In the Supreme Court of Pennsylvania

No. 17 EAP 2011

PATSY LANCE, Administratrix for the Estate of
Catherine Ruth Lance, Deceased,

Appellee,

v.

WYETH, formerly known as
American Home Products Corporation,

Appellant.

BRIEF FOR APPELLEE/CROSS–APPELLANT

On Allowance of Appeal from the judgment of the Superior Court entered August 2, 2010 at No. 2905 EDA 2008 (reargument denied October 1, 2010) affirming in part, reversing in part, and remanding in part the judgment entered September 19, 2008 in the Court of Common Pleas, Philadelphia County, Civil Division at No. 926, November Term 2006

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I. STATEMENT OF JURISDICTION

The Superior Court of Pennsylvania issued its ruling in this case on August 2, 2010. *See Lance* v. *Wyeth*, 4 A.3d 160 (Pa. Super. Ct. 2010). Defendant Wyeth thereafter timely filed an application for reargument or reconsideration, which the Superior Court denied by means of an order dated October 1, 2010.

On November 1, 2010, both plaintiff Lance and defendant Wyeth filed timely petitions for allowance of appeal in this Court. On March 15, 2011, this Court issued an order granting both petitions for allowance of appeal and setting forth, verbatim, the questions presented in both petitions for allowance of appeal. This Court possesses jurisdiction pursuant to 42 Pa. Cons. Stat. Ann. §724(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 the Superior Court and this Court have recognized 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. 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 Appendix B to Wyeth's Brief for Appellant at page 18, ¶33.

IV. STATEMENT OF THE QUESTIONS INVOLVED

This Court's order dated March 15, 2011 granted the petitions for allowance of appeal that both defendant Wyeth and plaintiff Lance had filed. That order stated, in pertinent part:

> The issues in No. 600 EAL 2010, as stated by petitioner/ appellant Wyeth are:
>
> (1) Whether the Superior Court erred in creating a new claim for "negligent design defect" of a prescription drug, despite Plaintiff–Respondent Patsy Lance's repeated waiver of that claim?
>
> (2) Whether the Superior Court's creation of a new cause of action for "negligent design defect" conflicts with this Court's settled precedent limiting product liability claims against manufacturers and sellers of prescription drugs?
>
> (3) Whether the Superior Court's creation of a new cause of action for "negligent design defect" should properly be argued before this Court because it may affect hundreds or thousands of cases and ignores that: (a) plaintiffs in design defect cases must plead and prove a "feasible alternative design;" and (b) there should be deference to regulatory authorities?
>
> The issues in No. 610 EAL 2010, as stated by petitioner/cross–appellant Lance are:
>
> (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?

Lance v. *Wyeth*, 15 A.3d 429, 430 (Pa. 2011).

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 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 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.146a–47a. 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.153a–55a, 169a–70a, 174a–75a, 180a–83a, 188a–93a. 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.218a–368a. 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.381a–409a. 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.415a–17a, 422a–23a, 429a–30a, 434a–63a, 466a–74a.

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.480a.

As early as 1994 and 1995, Wyeth knew of far more reports of heart valve disease cases than it reported to the FDA. R.487a, 494a–99a. 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.515a–16a. 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.515a. 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.520a–48a. Faced with these mounting pressures, on September 15, 1997, Wyeth withdrew both Redux and Pondimin from the market. R.553a–54a.

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.

It is thus plaintiff's contention in this lawsuit that Wyeth's negligent failure to disclose the actual known risks of Redux, Wyeth's negligent failure to adequately test to ascertain those risks, and Wyeth's negligence in designing Redux so as to produce a medication whose risks fail to outweigh its benefits as to any class of patients resulted in Catherine Lance's untimely death at the age of 35 as the result of having ingested Redux.

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 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–39a), and then Wyeth filed a reply

brief (R.555a–62a). On September 19, 2008, the trial court entered an order granting Wyeth's motion for summary judgment. R.7a.

Thereafter, on October 10, 2008, plaintiff filed a timely notice of appeal. R.8a, 569a. 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 (R.578a–80a), the trial court issued its opinion explaining the basis for its summary judgment order on January 7, 2010. *See* Appendix A to Brief for Appellant.

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* Appendix B to Wyeth's Brief for Appellant. 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* Appendix B 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*

Appendix B at page 16, ¶28, the Superior Court ruled that no such claim exists under Pennsylvania law, *see* Appendix B 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* Appendix B at pages 11–12, ¶20.

VI. SUMMARY OF THE ARGUMENT

The Superior Court did not err or otherwise abuse its discretion in recognizing that plaintiff had properly preserved a challenge to the trial court's entry of summary judgment against plaintiff's negligent design defect claim.

Plaintiff's complaint, it is undisputed, contained a negligent design defect claim. When Wyeth moved for summary judgment, Wyeth's argument was simply that the *only* negligence claim that someone injured or killed as the result of ingesting a prescription drug can assert against the drug's manufacturer is a claim for negligent failure to warn. In seeking summary judgment, Wyeth did not argue that plaintiff's negligent design defect claim should be rejected for any reason other than that it was not a claim for negligent failure to warn. As a result, it was unnecessary for plaintiff, in opposing summary judgment, to establish anything beyond that Pennsylvania appellate courts have never held or implied that someone injured as the result of ingesting a harmful prescription drug is limited solely to a claim against the manufacturer for negligent failure to warn.

Nevertheless, at every necessary step along the way — in plaintiff's complaint, in plaintiff's opposition to Wyeth's summary judgment motion, in

plaintiff's Rule 1925(b) statement of errors complained of on appeal, and in plaintiff's Superior Court briefing and the questions presented therein — plaintiff asserted a claim for negligent design defect, opposed Wyeth's effort to obtain the entry of summary judgment against her negligent design defect claim, and sought appellate review and reversal of the entry of summary judgment against her negligent design defect claim. For these reasons, this Court should reject Wyeth's contention that plaintiff somehow waived her ability to obtain reinstatement of her negligent design defect claim from the Superior Court.

