

In the Superior Court of Pennsylvania

No. 2905 EDA 2008

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

v.

WYETH, f/k/a
AMERICAN HOME PRODUCTS CORP.

BRIEF FOR APPELLANT

On Appeal from the Judgment of the
Court of Common Pleas of Philadelphia County, Pennsylvania,
Civil Trial Division, November Term 2006, No. 926

Howard J. Bashman
2300 Computer Avenue
Suite G-22
Willow Grove, PA 19090
(215) 830-1458

Linda C. Love
Michael L. Williams
Williams Love O'Leary & Powers, P.C.
9755 S.W. Barnes Road
Suite 450
Portland, OR 97225-6681
(503) 946-5412

Counsel for Plaintiff/Appellant

TABLE OF CONTENTS

	Page
I. STATEMENT OF JURISDICTION	1
II. STATEMENT OF THE SCOPE AND STANDARD OF REVIEW	1
III. TEXT OF THE ORDER IN QUESTION	2
IV. STATEMENT OF THE QUESTION PRESENTED	3
V. STATEMENT OF THE CASE	4
A. Relevant Factual History	4
B. Relevant Procedural History	7
VI. SUMMARY OF THE ARGUMENT	8
VII. ARGUMENT	9
A. The Trial Court Erred In Entering Summary Judgment In Favor Of Wyeth On Plaintiff's Claims For Negligently Marketing Redux And Negligently Failing To Withdraw Redux From The Market	9
1. Plaintiff's claims against Wyeth for negligently marketing Redux and negligently failing to withdraw Redux from the market are cognizable under Pennsylvania law	9
VIII. CONCLUSION	19

TABLE OF AUTHORITIES

	Page
Cases	
<i>Baldino v. Castagna</i> , 505 Pa. 239, 478 A.2d 807 (1984)	10, 12
<i>Bruesewitz v. Wyeth Inc.</i> , 561 F.3d 233 (3rd Cir. 2009), <i>cert. granted</i> , 2010 WL 757696 (U.S. Mar. 08, 2010) (No. 09–152).....	17
<i>Chanceford Aviation Properties, L.L.P. v. Chanceford Tp. Bd. of Supervisors</i> , 592 Pa. 100, 923 A.2d 1099 (2007)	1, 2
<i>Freeman v. Hoffman La–Roche, Inc.</i> , 618 N.W.2d 827 (Neb. 2000).....	16
<i>Hahn v. Richter</i> , 543 Pa. 558, 673 A.2d 888 (1996).....	12, 16
<i>Harris v. Toys “R” Us–Penn, Inc.</i> , 880 A.2d 1270 (Pa. Super. Ct. 2005)	17
<i>Hoffman v. Sterling Drug, Inc.</i> , 485 F.2d 132 (3d Cir. 1973).....	11, 13
<i>Incollingo v. Ewing</i> , 444 Pa. 263, 282 A.2d 206 (1971)	9–12
<i>Leibowitz v. Ortho Pharmaceutical Corp.</i> , 307 A.2d 449 (Pa. Super. Ct. 1973) (en banc)	9, 13, 14
<i>Mensing v. Wyeth, Inc.</i> , 588 F.3d 603 (8th Cir. 2009)	18
<i>Simon v. Wyeth Pharmaceuticals, Inc.</i> , 2009 PA Super 263, 2009 WL 5154031 (Pa. Super. Ct. Dec. 31, 2009)	18
<i>Taurino v. Ellen</i> , 579 A.2d 925 (Pa. Super. Ct. 1990)	10–12
<i>Trowbridge v. Scranton Artificial Limb Co.</i> , 560 Pa. 640, 747 A.2d 862 (2000)	2
<i>Wells Fargo Bank, N.A. v. Long</i> , 934 A.2d 76 (Pa. Super. Ct. 2007)	2
<i>Wyeth v. Levine</i> , 129 S. Ct. 1187 (2009).....	18

Court Rules

Pa. R. App. P. 302(a)..... 17
Pa. R. App. P. 341(a)..... 1
Pa. R. App. P. 1925(b)..... 7

Other Authorities

Restatement (Second) of Torts §402A comment k..... 12, 13
Restatement (Third) of Torts: Prods. Liab. §6(c)..... 15, 16

**Exhibits Attached to Brief for Appellant in Accordance
with the Pa. Rules of Appellate Procedure**

Trial court’s Rule 1925(a) opinion..... Exhibit A
Trial court’s order granting Wyeth’s summary judgment motion..... Exhibit B
Plaintiff’s Rule 1925(b) statement Exhibit C

I. STATEMENT OF JURISDICTION

On September 19, 2008, Judge Allan Tereshko of the Court of Common Pleas of Philadelphia County entered an order granting summary judgment against plaintiff Patsy Lance, administratrix for the estate of Catherine Ruth Lance, deceased, and in favor of defendant Wyeth, holding as a matter of law that the claims Mrs. Lance was asserting against Wyeth arising from its medication's having caused the death of Mrs. Lance's daughter were neither recognized nor valid under Pennsylvania law. R.8a; *see also* Exhibit B attached hereto.

