In The

Supreme Court of Pennsylvania

No. _____, E.A.L. 2010
(Superior Court No. 2905 EDA 2008)

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

Plaintiff-Respondent,

v.

WYETH, f/k/a
AMERICAN HOME PRODUCTS CORPORATION,

Defendant-Petitioner,

PETITION FOR ALLOWANCE OF APPEAL OF WYETH, f/k/a AMERICAN HOME PRODUCTS CORPORATION

Petition for Allowance of Appeal from the Order of the Superior Court, Entered August 2, 2010, at No. 2905, EDA, 2008, Reargument Denied, October 1, 2010, Affirming in Part and Reversing in Part the Judgment of the Court of Common Pleas of Philadelphia County, entered September 19, 2008, at November Term, 2006, No. 000926

Robert C. Heim, I.D. No. 15758
Judy L. Leone, I.D. No. 41165
Will W. Sachse, I.D. No. 84097
Dechert LLP
Cira Centre
2929 Arch Street
Philadelphia, PA 19104-2808
(215) 994-2570

Counsel for Defendant-Petitioner
Wyeth, f/k/a American Home Products Corporation

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I. REFERENCE TO THE OPINIONS DELIVERED IN THE COURTS BELOW

On January 7, 2010, the Court of Common Pleas of Philadelphia County entered its Pa. R.A.P. 1925(a) Opinion (Hon. Allan L. Tereshko, J.), in support of the final judgment entered on September 19, 2008 (attached at Appendix A).

On August 2, 2010, the Superior Court issued its published opinion (Stevens and Allen, JJ., with Gantman, J. concurring in the result), which affirmed in part and reversed in part the Court of Common Pleas (attached at Appendix B). The Superior Court's opinion is reported as *Lance v. Wyeth*, 4 A.3d 160 (Pa. Super. Ct. 2010).

On October 1, 2010, the Superior Court denied Defendant-Petitioner Wyeth's Application for Reargument (attached at Appendix C).

II. TEXT OF THE ORDER IN QUESTION

No separate judgment order accompanied the Superior Court's August 2, 2010 opinion. That opinion stated, in pertinent part: "Order affirmed in part and reversed in part. Case remanded. Jurisdiction relinquished." (Appendix B, at 18).

III. QUESTIONS PRESENTED FOR REVIEW

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?

IV. CONCISE STATEMENT OF THE CASE

A. Summary

This is a prescription drug negligence case where Plaintiff-Respondent Patsy Lance ("Plaintiff") claimed her daughter, Catherine Ruth Lance, died from primary pulmonary hypertension ("PPH") after taking the diet drug Redux. The Food and Drug Administration ("FDA") had approved Redux as "safe and effective," and the drug carried a conspicuous, FDA-approved warning about the relevant risks. While Plaintiff incorporated certain aspects of the standard "Long Form" Complaint used in the Phen-Fen litigation, the specific "Short-Form" Complaint alleged that Defendant-Petitioner Wyeth, Inc. ("Wyeth") was liable for "unreasonable marketing" of the drug and failure to remove it from the market. There was no claim for negligent failure to warn. The trial judge granted summary judgment, concluding that Plaintiff had not made out a viable claim under Pennsylvania law. The three-judge panel of the Superior Court affirmed the trial court as to the "Short-Form" Complaint claims that the parties briefed and argued. However, the panel, on its initiative, examined a general negligence paragraph of the "Long-Form" Complaint in which Plaintiff alleged many concepts, including "design," "research," "development," "manufacture," "sale," "testing," "inspect[ion]," "prepar[ation]," "quality assurance," "quality control," and "label[ing]." The panel extracted "design" from this boilerplate, invented a "negligent design defect" claim, and remanded the case on that issue.