Turning to the merits, the Superior Court correctly recognized that Pennsylvania law ordinarily allows plaintiffs to assert design defect claims sounding in negligence and/or strict liability. Merely because this Court has ruled that strict liability claims cannot be brought against the manufacturer of a prescription drug for injury or death caused by medications does not foreclose a plaintiff from prevailing on a negligent design defect claim. Indeed, under products liability law in general, claims sounding in both strict liability and negligence can be brought alleging defective manufacturing, defective warning, and defective design. This Court's earlier rulings, while prohibiting strict liability claims against prescription drug manufacturers, expressly allow claims for manufacturing defect and warning defect sounding in negligence. This Court should similarly hold that a design defect claim sounding in negligence is cognizable under Pennsylvania law.

Wyeth's argument that this Court's earlier holding that prescription drugs are unavoidable unsafe under comment k to Restatement (Second) of Torts 402A

should preclude recognition of a negligent design defect claim is unpersuasive both as a matter of law and as a matter of simple logic. First, the mere fact that a useful prescription is unavoidably unsafe does not mean that it cannot be a should not be designed in a matter that reduces or eliminates those safety risks that are indeed avoidable. Second, a drug such as Redux, whose risks outweigh its benefits as to all possible classes of patients, is defectively designed by definition because it serves no useful purpose whatsoever. And third, other courts that likewise preclude all strict liability claims against prescription drug manufacturers nevertheless allow negligent design defect claims to be pursued against such defendants.

Finally, this Court should reverse the Superior Court's decision to the extent that the Superior Court failed to reinstate plaintiff's claims for negligent failure to test, negligent marketing, and negligent failure to withdraw from the market. Where, as here, the FDA has prohibited the sale of the medication in question for any purpose whatsoever, the manufacturer of the medication should face liability where the manufacturer was negligent in testing to determine the medication's harmful side–effects, in offering the medication for sale, and in failing to withdraw the medication from the market sooner.

Accordingly, this Court should affirm the Superior Court's reinstatement of plaintiff's negligent design defect claim and reverse the Superior Court's refusal to reinstate plaintiff's claims alleging negligent failure to test, negligent marketing, and negligent failure to withdraw from the market.

VII. ARGUMENT

A. The Superior Court Did Not Abuse Its Discretion In Finding That Plaintiff Preserved Her Ability To Obtain Reversal Of The Trial Court's Entry of Summary Judgment Dismissing Her Negligent Design Defect Claim

The Superior Court's opinion recognizes — and Wyeth's Brief for Appellant does not deny — that plaintiff's complaint asserted a claim for negligent design defect against Wyeth. Plaintiff accomplished this both by expressly alleging negligent design defect (R.19a) and by incorporating the negligence count contained in the master long form complaint filed in the underlying Fen–phen mass tort proceedings pending in the Court of Common Pleas for Philadelphia County (R.17a). The master long form complaint's negligence count included a claim for negligent design defect. R.45a–47a.

Thus, Wyeth's suggestion that this case is somehow unusual is incorrect. A design defect claim has been asserted by each and every plaintiff in the Fen–phen mass tort proceedings who has incorporated the master long form complaint's negligence count. Moreover, such design defect claims are commonly asserted in prescription drug personal injury cases filed in Pennsylvania and throughout the Nation.

Wyeth maintains in its Brief for Appellant that the Superior Court should have found that plaintiff's challenge to the trial court's entry of summary judgment on plaintiff's negligent design defect claim was waived because plaintiff supposedly: (1) failed to argue against dismissal of her negligent design defect claim in opposing Wyeth's motion for summary judgment; (2) failed to raise the issue in her Rule

1925(b) statement of errors complained of on appeal; and (3) failed to raise the issue with sufficient specificity in her statement of issues in the Brief for Appellant filed in the Superior Court.

This argument lacks merit, because — as the record in this case reflects — plaintiff did not waive her appellate challenge to the trial court's entry of summary judgment against plaintiff's negligent design defect claim. Plaintiff now responds in turn to each of Wyeth's unsubstantiated allegations of waiver.

(1). At page 10 of her brief filed in the trial court in opposition to Wyeth's motion for summary judgment, plaintiff made clear that she incorporated from the master long form complaint a claim against Wyeth for negligent design defect. R.134a. In relevant part, plaintiff's brief in opposition to Wyeth's motion for summary judgment stated:

> First, in ¶ 64 of the Master Complaint, plaintiffs allege that the pharmaceutical defendants had a duty to exercise reasonable care to properly *design*, research, develop, test, inspect, label, and prepare the drugs in the manufacture, sale, and/or distribution of the drugs to insure the product did not cause unreasonable, dangerous or untoward adverse side effects. Second, in ¶ 65 of the Master Complaint, plaintiffs allege that the defendants failed to exercise ordinary care in their conduct described in ¶ 64. Next, in the Master Complaint plaintiffs allege: defendants were *negligent in designing*, testing, and manufacturing these diet drugs, ¶ 67(a); defendants failed to test and to follow up, ¶67(c); defendants failed to test, ¶67(f); and, defendants were otherwise careless and/or negligent, ¶ 67(j).

R.134a (emphasis added). Thus, plaintiff expressly and repeatedly noted for the trial court's benefit that she was asserting a negligent design defect claim against Wyeth, and plaintiff argued in her trial court brief in opposition that Wyeth's motion for summary judgment should be denied as to all of plaintiff's claims.

Importantly, Wyeth began the substance of the "Argument" section of its motion for summary judgment as follows:

> Having disavowed any claim that Wyeth provided inadequate warnings, Plaintiff does not have a cognizable claim for negligence.