Plaintiff filed a timely notice of appeal on October 10, 2008. R.8a, 526a. This Court possesses appellate jurisdiction pursuant to Pennsylvania Rule of Appellate Procedure 341(a).

II. STATEMENT OF THE SCOPE AND STANDARD OF REVIEW

This Court exercises *de novo*, entirely non-deferential review of a trial court's order granting summary judgment. As this Court has explained:

Since the issue as to whether there are no genuine issues as to any material fact presents a question of law, our standard of review is *de novo*; thus, we need not defer to the determinations made by the lower tribunals. Our scope of review, to the extent necessary to resolve the legal question before us, is plenary.

Chanceford Aviation Properties, L.L.P. v. Chanceford Tp. Bd. of Supervisors, 592 Pa. 100, 107, 923 A.2d 1099, 1103 (2007). *Chanceford* recognizes that an appellate court "must view the record in the light most favorable to the non-moving party, and all

doubts as to the existence of a genuine issue of material fact must be resolved against the moving party.” *Id.*

Both this Court and the Pennsylvania Supreme Court have held that “[s]ummary judgment is to be entered only in the clearest of cases where there is not the slightest doubt as to the absence of a triable issue of fact.” *See Wells Fargo Bank, N.A. v. Long*, 934 A.2d 76, 77 (Pa. Super. Ct. 2007); *see also Trowbridge v. Scranton Artificial Limb Co.*, 560 Pa. 640, 644, 747 A.2d 862, 864 (2000) (“Because this is an appeal from the grant of a motion for summary judgment, our standard of review is well settled. Summary judgment may be granted only in the clearest of cases where the record shows that there are no genuine issues of material fact and also demonstrates that the moving party is entitled to judgment as a matter of law.”).

III. TEXT OF THE ORDER IN QUESTION

On September 19, 2008, the trial court issued the following order:

AND NOW, this 19th day of September, 2008, upon consideration of the Wyeth Defendants’ Motion for Summary Judgment and any responses thereto, it is hereby **ORDERED, ADJUDGED, and DECREED** that Summary Judgment is hereby **GRANTED** in favor of the Wyeth Defendants and against Plaintiff Patsy Lance, Administratrix for the Estate of Catherine Lance.

IT IS FURTHER ORDERED that Plaintiff Patsy Lance’s case is **DISMISSED WITH PREJUDICE**.

Exhibit B attached hereto.

IV. STATEMENT OF THE QUESTION PRESENTED

Did the trial court err as a matter of law in holding on summary judgment that Pennsylvania law would not recognize plaintiff's claims that Wyeth was negligent in bringing Redux to the market and in failing to withdraw Redux from the market before the drug was prescribed to plaintiff's decedent, Catherine Lance?

V. STATEMENT OF THE CASE

A. Relevant Factual History

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. Catherine used 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. Plaintiff’s expert witness will testify that Catherine Lance’s use of Redux caused her PPH and resulted in her death. R.127aa.

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. 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.

B. Relevant Procedural History

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 disclaims 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 and negligent failure to withdraw Redux from the market sooner. R.17a–19a.

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 B attached 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 (Exhibit C attached hereto), the trial court issued its opinion explaining the basis for its summary judgment order on January 7, 2010 (Exhibit A attached hereto).

VI. SUMMARY OF THE ARGUMENT

The trial court erred as a matter of law in holding on summary judgment that Pennsylvania law does not recognize and would not recognize claims for negligent marketing and negligently failing to withdraw from the market a prescription drug, such as Redux, that the federal Food and Drug Administration ultimately determines is too unsafe for human ingestion for any purpose whatsoever.

Contrary to the trial court's erroneous ruling herein, established case law from the Supreme Court of Pennsylvania and the U.S. Court of Appeals for the Third Circuit, applying Pennsylvania law, recognizes claims for negligent marketing and negligent failure to test. And, for reasons explained herein, Pennsylvania law would also recognize a negligent design defect claim against the manufacturer of a prescription drug, such as Redux, whose risks outweigh its benefits for all possible classes of patients.