Despite the hundreds of similar cases in the complex litigation program in Philadelphia, no other case has proceeded on the theory of negligent design defect, because Pennsylvania follows Comment k of §402A of the Restatement of Torts and recognizes all prescription drugs as "unavoidably unsafe." In this case, "negligent design defect" was neither briefed nor argued. Therefore, were this case to stand, it would: (a) represent a new cause of action created by the intermediate appellate court that conflicts with long-standing Pennsylvania Supreme Court case

law; (b) it would *reverse* the trial court and create a new cause of action that was *waived* because this specific issue was never presented; and (c) it would create dramatic new law potentially affecting hundreds or thousands of cases without the benefit of any briefing or argument either in the trial or intermediate appellate court.

B. Procedural History

Redux (dexfenfluramine) was a prescription medication sold by Wyeth. The FDA approved it as "safe and effective" for "management of obesity" on April 29, 1996, following the Agency's three-year review. (R. 87a). On September 15, 1997, Wyeth voluntarily withdrew Redux from the market. (R. 100-01a).

Plaintiff alleged that her daughter, Ms. Lance, used Redux for approximately three months between January and April 1997, causing her to develop PPH. (R.17a ¶5). Ms. Lance was diagnosed with PPH on November 15, 2004, and later died from that condition. (R. 18-19a ¶¶7, 16). During Ms. Lance's entire period of use, the FDA viewed Redux as "safe and effective," and the drug carried a conspicuous, FDA-approved warning about the risks of PPH potentially associated with Redux. (R. 82a-95a). Indeed, on September 3, 1997, four months after Ms. Lance discontinued her Redux treatment, the FDA reaffirmed that Redux was "safe and effective" when it rejected a citizen's petition seeking the drug's withdrawal from the market. (R. 94a, 97a).

Plaintiff filed this lawsuit as the administratrix for Ms. Lance's estate. (R. 1a, 12a). Although Plaintiff incorporated parts of the standard "Long-Form" Complaint used in the "Phen-Fen" mass tort litigation pending in the Philadelphia County Court of Common Pleas, (R.17a, 24-69a), she also filed a "Short-Form" Complaint providing "additional allegations" and "clarification" of her claims. (R. 18a, ¶12). This "Short-Form" Complaint asserted claims based on: (1) alleged "unreasonable marketing" of Redux; and (2) unreasonable "failure to remove"

Redux from the market before January 1997, because Redux was allegedly "so unreasonably dangerous and defective in design that it should never have been on the market." (R. 18-19a ¶¶13-15). Plaintiff expressly declined to assert a negligent failure to warn claim. (R.19a ¶17).

Wyeth moved for summary judgment on March 6, 2008. (R.70-80a). Plaintiff's opposition confirmed that she was asserting only claims "for negligently marketing Redux and negligently failing to remove Redux from the market." (R.125a). On September 19, 2008, the trial court (Tereshko, J.) granted summary judgment, holding that Plaintiff had not asserted any cognizable claims under Pennsylvania law. (Appendix A). The court did not specifically address any design-based negligence claim. *Id.*

Plaintiff appealed to the Superior Court, where this case was argued in conjunction with two other cases: *Cochran v. Wyeth*, 3 A.3d 673 (Pa. Super. Ct. 2010), *pet. for allocatur filed*, No. 459 EAL 2010 (Pa. filed Aug. 19, 2010); and *Owens v. Wyeth*, 2010 WL 2965014, No. 185 EDA 2009 (Pa. Super July 26, 2010), *pet. for allocatur filed*, No. 572 EAL 2010 (Pa. filed Oct. 12, 2010). On August 2, 2010, the Superior Court affirmed in part and reversed in part the trial court's summary judgment order in a published decision. *Lance v. Wyeth*, 4 A.3d 160 (Pa. Super. Ct. 2010) (Appendix B). The Superior Court's decision correctly rejected Plaintiff's novel claims for "unreasonable marketing," and negligent "failure to remove" Redux from the market. *Id.* at 164-65, 166-69.[1]

The Superior Court, however, created a new cause of action for "negligent design defect" of a prescription drug, *id.* at 165-66, which has never before been recognized in Pennsylvania and is contrary to this Court's settled precedent. In so ruling, the Superior Court addressed an issue that Plaintiff waived on at least three separate occasions: (1) in Plaintiff's Pa. R.A.P.