R.75a. Wyeth's motion for summary judgment filed in the trial court did not directly address or even acknowledge the existence of plaintiff's negligent design defect claim. Rather, Wyeth instead advanced the following three sub–arguments:

> (1). The only negligence claim that may be brought against the manufacturer of a prescription drug under Pennsylvania law is a claim for negligent failure to warn;
>
> (2) Pennsylvania law does not allow strict liability claims against the manufacturer of a prescription drug; and
>
> (3) Pennsylvania law does not recognize a claim for "implied warranty of merchantability" against the manufacturer of a prescription drug.

R.75a–79a.

Had Wyeth directly challenged plaintiff's ability to maintain a claim for negligent design defect, plaintiff assuredly would have responded in opposition to Wyeth's argument. Yet Wyeth did not advance any such argument in its summary judgment motion. Thus, plaintiff sufficiently preserved her negligent design defect claim by noting in her brief in opposition that she was asserting such a claim and by arguing that Wyeth was incorrect that the only negligence claim that could be asserted against the manufacturer of a prescription drug was a claim for negligent failure to warn. The consequence of plaintiff's argument, had it prevailed in the

trial court, would have been to keep alive all of her negligence claims, including her claim for negligent design defect.

Wyeth's assertion that plaintiff waived her negligent design defect claim in opposing Wyeth's motion for summary judgment is accordingly incorrect.

(2). Plaintiff also preserved her appellate challenge to the trial court's entry of summary judgment against plaintiff's negligent design defect claim in the Rule 1925(b) statement that plaintiff filed in the trial court. The second numbered specification of error that plaintiff included in her Rule 1925(b) statement filed in this matter stated, in relevant part:

> 2. The trial court erred or otherwise abused its discretion in granting the Wyeth defendants' Motion for Summary Judgment based on Wyeth's contention that plaintiff, choosing not to pursue a claim of inadequate warning, has no cognizable claim against Wyeth, when no Pennsylvania case requires plaintiffs to prove inadequate warnings as an element of negligence claims against drug manufacturers * * *.

R.579a.

The trial court in this case ruled (as evidenced by its later Rule 1925(a) opinion) that the only type of negligence claim that Pennsylvania law recognized against a prescription drug manufacturer was a claim for negligent failure to warn. In the above–quoted specification of error, plaintiff asserted that the other claims of negligence that she had asserted against Wyeth in this case (including plaintiff's claim for negligent design defect) were cognizable under Pennsylvania law.

(3). The Superior Court's opinion in this case quotes the question presented in plaintiff's Brief for Appellant, and thus Wyeth's assertion that the question presented did not fairly encompass plaintiff's challenge to the trial court's grant of

summary judgment on plaintiff's negligent design defect claim is simply not credible. *See Lance* v. *Wyeth*, 2010 PA Super 137, slip op. at 4 ¶7, 4 A.3d 160, 163 (Pa. Super. Ct. 2010). The question presented in plaintiff's Brief for Appellant filed in the Superior Court stated:

> 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?

R.588a. Plaintiff's negligent design defect claim is encompassed within plaintiff's assertion that "Wyeth was negligent in bringing Redux to the market." In other words, it is and has always been one of plaintiff's main arguments that as a result of Wyeth's negligent design of Redux, resulting in a medication whose risks outweighed its benefits as to all classes of patients, Wyeth was negligent in ever bringing Redux to the market. Plaintiff's negligent design defect claim is included within plaintiff's negligent marketing claim against Wyeth, as any examination of the entirety of plaintiff's Brief for Appellant filed in the Superior Court makes clear.

Pennsylvania Rule of Appellate Procedure 2116(a), which furnishes the "[g]eneral rule" for the section of an appellate brief titled "Statement of Questions Involved," states in pertinent part that the "Questions Involved" section of an appellate brief "will be deemed to include every subsidiary question fairly comprised therein." Rule 2116(a) proceeds to state that "[n]o question will be considered unless it is stated in the statement of questions involved or is fairly suggested thereby." Rule 2116(a)'s express statement that the "Statement of Questions Involved" will be

deemed to "include every subsidiary question fairly comprised therein" and will be understood to include whatever issues are "fairly suggested" communicate that it is proper to look at the balance of an appellate brief to ascertain, in conjunction with the brief's "Statement of Questions Involved," what issues are being advanced on appeal.

It is thus indeed telling that Wyeth asks this Court to focus exclusively on the question presented in plaintiff's Brief for Appellant filed in the Superior Court while Wyeth would have this Court ignore the remainder of that Brief for Appellant. This Court should not take such an ostrich–like approach to the balance of plaintiff's Superior Court opening brief. In the "Summary of the Argument" section of plaintiff's Brief for Appellant, counsel for plaintiff wrote:

> 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*.

R.593a (emphasis added). Thus, the "Summary of the Argument" section resolved any doubt that plaintiff was asking the Superior Court to reinstate her negligent design defect claim.

And in the "Argument" section of her Brief for Appellant filed in the Superior Court, plaintiff's counsel wrote:

> 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.

R.601–02a (emphasis added). Plaintiff's Brief for Appellant filed in the Superior Court in this case mentioned the phrase "design defect" in the context of seeking restoration of plaintiff's negligent design defect claim a total of five times. R.593a, 601a–02a.

The "Question Presented" in an appellate brief cannot and should not be viewed in isolation, but rather must be viewed in the context of the entirety of the appellate brief in which it is contained. Here, there can be no question, when one reviews the Brief for Appellant that plaintiff filed in the Superior Court, that plaintiff was asking the Superior Court to reinstate her negligent design defect claim and that the question presented sufficed to encompass that claim.

For these reasons, Wyeth is incorrect in contending that the question presented in the Brief for Appellant filed in the Superior Court failed to include or encompass plaintiff's negligent design defect claim.

The meritless nature of Wyeth's waiver argument being pursued in this Court is further evidenced by the fact that Wyeth never argued in its Brief for Appellee filed in the Superior Court that plaintiff's challenge to the entry of

summary judgment against her negligent design defect claim was waived, even though that challenge was unquestionably being advanced in plaintiff's opening brief on appeal. R.593a, 601a–02a. If Wyeth's waiver argument actually had merit, Wyeth's counsel would have and should have advanced that argument in Wyeth's Brief for Appellee filed in the Superior Court, instead of waiting until after the Superior Court issued its ruling on the merits of plaintiff's appeal to do so.