For these reasons, the trial court's entry of summary judgment in Wyeth's favor should be reversed, and this case should be remanded for trial.

VII. ARGUMENT

A. The Trial Court Erred In Entering Summary Judgment In Favor Of Wyeth On Plaintiff's Claims For Negligently Marketing Redux And Negligently Failing To Withdraw Redux From The Market

1. Plaintiff's claims against Wyeth for negligently marketing Redux and negligently failing to withdraw Redux from the market are cognizable under Pennsylvania law

In moving for summary judgment, Wyeth argued that claims for negligently marketing a prescription drug and negligently failing to withdraw a prescription drug from the market are not cognizable under Pennsylvania law. More specifically, Wyeth argued that *Leibowitz v. Ortho Pharmaceutical Corp.*, 307 A.2d 449 (Pa. Super. Ct. 1973) (en banc), and other similar cases hold that the only claim available to a plaintiff injured by a product manufactured by a prescription drug manufacturer is a claim for negligent failure-to-warn. This is an incorrect reading of Pennsylvania case law. A careful analysis of *Leibowitz* and its progeny reveals that all of the statements to the effect that a drug manufacturer is liable only if it fails to adequately warn the prescribing physician were made in the context of plaintiffs' claims based on a manufacturer's failure to adequately warn.

To disprove Wyeth's assertion that a plaintiff can only prevail in a prescription drug injury case by proving failure-to-warn, this Court need look no further than the Supreme Court of Pennsylvania's critically significant ruling in *Incollingo v. Ewing*, 444 Pa. 263, 282 A.2d 206 (1971). There, the Supreme Court noted that the plaintiff originally asserted claims for negligent manufacture,

negligent failure to test, and negligent failure to warn. Since the plaintiff did not have evidence of negligent manufacture or negligent failure to test, the case proceeded solely on the negligent failure to warn claim. Nevertheless, the *Incollingo* decision recognized that plaintiff had a negligence claim against the manufacturer even if the warnings were adequate:

The question, therefore, in this case is whether the warning that was given to the prescribing doctors was proper and adequate. A corollary question is whether, if the printed warning was proper and adequate, it was in effect nullified by the representations of the so-called ‘detail men’.

444 Pa. at 288, 282 A.2d at 220.

Ultimately, the Pennsylvania Supreme Court removed all doubt on this question in *Baldino v. Castagna*, 505 Pa. 239, 478 A.2d 807 (1984), when the Court acknowledged the validity of plaintiff’s negligent marketing theory of liability against a drug manufacturer. The Supreme Court stated:

The theory of liability against CIBA–GEIGY was primarily based on this Court’s decision in *Incollingo v. Ewing*, 444 Pa. 263, 282 A.2d 206 (1971), where we recognized a cause of action against drug manufacturers for the overpromotion of a drug that nullify otherwise adequate warnings.

505 Pa. at 244, 478 A.2d at 810.

And most recently, in *Taurino v. Ellen*, 579 A.2d 925 (Pa. Super. Ct. 1990), this Court observed:

We recognize that under *Incollingo* and subsequent cases applying it *a manufacturer of a prescription drug may be shown to be negligent despite the fact that adequate warnings were given to the prescribing physician*. Negligence may be shown where, for example, the manufacturer employs “detail” men who instruct physicians on the use of the drug and who are proven to have promoted the product in

such a way as to encourage the physicians to ignore the warnings *or where the manufacturer knows its warnings are being widely ignored and does nothing about it*. See *Incollingo*, *supra*, 444 Pa. at 292–94, 282 A.2d at 222; *Baldino v. Castagna*, 505 Pa. 239, 247–49, 478 A.2d 807, 812 (1984). Thus, *it is clear that there are grounds on which a manufacturer of such a drug may be found liable in negligence despite the adequacy of its written warnings to physicians*.

Id. at 929 n.3 (emphasis added).

The above–quoted footnote from this Court’s ruling in *Taurino* recognizes that negligence claims against a prescription drug manufacturer for injuries caused by consuming the medication are not limited to negligent failure–to–warn claims and that the “detail” men claim described in *Incollingo* is just one of the types of negligence claims against prescription drug manufacturers recognized under Pennsylvania law.