[1] The court also correctly rejected any purported independent claim for negligent failure to test, which Plaintiff asserted in support of her "unreasonable marketing" and "failure to remove" claims.

1925(b) statement of issues, which did not mention any negligent design defect theory; (2) in Plaintiff's trial court briefing in opposition to Wyeth's motion for summary judgment; and (3) in Plaintiff's Pa. R.A.P. 2116 Statement of Questions Presented to the Superior Court. Indeed, the Superior Court's unprecedented decision relied on Restatement (Second) of Torts § 395 (1965) and two non-Pennsylvania cases – none of which was discussed or cited in the parties' briefing.

Because neither party had briefed the issue of whether Pennsylvania law recognized a cause of action for "negligent design defect" of a prescription drug, Wyeth sought reconsideration or *en banc* reargument. On October 1, 2010 the Superior Court denied Wyeth's Application. (Appendix C).

Wyeth filed this timely Petition for Allowance of Appeal seeking this Court's review of the Superior Court's precedential decision to create a new cause of action for "negligent design defect" in prescription drug cases.

V. REASONS FOR ALLOWING AN APPEAL

The Superior Court exceeded its power as an intermediate appellate court by creating a new cause of action for "negligent design defect" in a case involving a prescription drug – a claim never before recognized in any Pennsylvania precedent. Moreover, because Plaintiff had repeatedly waived any "negligent design defect" claim in both the trial court and Superior Court, the court took this unprecedented step on a nonexistent record and minimal argument. Thus, this case is appropriate for review so this Court may decide whether the Superior Court acted in accordance with Pennsylvania's carefully defined limits on the proper scope of appellate review.

Should the Court decide to review this claim on the merits, rather than reversing on waiver grounds, the Superior Court's new "negligent design defect" claim conflicts with this Court's settled precedent limiting the claims that may be brought against prescription drug sellers. In *Incollingo v. Ewing*, 444 Pa. 263, 287-88, 282 A.2d 206, 219-20 (1971), *overruled on*

other grounds, *Kaczkowski v. Bolubasz*, 491 Pa. 561, 421 A.2d 1027 (1980), *Baldino v. Castagna*, 505 Pa. 239, 244, 478 A.2d 807, 810 (1984), and *Hahn v. Richter*, 543 Pa. 558, 563, 673 A.2d 888, 891 (1996), this Court specified that negligent failure to warn is the only available liability theory against a seller of a properly manufactured drug. Thus, no claim should survive where a properly manufactured drug is accompanied by risk information that adequately warns the prescribing physician of the risks associated with the drug. The result below is contrary to this established law. By potentially radically expanding Pennsylvania law and ignoring this Court's guidance, the Superior Court exceeded its authority.

The Court should also grant review because the Superior Court created an ill-defined cause of action that conflicts with Pennsylvania law in three material ways. First, it conflicts with Pennsylvania's decades-long adherence to comment k to Restatement (Second) of Torts §402A, and the special treatment it affords to prescription drugs. Second, the "negligent design defect" claim recognized by the Superior Court conflicts with Pennsylvania law requiring plaintiffs asserting negligent design defect claims to plead and prove the existence of a feasible alternative design. Third, the Superior Court's new cause of action conflicts with Pennsylvania law according deference to the FDA's considered judgments about the safety and efficacy of prescription medical products. This Petition therefore raises matters of first impression requiring this Court's guidance, including: (1) whether a "negligent design defect" cause of action is cognizable in a prescription drug case; and (2) if so, the necessary elements of such a claim. These are questions of substantial importance, particularly because the Superior Court's decision potentially greatly expands liability against prescription drug manufacturers. In fact, Plaintiff's failure to put forth any "feasible alternative design" makes clear that her "negligent design defect" cause of action is nothing more than a disguised claim that Redux should never have

been approved by the FDA, or should have been withdrawn sooner than it was – a claim even the Superior Court recognized is not cognizable under Pennsylvania law. *Lance*, 4 A.3d at 166-67.