Indeed, Wyeth's failure to argue waiver of plaintiff's effort to reinstate her negligent design defect claim in Wyeth's Brief for Appellee filed in the Superior Court gives rise to Wyeth's own irrevocable waiver of any such waiver argument now being advanced against plaintiff. As this Court has repeatedly recognized, arguments that were not properly raised in the Superior Court are not properly considered by this Court on allowance of appeal. *See* Pa. R. App. P. 302(a); *Pentlong Corp.* v. *GLS Capital, Inc.*, 573 Pa. 34, 48 n.17, 820 A.2d 1240, 1248 n.17 (2003) (holding that argument not presented to intermediate appellate court is waived and will not be considered by this Court); *Commonwealth* v. *Piper*, 458 Pa. 307, 309–11, 328 A.2d 845, 847 (1974) (issue not raised in trial court or Superior Court cannot be raised for first time on allocatur).

If Wyeth wished to argue that plaintiff had waived her ability to have her negligent design defect claim reinstated on appeal to the Superior Court based on the manner in which plaintiff originally opposed Wyeth's motion for summary judgment filed in the trial court, based on plaintiff's Rule 1925(b) statement, and/or based on the "Question Presented" contained in plaintiff's Pa. Superior Court Brief

for Appellant, Wyeth could have and should have advanced such a waiver argument in Wyeth's Brief for Appellee filed in the Superior Court. Wyeth, however, advanced no such waiver argument in its Brief for Appellee filed in the Superior Court.

Wyeth's waiver argument also lacks merit as a matter of simple logic. If this Court were to conclude that the Superior Court should not have considered whether Pennsylvania law would recognize a claim for negligent design defect against the manufacturer of a prescription drug due to waiver, the Superior Court would then need to readdress that question in the context of another case. There is no reason to suspect that the Superior Court would reach a different outcome in any other case. This Court would then need to resolve the issue on the merits later in the context of another case. There is no reasons to suspect that this issue could be any better briefed or argued than it already has been in the context of this case.

Moreover, and in any event, this Court would nevertheless still need to resolve in the context of plaintiff's cross–appeal whether Pennsylvania law recognizes plaintiff's claims against a prescription drug manufacturer for negligent failure to test, negligent marketing, and negligent failure to withdraw from the market. Plaintiff's claim for negligent failure to test was not mentioned by name in plaintiff's Statement of Question Presented in her Superior Court Brief for Appellant, yet there was no doubt based on the balance of that brief that plaintiff was seeking to have the trial court's entry of summary judgment against that claim reversed. Wyeth, in opposing plaintiff's Petition for Allowance of Appeal in this case, did not argue that this Court should deny review of plaintiff's effort to

reinstate her negligent failure to test claim based on waiver, nor has Wyeth ever argued that the Superior Court exceeded its power in rejecting plaintiff's failure to test claim.

All of the questions arising from the merits of this dispute, involving what sort of negligence claims may be maintained against the manufacturer of a prescription drugs, are questions of great importance to the citizens of Pennsylvania that this Court has granted review to decide on the merits. The parties and their amici have submitted thoughtful briefs that will allow this Court to resolve those issues in this case in a definitive and fully informed manner.

Finally, as this Court is well–aware, the Superior Court of Pennsylvania is hardly reluctant to invoke the doctrine of waiver whenever that doctrine appears to have any conceivable applicability. In this case, Wyeth asks this Court to conclude that the Superior Court went out of its way to decide a question that the appellant had failed to properly preserve. As plaintiff has demonstrated above, nothing could be further from the truth. Plaintiff's Superior Court brief expressly and repeatedly argued that the Superior Court should reinstate plaintiff's negligent design defect claim. Plaintiff's brief filed in the trial court opposing Wyeth's motion for summary judgment likewise sought to keep her negligent design defect claim alive. Finally, plaintiff's Rule 1925(b) statement and the "Statement of Question Presented" contained in plaintiff's Brief for Appellant filed in the Superior Court both preserved plaintiff's right to appellate review of the trial court's entry of summary

judgment on plaintiff's negligence claims, including her claim for negligent design defect, against Wyeth.

For the reasons explained above, Wyeth is incorrect in contending that plaintiff waived her challenge to the trial court's grant of summary judgment against plaintiff's negligent design defect claim. No such waiver occurred. Moreover, it is Wyeth that has waived its own belated waiver argument by failing to raise it in Wyeth's Brief for Appellee filed in the Superior Court.

B. The Superior Court Correctly Ruled That One Who Is Injured As The Result Of Consuming A Dangerous Prescription Drug Can Sue The Manufacturer For Negligent Design Defect

In common with the law of most other states, Pennsylvania generally recognizes three types of product liability claims: (1) manufacturing defects; (2) design defects; and (3) warning defects. *See Feldman* v. *Lederle Labs.*, 479 A.2d 374, 385 (N.J. 1984). Ordinarily, a plaintiff may assert claims on any or all of those three theories based on strict liability or negligence. *See id.* Strict liability focuses on the product in question, while negligence focuses on the conduct of the defendant. *See Phillips* v. *Cricket Lighters*, 576 Pa. 644, 658, 841 A.2d 1000, 1008 (2003) (plurality opinion).

In a series of rulings that focused on comment k to Restatement (Second) of Torts §402A, this Court has recognized that prescription drugs as a class are unavoidably unsafe products. As a consequence, this Court has held that the manufacturer of prescription drugs will not be subject to strict liability for failure to

warn; rather, a manufacturer of prescription drugs is subject to liability only for negligent failure to warn. Similarly, this Court has recognized that the manufacturer of a prescription drug can be held liable on a negligence theory for manufacturing defects. This case involves the third type of product liability claim: a claim for design defect.

