced Wyeth to pull Redux from the market, and thereafter the FDA prohibited Wyeth from offering Redux for sale to anyone.

Even in the unlikely event that the FDA's initial approval of Redux would suffice to preempt plaintiff's claim that Wyeth was negligent in bringing Redux to the market, federal law did not require Wyeth to maintain Redux on the market simply because that medication had initially achieved FDA approval. For evidence of that fact, this Court need look no further than Wyeth's voluntary withdrawal of Redux from the marketplace even before the FDA barred the product from sale. R.510a–11a; *see also Mensing* v. *Wyeth, Inc.*, 588 F.3d 603, 611 (8th Cir. 2009) (recognizing that federal law did not preempt a state law personal injury claim against the manufacturer of the generic version of a prescription drug because, even if the generic manufacturer could not change the drug's warning label, it had the option of ceasing to offer the drug for sale).

In holding that the manufacturer of a dangerous prescription drug such as Redux has no duty to recall or retrofit the product, the Superior Court relied

principally on cases involving products other than prescription drugs. *See* Exhibit A at pages 12–13, ¶22. Of course, this case does not involve a product, such as an automobile, that requires a post–sale repair in order to be rendered safe for its intended use. Rather, in this case, it is plaintiff's contention — as confirmed by the FDA's own subsequent, fully informed decision that Redux was too dangerous to be approved for use by any class of patients — that Wyeth should have removed Redux from the market as too dangerous before that medication was first prescribed for use by plaintiff's decedent, Catherine Lance. The Superior Court's rationale that decisions about what prescription drugs should be available on the market should be left up to the FDA overlooks that, in this very case, Wyeth voluntarily withdrew Redux from the market due to safety concerns in the absence of any FDA–mandated withdrawal. R.510a–11a. The Superior Court's explanation for refusing to reinstate plaintiff's claim that Wyeth was negligent in not withdrawing Redux from the market at an earlier time thus fails to withstand scrutiny.

For these reasons, this Court should grant allowance of appeal to consider whether Pennsylvania law would recognize claims against the manufacturer of a dangerous prescription drug for negligently marketing and negligently failing to withdraw from the market that medication.

VI. CONCLUSION

For the reasons set forth above, the Petition for Allowance of Appeal should be granted.

Respectfully submitted,

Dated: November 1, 2010

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CERTIFICATE OF SERVICE

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