A. Plaintiff Specifically Waived Any Claim For "Negligent Design Defect" And Therefore The Superior Court Created A New Cause Of Action Without The Benefit Of Briefing Or Argument.

"Issue preservation is foundational to proper appellate review." *In re F.C. III*, 2 A.3d 1201, 1212 (Pa. 2010). Here, the Superior Court erred at the outset in considering a claim that Plaintiff had waived on three separate occasions.

First, Plaintiff's Rule 1925(b) Statement did not mention "design," much less identify any error in the trial court's grant of summary judgment with respect to a "negligent design defect" claim. *See* Appellant Patsy Lance's Concise Statement of Errors Complained of on Appeal, attached as Ex. C to Appellant's Brief ("Appellant's Br."), No. 2905 EDA 2008 (Pa. Super. Ct. filed March 24, 2010) (attached as Appendix D). Rather, Plaintiff asserted only that Judge Tereshko erred by not recognizing "the validity of plaintiff's claims that Wyeth was negligent in marketing Redux and in failing to withdraw Redux from the market." *Id.* ¶1. Under this Court's "bright-line rule," Plaintiff plainly waived any "negligent design defect" claim by failing to even mention it in her Rule 1925(b) Statement. *Commonwealth v. Butler*, 571 Pa. 441, 445, 812 A.2d 631, 633 (2002) ("Any issues not raised in a 1925(b) statement *will be deemed waived.*") (emphasis in original); *see also Commonwealth v. Bond*, 604 Pa. 1, 985 A.2d 810, 823 (2009) ("Appellant failed to include this claim in his Statement of Matters Complained of on Appeal pursuant to Pa. R.A.P. 1925(b). Accordingly, this claim has been waived.").

Second, in opposing summary judgment, (R. 125-40a), Plaintiff repeatedly argued that the "claims against Wyeth are for negligently marketing Redux and for negligently failing to

withdraw Pondimin from the market." (R. 125a).[2] Plaintiff never even suggested that summary judgment was inappropriate because she was also asserting a claim for "negligent design defect," much less explained to the trial court why such a claim was cognizable.[3] Plaintiff thus waived any "negligent design defect" claim. *See, e.g., Krentz v. Consolidated Rail Corp.*, 589 Pa. 576, 604, 910 A.2d 20, 37 (2006) ("arguments not raised initially before the trial court in opposition to summary judgment cannot be raised for the first time on appeal") (citation and quotation marks omitted).

Third, Rule 2116 required Plaintiff to identify any claimed error with respect to her purported "negligent design defect" claim in the Statement of Questions Presented in her opening brief to the Superior Court. Again, Plaintiff claimed error solely with respect to "claims that Wyeth was negligent in bringing Redux to market and in failing to withdraw Redux from the market" – with no suggestion of any "negligent design defect" claim. (Appellant's Br. at 3). That continued failure to raise any claimed error with respect to "negligent design defect" likewise constitutes waiver. Pa. R.A.P. 2116(a); *see Commonwealth v. Lambert*, 568 Pa. 346, 362, 797 A.2d 232, 241 (2001) (finding waiver as to issues not raised "in appellant's statement of questions presented or even in his argument headings"); *see also Commonwealth v. LaCava*,

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[2] *Accord* (R. 126a) ("Wyeth acted unreasonably in marketing Redux and acted unreasonably in failing to remove Redux from the market sooner"); (R. 129a) ("had Wyeth acted reasonably . . . [it] would never have completed its application for FDA approval of Redux, or . . . would have taken [it] off the market"); (R. 134a) ("Wyeth was negligent in marketing and in failing to remove Redux from the market"); (R. 135a) ("Plaintiff's claims of negligent marketing of Redux and negligent failure to withdraw Redux from the market"); (R.140a) ("Plaintiff has cognizable claims against Wyeth for negligent marketing of Redux and for negligent failure to withdraw Redux from the market").