In recognition of this Court's earlier holdings that the manufacturer of a prescription drug cannot be held liable on a strict liability theory, here plaintiff does not assert a strict liability design defect claim against Wyeth. Rather, plaintiff's design defect claim against Wyeth sounds solely and exclusively in negligence. This Court has previously recognized that even where a plaintiff cannot prevail on a strict liability design defect claim, that outcome does not and should not preclude the plaintiff from pursuing a negligent design defect claim arising from the same facts and circumstances. *See Phillips*, 576 Pa. at 658, 841 A.2d at 1008 (plurality opinion).

Indeed, in *Phillips* this Court's plurality opinion described as "deeply flawed" the argument — which is identical to the argument that Wyeth advances here — that merely because a plaintiff could not survive summary judgment on a strict liability design defect claim, plaintiff should not be able to pursue a negligent design defect claim. *See id.* In holding that the plaintiff in *Phillips* could pursue a negligent design defect claim against the defendant even though she could not pursue a strict liability design defect claim based on the very same conduct against that same defendant, the plurality opinion in *Phillips* explained:

> As we discussed *supra*, negligence and strict liability are distinct legal theories. Strict liability examines the product itself, and sternly eschews considerations of the reasonableness of the conduct of the manufacturer. *See Lewis*, *supra*. In contrast, a negligence cause of action revolves around an examination of the conduct of the defendant. Were we to dispose of a negligence claim merely by an examination of the product, without inquiring into the reasonableness of the manufacturer's conduct in creating and distributing such a product, we would be divorcing our analysis from the elements of the tort. Thus, as the elements of the causes of action are quite distinct, it would be illogical for us to dispose of Appellee's negligence claim based solely on our disposition of her strict liability claim.

Id.

As this Court's ruling in *Phillips* makes clear, merely because plaintiff cannot maintain (and, of course, does not seek to maintain) a strict liability design defect claim against Wyeth does not preclude plaintiff, as a matter of Pennsylvania law, from maintaining a negligent design defect claim against Wyeth.

Wyeth next argues that because this Court's refusal to allow strict liability claims against the manufacturer of prescription drugs is based on a view that all prescription medications are unavoidably unsafe, this Court should therefore preclude plaintiffs from maintaining negligent design defect claims against the manufacturer of a prescription drug. Wyeth's argument, however, lacks merit both as a matter of law and as a matter of simple logic.

Turning first to the issue of simple logic, assume that a medication is available in the form of a pill that consists of a capsule containing the medication's active ingredients. If the capsule that the patient must swallow is made from a material that causes serious injury to a large number of patients, certainly the manufacturer could replace the capsule with a capsule made from an ingredient

that injured no one. This same hypothetical would apply equally to a medication swallowed in the form of a tablet where an inactive ingredient was causing injury to those who ingested the tablet. What these hypotheticals make clear is that even when dealing with an unavoidably unsafe medication that serves some useful purpose, simply because the medication is unavoidably unsafe does not mean that the medication could not be designed in a manner that made it safer to use and thus capable of causing fewer injuries and harmful side–effects to its users. It may be unsafe to ride a motorcycle without a helmet. It certainly is unsafe to drive oneself on a motorcycle at a high rate of speed from the edge of the Grand Canyon into the abyss while not wearing a helmet. Only the latter of those two motorcycle scenarios is guaranteed to result in death, however. As these hypotheticals demonstrate, the mere fact that two similar factual scenarios can be classified as unsafe does not mean that they are necessarily equally unsafe.

Even more importantly, Wyeth's argument also lacks merit as a matter of law. The Supreme Court of California, in *Brown* v. *Superior Court*, 751 P.2d 470 (Cal. 1988), held that prescription drugs as a class constitute unavoidably unsafe products under comment k of Restatement (Second) of Torts §402A, yet California's highest court in that very same ruling recognized that prescription drug manufacturers would remain liable "under general principles of negligence." *Id.* at 483 n.12; *see also In re Coordinated Latex Glove Litig*, 121 Cal. Rptr. 2d 301, 312 (Cal. Ct. App. 2002) (recognizing that, in *Brown*, the Supreme Court of California held that "[l]iability for defective [drug] design could not be premised on strict

liability, but would require proof of negligence."). The Supreme Court of Idaho reached the same result, allowing a claim for negligent design defect against the manufacturer of a prescription drug, one year earlier in *Toner* v. *Lederle Labs.*, 732 P.2d 297, 309–11 (Idaho 1987).

Similarly, the U.S. Court of Appeals for the Seventh Circuit, applying Wisconsin law in a products liability lawsuit that smokers brought against cigarette manufacturers, ruled in *Insolia* v. *Philip Morris Inc.*, 216 F.3d 596, 603–06 (7th Cir. 2000), that plaintiffs' inability to prevail against defendants on a strict products liability claim did not preclude plaintiffs from reaching a jury on their negligence claims against defendants targeting the very same allegedly wrongful conduct.

Perhaps most persuasively, the Superior Court of Pennsylvania, sitting en banc, correctly explained in *Wright* v. *Aventis Pasteur, Inc.*, 14 A.3d 850 (Pa. Super. Ct. 2011) (en banc), that "Comment K [to Restatement (Second) of Torts §402A] does not outright bar all design defect claims against FDA–approved drugs." *Id.* at 874. The Superior Court's en banc ruling in *Wright* recognizes that Pennsylvania law would allow a negligent design defect claim against the manufacturer of a vaccine whose dangerous side–effects were avoidable. *Id.* at 884. Although the U.S. Supreme Court's later ruling in *Bruesewitz* v. *Wyeth LLC*, 131 S. Ct. 1068 (2011), holds that the federal statute known as the National Childhood Vaccine Injury Act preempts the very sort of state law negligent design defect claim recognized against the manufacturer of a vaccine in *Wright*, the Superior Court's en banc ruling in *Wright* nonetheless recognizes that in the absence of preemption a state law

negligent design defect claim against the manufacturer of an avoidably dangerous vaccine would be available under Pennsylvania law. Importantly, the type of federal preemption at issue in *Wright* and *Bruesewitz* applies only in the case of vaccines, and does not apply to medications such as Redux at issue in this lawsuit.