Moreover, the U.S. Court of Appeals for the Third Circuit has applied Pennsylvania law on the question of negligence claims against a drug manufacturer, and it recognized a claim for negligent inadequate testing of the drug, in addition to a negligent failure–to–warn claim. See *Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132, 140–41 (3d Cir. 1973). The Third Circuit made no suggestion, and the manufacturer apparently made no argument, that the plaintiff was required to show inadequate warnings as a part of his negligent failure–to–test claim. Furthermore, the court recognized these claims as completely separate and freestanding. *Id.*

Plaintiff has extensively searched Pennsylvania case law and has found no case holding that the *only basis* for a negligence claim against a drug manufacturer

is failure-to-warn, and any such holding would of course be contrary to the precedent established in *Incollingo*, *Baldino*, and *Taurino*. Indeed, the claim recognized in the first two of those three cases involved negligence arising from the manner in which the prescription drug manufacturer marketed its medications. Finally, plaintiff have found no case requiring them to prove inadequate warning as an element of any other negligence claim, such as negligent marketing or negligent failure to withdraw from the market.

Wyeth, in moving for summary judgment, and the trial court, explaining its basis for granting summary judgment in favor of Wyeth, both reasoned that if a plaintiff was allowed to proceed with claims against Wyeth other than for negligent failure-to-warn, the plaintiff would be pursuing strict liability claims, which the Supreme Court of Pennsylvania ruled in *Hahn v. Richter*, 543 Pa. 558, 673 A.2d 888 (1996), could not be maintained against prescription drug manufacturers for injuries caused by consuming their medications. This reasoning, however, is erroneous. The claims that the plaintiff in this case seeks to assert against Wyeth are not strict liability claims. Rather, they are claims sounding in negligence.

In determining what type of negligence claims may be asserted against a prescription drug manufacturer for personal injuries resulting from prescription drugs, the Supreme Court of Pennsylvania, in *Incollingo*, 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 things as *separate* obligations and duties, for whose breach independent claims sounding in negligence may be brought.

The negligent marketing claim that plaintiff is asserting here is essentially identical to the negligent failure–to–test claim that the Third Circuit, applying Pennsylvania law, recognized in *Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132, 140–41 (3d Cir. 1973). Moreover, this Court, in an en banc decision issued in 1973, unanimously recognized that Pennsylvania law imposes the duty on a prescription drug manufacturer to adequately test its products before bringing them to market. *See Leibowitz v. Ortho Pharmaceutical Corp.*, 307 A.2d 449 (Pa. Super. Ct. 1973) (en banc).

Although *Leibowitz* failed to produce a majority opinion, all six judges who participated in that decision recognized a prescription drug manufacturer's duty under Pennsylvania law to adequately test its products before bringing them to market. *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).

Plaintiff's negligent marketing claim asserts that Wyeth was negligent in bringing Redux to market because, 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 is why the FDA later required Wyeth to remove both Pondimin and Redux from the market and is why, even today,

pharmacists are prohibited from compounding or selling to patients the active ingredients in those medications for any purpose whatsoever.

Similarly, 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 been banned from the market entirely by the FDA. In other words, there is no risk-benefit balancing test that can be performed with respect to Pondimin or Redux that would allow anyone to conclude that those medications should be available to any class of patients, as demonstrated by the FDA's decision completely banning these drugs from the market.

Wyeth's argument that Pennsylvania law does not recognize the negligent marketing and negligent failure to withdraw from the market claims that plaintiff is asserting is further undermined by the fact that such claims are even recognized as valid under Restatement (Third) of Torts: Products Liability §6(c). Section 6(c) states, in full:

A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risk of harm posed by the drug or medical device are sufficiently great in relation to the foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.

Restatement (Third) of Torts: Prods. Liab. §6(c) (1998).

Courts and commentators have broadly criticized this provision as too pro-manufacturer and not sufficiently protective of consumers, in addition to thus being inconsistent with existing case law. *See, e.g., Freeman v. Hoffman La-Roche, Inc.*, 618 N.W.2d 827, 839–40 (Neb. 2000) (“We conclude that §6(c) has no basis in the case law. We view §6(c) as too strict of a rule, under which recovery would be nearly impossible. Accordingly, we do not adopt §6(c) of the Third Restatement.”). As a result, Section 6(c) has been rejected by the vast majority of courts that have considered it, and Section 6(c) does not accurately reflect existing Pennsylvania law, nor do we urge its adoption in Pennsylvania.

That being said, however, it is noteworthy that even under the inappropriately restrictive standard for prescription drug manufacturer liability espoused in Section 6(c), plaintiff’s claims for negligent marketing and negligent failure to withdraw from the market would remain viable. This is because the FDA’s decision barring the sale of Redux for any purpose whatsoever conclusively establishes that “reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug * * * for any class of patients.” Restatement (Third) of Torts: Prods. Liab. §6(c).