[3] The word "design" was used, only in passing, as part of a laundry list of vague allegations set forth in support of Plaintiff's properly rejected "unreasonable marketing" and "failure to remove" claims. *See, e.g.*, (R. 134-35a) ("[P]laintiffs 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.") (citing Long Form Complaint ¶64).

542 Pa. 160, 181 n.10, 666 A.2d 221, 231 n.10 (1995) (refusing to consider issue not raised in appellant's Statement of Questions Presented).[4]

Any of these waivers, standing alone, should have barred the Superior Court from considering a "negligent design defect" claim. Instead, the Superior Court created a new cause of action without the benefit of any briefing or guidance from the parties. At a minimum, the Court should accept review to reverse the portion of the Superior Court's precedential decision that ignores Plaintiff's repeated waiver and instead creates a new cause of action for "negligent design" of a prescription drug. *See* Supreme Court Internal Operating Procedures §5(A)(5); *see also Stecher v. Ford Motor Co.*, 571 Pa. 312, 320 n.5, 812 A.2d 553, 558 n.5 (2002) ("[B]ecause the Superior Court erroneously addressed [an] issue, its determination . . . should be regarded as mere *dicta*.").

B. The Superior Court's Decision Conflicts With This Court's Settled Precedent By Creating A New Cause Of Action For "Negligent Design" Of A Prescription Drug.

If this Court chooses to reach the merits, review is also warranted because the Superior Court's decision could undo the careful limits this Court has placed on the permissible scope of product liability claims involving prescription drugs. In a trilogy of decisions stretching across

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[4] Plaintiff has wrongly claimed that passing reference to a general "negligence" claim was sufficient to preserve her "negligent design defect" claim for appellate review. *See* Appellant's Answer in Opp'n to Wyeth's Application for Recons. or Reargument, at 3-4. Such vague, boilerplate language is insufficient to preserve a claim for review. *See Commonwealth v. Allshouse*, 969 A.2d 1236, 1239 (Pa. Super. 2009) ("When a court has to guess what issues an appellant is appealing, that is not enough for meaningful review."); *accord, Lineberger v. Wyeth*, 894 A.2d 141, 148 (Pa. Super. 2006) ("a Concise Statement which is too vague to allow the court to identify the issues raised on appeal is the functional equivalent of no Concise Statement at all") (citation and quotation marks omitted). Furthermore, it is clear from the record and from the Superior Court's opinion that such passing references to "design" were made in an effort to substantiate Plaintiff's "negligent marketing" and "negligent failure to remove" claims. In any event, Plaintiff's attempt to salvage her waived claim is belied by her repeated insistence at the trial court level that she was pursuing only claims for "negligent marketing" and "negligent failure to remove" Redux. *See supra* at 8-9 & n.2.

three decades – *Hahn*, 543 Pa. 558, 673 A.2d 888; *Baldino*, 505 Pa. 239, 478 A.2d 807; and *Incollingo*, 444 Pa. 263, 282 A.2d 206 – this Court recognized negligent failure to warn as the "only" cognizable claim against a seller of a properly manufactured drug. The Superior Court's "negligent design defect" cause of action does not fit within this framework; instead, it represents a potentially radical expansion of liability, and an unwarranted departure from the settled principles that have served the interests of this Commonwealth for nearly forty years.