Notwithstanding all of the case law that Wyeth has amassed in its opening Brief for Appellant, Wyeth has failed to cite even a single case that affirmatively stands for the proposition that merely because a given state's courts prohibit strict liability design defect claims against the manufacturers of prescription drugs, that state consequently also prohibits negligent design defect claims against the manufacturers of prescription drugs. Wyeth cites absolutely no law that is directly on point in support of its argument that this Court should not recognize a negligent design defect claim against the manufacturer of a prescription drug.

Wyeth's argument that Pennsylvania law should not recognize a claim for negligent design defect against the manufacturer of a prescription drug under the circumstances of this case 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 does plaintiff herein 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 claim for negligent design defect 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 this Court 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), *aff'd*, 131 S. Ct. 1068 (2011).

To summarize: (1) there are three types of product liability claims that can be asserted, and they are claims for defects in manufacture, defects in design, and defects in warning; (2) such product liability claims can ordinarily be asserted sounding either in strict liability and in negligence; (3) under Pennsylvania law, the unavailability of a strict liability design defect claim does not preclude the plaintiff, as a matter of law, from pursuing a negligent design defect claim; and (4) this Court has already authorized plaintiffs to pursue warning defect and manufacturing defect claims sounding in negligence against the manufacturer of a prescription drug, notwithstanding that warning defect and manufacturing defect claims sounding in strict liability cannot be asserted against the manufacturer of a prescription drug; (5) other courts that prohibit strict liability design defect claims against the manufacturers of prescription drugs allow negligent design defect claims against those same defendants, and Wyeth's brief cites no decision that has held to the contrary; (6) accordingly, this Court should affirm the Superior Court's ruling that, under Pennsylvania law, a plaintiff can maintain a negligent design defect claim against the manufacturer of a prescription drug.

C. Wyeth's Arguments That Plaintiff Has Failed To Allege A Safer Alternate Design And That The Superior Court's Ruling Fails To Defer Adequately To The FDA Are Waived And Without Merit

Wyeth's final two challenges to the Superior Court's decision reinstating plaintiff's negligent design defect claim consist of contentions that Wyeth failed to raise until after the Superior Court issued its opinion in this case. In the aftermath of the Superior Court's opinion, Wyeth is now seeking to raise for the very first time the argument that plaintiff's complaint supposedly does not adequately allege the elements of a negligent design defect claim. Wyeth further asserts, for the very first time in this litigation, that the recognition of a negligent design defect claim does not adequately defer to the FDA's expertise.

Before this Court considers what a complaint asserting a claim for negligent design defect against the manufacturer of a prescription drug must allege in order to avoid dismissal, that question should first be advanced by the defendant in the trial court and addressed by both the trial court and the Superior Court. Here, neither the trial court nor the Superior Court has addressed that question, because Wyeth did not argue to either of those courts (until Wyeth filed its petition for reargument in the Superior Court) that plaintiff's complain does not adequately allege a negligent design defect claim. As a result, Wyeth has failed to preserve that issue for this Court's review. *See* Pa. R. App. P. 302(a); *Pentlong Corp.* v. *GLS Capital, Inc.*, 573 Pa. 34, 48 n.17, 820 A.2d 1240, 1248 n.17 (2003) (holding that argument not presented to intermediate appellate court is waived and will not be considered by this Court); *Commonwealth* v. *Piper*, 458 Pa. 307, 309–11, 328 A.2d

845, 847 (1974) (issue not raised in trial court or Superior Court cannot be raised for first time on allocatur).

In this case, the Brief for Appellant that plaintiff filed in the Superior Court mentioned the phrase "design defect" five times. And, as explained above, plaintiff's complaint initiating suit also mentioned multiple times that plaintiff was asserting a negligent design defect claim against Wyeth. Notwithstanding that plaintiff's negligent design defect claim against Wyeth was unquestionably at issue in both the trial court and on appeal to the Superior Court, Wyeth did not once argue either the issue of judicial deference to the FDA or the supposed need to allege a feasible alternative design.

In addition to being waived, Wyeth's newly raised argument that the recognition of a claim under Pennsylvania law against a manufacturer of a dangerous prescription drug for negligent design defect fails to afford adequate deference to the FDA is contrary to the U.S. Supreme Court's recent ruling in *Wyeth* v. *Levine*, 129 S. Ct. 1187 (2009). Therein, the U.S. Supreme Court greatly curtailed the instances when federal law will preempt state law personal injury claims sounding in negligence against prescription drug manufacturers.

Wyeth's argument about the need to defer to the expertise of the FDA also proves too much. That argument, if accepted, would deny a claim under Pennsylvania law for negligent failure to warn, despite this Court's repeated holdings that such a claim exists and may be pursued by plaintiffs injured as a result of ingesting dangerous prescription drugs. Even though the FDA approves

the warnings that accompany a prescription drug, Pennsylvania law nevertheless allows claims against the manufacturers of prescription drugs for negligent failure to warn. Thus, the mere fact that the FDA approves a prescription drug for sale should likewise not preclude a claim for negligent design defect against the manufacturer of that prescription drug.