The type of design defect claim recognized in Section 6(c) differs from strict liability claims against prescription drug manufacturers that the Supreme Court of Pennsylvania refused to recognize in *Hahn v. Richter*, 543 Pa. 558, 673 A.2d 888 (1996). Here, plaintiff is asserting a prescription drug design defect claim sounding

in negligence, not in strict liability. R.17a–19a; *see, e.g., Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 248 (3rd Cir. 2009) (recognizing that prescription drug design defect claims can sound in either strict liability or negligence), *cert. granted on other grounds*, 2010 WL 757696 (U.S. Mar. 08, 2010) (No. 09–152).

Regardless of whether plaintiff’s claims against Wyeth are characterized as claims alleging negligent marketing and negligent failure to withdraw from the market; claims alleging negligent failure to test; or claims alleging negligent design defect, such claims are recognized as valid under Pennsylvania law. This Court should therefore reverse the trial court’s entry of summary judgment as to plaintiff’s claims.

Last but not least, in moving for summary judgment, Wyeth suggested in passing, solely in a footnote, that if plaintiff’s claims were cognizable under Pennsylvania law, they would nevertheless be preempted under federal law. R.79a. Because Wyeth did not adequately raise any preemption argument in the trial court, this argument is waived for purposes of appeal. *See* Pa. R. App. P. 302(a) (“Issues not raised in the lower court are waived and cannot be raised for the first time on appeal”); *Harris v. Toys “R” Us–Penn, Inc.*, 880 A.2d 1270, 1279 (Pa. Super. Ct. 2005) (“We have repeatedly held that failure to develop an argument with citation to, and analysis of, relevant authority waives that issue on review.”). Moreover, the trial court did not rule that federal law would preempt plaintiff’s claims even if they were valid under Pennsylvania law.

The law of federal conflict preemption has changed significantly since Wyeth originally moved for summary judgment in this case in 2008. The Supreme Court of the United States, in March 2009, issued its ruling in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), which greatly curtailed the instances when federal law will preempt state law personal injury claims sounding in negligence against prescription drug manufacturers. In the aftermath of the U.S. Supreme Court's ruling in *Levine*, Wyeth withdrew the preemption argument that it had briefed on appeal to this Court in the *Simon v. Wyeth* case, see 2009 PA Super 263, at ¶14 n.6, 2009 WL 5154031, at *4 n.6 (Pa. Super. Ct. Dec. 31, 2009). Wyeth should likewise acknowledge here that the record in this case is insufficient under *Levine* to establish federal conflict preemption of plaintiff's claims.

Moreover, even in the unlikely event that the FDA's initial approval of Redux sufficed 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. 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 sum, federal preemption does not preclude plaintiff's claims against Wyeth for negligently marketing Redux and for negligently failing to withdraw Redux from the market.

VIII. CONCLUSION

For the reasons set forth above, this Court should reverse the trial court's entry of summary judgment in Wyeth's favor and should remand this case for trial.

Respectfully submitted,

Dated: March 24, 2010

Linda C. Love
Michael L. Williams
Williams Love O'Leary & Powers, P.C.
9755 S.W. Barnes Road
Suite 450
Portland, OR 97225-6681
(503) 946-5412

Howard J. Bashman
2300 Computer Avenue
Suite G-22
Willow Grove, PA 19090
(215) 830-1458

Counsel for Plaintiff/Appellant

CERTIFICATE OF SERVICE

I hereby certify that I am this day serving two true and correct copies of the foregoing document upon the persons and in the manner indicated below which service satisfies the requirements of Pa. R. App. P. 121:

Service by First Class U.S. Mail addressed as follows:

Michael T. Scott, Esquire
Henry F. Reichner, Esquire
Barbara R. Binis, Esquire
Ira S. Lefton, Esquire
Reed Smith, L.L.P.
2500 One Liberty Place
Philadelphia, PA 19103
(215) 851-8100
Counsel for Wyeth

Tobias L. Millrood, Esquire
Pogust, Braslow & Millrood, L.L.C.
161 Washington Street
Suite 1520
Conshohocken, PA 19428
(610) 941-4204
Co-counsel for Appellant

Dated: March 24, 2010

Howard J. Bashman
2300 Computer Avenue
Suite G-22
Willow Grove, PA 19090
(215) 830-1458