In his article "The True Test: Alternative Safer Designs for Drugs and Medical Devices in a Patent–Constrained Market," 49 U.C.L.A. L. Rev. 1 (2002) (freely available online at http://papers.ssrn.com/abstract=869746), law professor George W. Conk writes:

> Nor does the existence of FDA premarketing review substitute for tort system review. The FDA does not test for the best feasible design—only for reasonable safety and effectiveness. As an essentially passive, gatekeeping agency, it is beyond the competency of the FDA to initiate design processes, or to compare the product presented with the options rejected or ignored by the designer. The FDA asks only if the drug does more good than harm. And if it does, the new drug application is approved—except for the rare cases in which the approval of one drug leads to withdrawal of approval of an already licensed drug or in which reports of adverse effects attributed to an approved drug or device lead to withdrawal from the market.
>
> The FDA may compare one drug with an equivalent, and may refuse permission to market because there is a safer and more effective drug on the market. It may also withdraw permission to market because a new drug comes on the market that is of superior safety. But the agency does not otherwise ask what it cannot answer: whether there was an alternative, safer design realistically available to the designer–manufacturer. For that regulatory weakness the tort system, with its powerful discovery mechanisms, must compensate.

Id. at 18–19 (footnotes omitted).

Wyeth's deference argument also overlooks the facts of this very case. Once the FDA became fully informed about the actual risks of Redux, the FDA first

convinced Wyeth to voluntarily withdraw that medication from the market. Soon thereafter, the FDA prohibited Wyeth from continuing to sell Redux or that medication's active ingredient for any purpose whatsoever. Plaintiff is not asking any court to second–guess the FDA's fully informed decision that Redux was too dangerous and never should have reached the market. Rather, the FDA's ultimate findings about Redux provide conclusive evidence that the medication was negligently designed.

Wyeth's argument is not only waived, but it is unquestionably premature. What level of deference to the FDA is Wyeth suggesting in the context of a negligent design defect claim? To be sure, as in a case alleging negligent failure to warn, the drug manufacturer can certainly introduce into evidence and argue to the jury that the FDA's approval of the medication or its warnings constitute evidence of due care. But here, it seems that Wyeth is arguing that FDA approval, without more, should preclude a negligent design defect claim against an FDA approved prescription drug, even while affirmatively disavowing any federal preemption argument given the U.S. Supreme Court's rejection of such preemption in *Wyeth* v. *Levine*, *supra*. *See also Tobin* v. *Astra Pharmaceutical Prods., Inc.*, 993 F.2d 528, 537 (6th Cir. 1993) ("We reject the argument that FDA approval preempts state product liability claims based on design defect."). The result that Wyeth seeks — the refusal to recognize a claim for negligent design defect against the manufacturer of a prescription drug under the guise of FDA deference — is not and should not be the law.

Turning next to Wyeth's argument that this Court should reject plaintiff's negligent design defect claim for failure to allege a safer alternate design, that argument is likewise waived due to Wyeth's failure to assert it thus far either in the trial court or in response to plaintiff's Brief for Appellant filed in the Superior Court.

In addition, Wyeth's argument that a plaintiff alleging that a prescription drug suffered from a negligent design defect must allege a feasible alternate design is also incorrect as a matter of law. Regardless of whether a feasible alternate design must be alleged in an ordinary case involve a product or medication that possesses some beneficial uses, this case involves a medication that the FDA has deemed too dangerous to be offered for sale to any potential class of patients.

As Section 6(c) of Restatement (Third) of Torts: Products Liability explains:

> 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). The central principle that Section 6(c) recognizes is that a prescription drug whose risks outweigh its benefits as to all potential classes of patients qualifies as defectively designed without any need to show that some other alternate design would produce a medication that was equally effective yet less risky. *See also Tobin*, 993 F.2d at 540.

The fact that a medication such as Redux, which the FDA once fully informed of the medication's risks and benefits ultimately concludes never should have been

approved for sale to the public, qualifies as defectively designed without the need for a plaintiff to allege any feasible safer alternate design renders academic Wyeth's remaining arguments on this point. For example, Wyeth argues that changing the chemical composition of Redux would result in a substance that was not Redux and that might not qualify for FDA approval. But the same type of argument could be made about a lawnmower that was originally sold in a dangerous condition because its blades were completely exposed. A redesigned lawnmower whose blades were behind a cover that assured user safety while not impeding the lawnmower's functionality would not be the same product as originally marketed. By definition, a safer alternate design can never be identical to the original, unsafe product whose negligent design is at issue in the lawsuit.

The Supreme Court of California, in *Brown*, rejected the unnecessarily restrictive "safer alternate design" argument that Wyeth favors:

> The second test, which calls for the balancing of risks and benefits, is inapposite to prescription drugs, according to defendants, because it contemplates that a safer alternative design is feasible. While the defective equipment in *Barker* and other cases involving mechanical devices might be "redesigned" by the addition of safety devices, there is no possibility for an alternative design for a drug like DES, which is a scientific constant compounded in accordance with a required formula.
>
> We agree with defendants that *Barker* contemplates a safer alternative design is possible, but we seriously doubt their claim that a drug like DES cannot be "redesigned" to make it safer. For example, plaintiff might be able to demonstrate at trial that a particular component of DES rendered it unsafe as a miscarriage preventative and that removal of that component would not have affected the efficacy of the drug. Even if the resulting product, without the damaging component, would bear a name other than DES, it would do no violence to semantics to view it as a "redesign" of DES.

> Or plaintiff might be able to prove that other, less harmful drugs were available to prevent miscarriage; the benefit of such alternate drugs could be weighed against the advantages of DES in making the risk/benefit analysis of *Barker*. As the Court of Appeal observed, defendants' attempt to confine the issue to whether there is an "alternative design" for DES poses the problem in an "unreasonably narrow" fashion.

Brown, 751 P.2d at 478.

In sum, this Court should hold that Wyeth's FDA deference and safer alternate design arguments are waived, because Wyeth did not previously raise them either in the trial court or in the Superior Court. Those arguments can be addressed, if appropriate, on remand in the trial court once plaintiff's negligent design defect claim is reinstated. If this Court does wish to reach the merits of those arguments, however, this Court should rule that neither argument provides a basis for upholding the trial court's entry of summary judgment in favor of Wyeth on plaintiff's negligent design defect claim.

D. This Court Should Permit A Negligent Failure To Test Claim Against The Manufacturer Of A Prescription Drug Where The Plaintiff Alleges That Adequate Testing Would Have Prevented The Drug From Ever Reaching The Market

This case is unusual, but sadly far from unique, in that it involves a claim for personal injury — indeed death — resulting from the ingestion of a prescription medication that the FDA, once fully informed of all of the medication's risks, concluded should never have been approved for sale to anyone.

Under these circumstances — where a plaintiff has alleged that adequate testing would have prevented the medication that caused her injury from ever

reaching the market — a plaintiff should be permitted to assert a freestanding negligent failure to test claim against the manufacturer of a prescription drug.

As the Superior Court's opinion in this case correctly recognizes (*see* Appendix B to Brief for Appellant 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.

The Superior Court's rejection of plaintiff's claim for negligent failure to test 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).

Under Pennsylvania law, a claim for negligent failure to test has been recognized outside of the realm of prescription drug personal injury litigation. In *Romah* v. *Hygienic Sanitation Co.*, 705 A.2d 841 (Pa. Super. Ct. 1998), the Superior Court allowed a plaintiff to pursue a personal injury claim alleging, among other things, a claim for negligent failure to test against the manufacturer of an insecticide that harmed the plaintiff in various ways when he was exposed to it. *See id.* at 853, 855. It is difficult to imagine why someone injured by exposure to an insecticide should be able to pursue a claim against the manufacturer for negligent failure to test while someone injured as the result of ingesting a prescription drug designed for human consumption cannot pursue that very same claim.

Moreover, in *Romah*, the Superior Court *rejected* the argument that a claim for negligent failure to test is necessarily subsumed within a claim for negligent failure to warn. *See id.* at 855. That holding was of special significance in *Romah*, because the Federal Insecticide, Fungicide, and Rodenticide Act preempted state law failure to warn claims, *see id.* at 853, but *did not* preempt state law negligent failure to test claims, *see id.* at 855.

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 an inability to assert a claim for negligent failure to test. Because this is that very sort of case, this Court should hold that a 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.

For these reasons, this Court should reverse the Superior Court's affirmance of plaintiff's claim against Wyeth alleging negligent failure to test.

E. This Court Should Hold That 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* Appendix B to Brief for Appellant 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.

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. Plaintiff's appeal does not challenge this Court's actual holding in *Hahn*. Rather, plaintiff 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 remaining two 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.

As the Sixth Circuit explained in *Tobin*:

> We do not sit to review the findings of the FDA; our only role in this appeal is to decide if there was sufficient evidence on which the jury

> could base its verdict. Plaintiff introduced evidence, through the cross–examination of Astra officials, that a reasonably prudent manufacturer would not market ritodrine if the evidence of its efficacy was inconclusive. Plaintiff also introduced sufficient evidence regarding the various clinical studies concerning the efficacy of ritodrine. The jury found that ritodrine, as manufactured and marketed by Astra, was in a defective condition and unreasonably dangerous to plaintiff. We find that there was sufficient evidence before the jury to conclude that a prudent manufacturer knowing all the risks would not market ritodrine.

993 F.2d at 540. It is this very sort of negligent marketing claim involving an FDA–approved prescription drug, which the Sixth Circuit recognized as actionable under Kentucky law in *Tobin*, that this Court should likewise recognize as actionable under Pennsylvania law in the context of this case.

Turning next to plaintiff's claim for negligent failure to withdraw Redux from the market, by means of that claim plaintiff 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.

As the Supreme Court of the United States acknowledged in *Wyeth* v. *Levine*, 129 S. Ct. 1187, 1202 (2009), recognizing claims under state law for negligently marketing and negligently failure to withdraw from the market dangerous prescription drugs can 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 — which it should not, because even FDA approval does not require the manufacturer of a prescription drug to place the medication on 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.553a–54a.

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* Appendix B to Brief for Appellant 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.553a–54a. The Superior Court's rationale 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.

* * * * *

In language that still rings true today, this Court observed in 1942 in *Henderson* v. *National Drug Co.*, 343 Pa. 601, 23 A.2d 743 (1942), that:

> [W]e are not unmindful that the public interest requires the holding of companies which make and sell drugs and medicines for use in the human body to a high degree of responsibility under both the criminal and the civil law for any failure to exercise *vigilance* commensurate with the harm which would be likely to result from relaxing it.

Id. at 610, 23 A.2d at 748.

Although Wyeth and its amicus blithely contend that Pennsylvania law would assure an adequate opportunity for recovery if plaintiffs injured by

prescription drugs were limited to a claim for negligent failure to warn, this case starkly evidences the fallacy of that argument. The outcome that Wyeth and its amicus are in fact arguing in favor of — as one would expect under our adversarial system of justice — is an outcome that limits the liability of prescription drug manufacturers to the greatest possible extent.

This Court, by contrast, is not in the business of favoring one side or the other in litigation. Rather, it is this Court's sworn obligation to apply Pennsylvania law fairly and impartially regardless of who the parties are. Above, plaintiff has demonstrated that Pennsylvania law ordinarily allows a claim for negligent design defect to be brought against the manufacturer of a dangerous product, even if a claim for strict liability design defect cannot be maintained. This Court should hold that the very same sort of negligent design defect claim should likewise be available to a plaintiff who has been injured due to ingesting a prescription drug.

And, in a case such as this, where the medication in question is revealed to be so dangerous that the FDA never would have approved its sale had all of the medication's material risks been identified and disclosed in a non–negligent manner, this Court should allow a plaintiff to pursue claims for negligent testing, negligent marketing, and negligent failure to withdraw from the market against the drug's manufacturer.

VIII. CONCLUSION

For all of the reasons set forth above, this Court should affirm the Superior Court's reinstatement of plaintiff's negligent design defect claim and reverse the Superior Court's refusal to reinstate plaintiff's claims alleging negligent failure to test, negligent marketing, and negligent failure to withdraw from the market.

Respectfully submitted,

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