In *Incollingo*, this Court disapproved of strict liability claims and left no room for design-related claims against an FDA-approved and properly labeled drug. Rather, negligent failure to warn is the sole basis for liability in a case involving a properly manufactured prescription drug. 444 Pa. at 287, 282 A.2d at 219. The *Incollingo* opinion did not suggest that Pennsylvania recognizes any prescription drug claims sounding in negligence, other than negligent failure to warn or negligent manufacturing claims. "The question . . . is whether the warning that was given to the prescribing doctors was proper and adequate." *Id.*

In *Baldino*, the Court revisited *Incollingo* and emphasized that failure to warn is the only allowable claim against sellers of properly manufactured prescription drugs:

> [S]uch a manufacturer is *liable only if he fails to exercise reasonable care to inform those for whose use the article is supplied of the facts* which make it likely to be dangerous.

505 Pa. at 244, 478 A.2d at 810 (citations to *Incollingo* omitted) (emphasis added).

Similarly, in *Hahn v. Richter*, the Court adhered to *Incollingo* and *Baldino*, and reaffirmed the proper scope of liability in prescription drug cases. 543 Pa. at 562, 673 A.2d at 890-91; *see also id.* at 563, 673 A.2d at 981 (rejecting strict liability in prescription drug cases). *Hahn* neither expanded the cognizable theories of liability set out in *Incollingo* and *Baldino*, nor suggested that Pennsylvania would nonetheless recognize a "negligent design defect" claim even in a case where adequate warnings accompanied the prescription drug at issue.

Numerous Superior Court decisions, ignored by the panel below, have followed this Court's guidance and limited liability to negligent warning or manufacturing claims in prescription drug cases. *Lineberger v. Wyeth*, 894 A.2d 141, 150 (Pa. Super. Ct. 2006) ("a manufacturer will be held liable only where it fails to exercise reasonable care to inform the one for whose use the product is supplied of the facts which make the product likely to be dangerous") (quoting *Rosci*); *Rosci v. AcroMed, Inc.*, 447 Pa. Super. 403, 423, 669 A.2d 959, 969 (1995) (same; quoting *Baldino*); *Taurino v. Ellen*, 397 Pa. Super. 50, 59, 579 A.2d 925, 930 (1990) ("adequate warnings given to the prescribing physician are the only protection the law of negligence in Pennsylvania provides"), *allocatur denied*, 527 Pa. 603, 589 A.2d 693 (1991); *Brecher v. Cutler*, 396 Pa. Super. 211, 219, 578 A.2d 481, 485 (1990) (same as *Rosci*); *White v. Weiner*, 386 Pa. Super 111, 123, 562 A.2d 378, 384 (1989) (same as *Rosci*), *aff'd*, 525 Pa. 572, 583 A.2d 789 (1991) (per curiam); *Leibowitz v. Ortho Pharmaceutical Corp.*, 224 Pa. Super. 418, 434, 307 A.2d 449, 458 (1973) ("a person claiming to have suffered adverse effects from using such a drug, unless he can prove an impurity or an inadequacy in labeling, may not recover") (equally divided court) (opinion in support of affirmance); *cf. Aaron v. Wyeth*, 2010 WL 653984, at *7 (W.D. Pa. Feb. 19, 2010) ("the only cognizable claims Plaintiff has against Wyeth, as a manufacturer of prescription drugs, are negligence claims based upon (1) manufacturing defect or (2) failure to warn").

The panel here, however, ignored this Pennsylvania precedent. Instead, the Superior Court crafted its new cause of action based on an inapplicable section of the Restatement (Second) of Torts and two inapposite out-of-state cases:

(1) Restatement (Second) of Torts §395 (1965), which this Court has never cited, let alone adopted, and which on its face applies to "Negligent *Manufacture* of Chattel Dangerous Unless Carefully Made," not negligent *design defect*;[5]

(2) A 1987 Idaho Supreme Court case interpreting Idaho law and addressing design defect claims against a vaccine manufacturer, where, unlike this case, the plaintiff alleged the existence of a feasible alternative design, *Toner v. Lederle Laboratories*, 732 P.2d 297, 300 (Idaho 1987); and

(3) An intermediate appellate court decision from California holding that strict liability design defect claims are not available against medical device manufacturers, and suggesting in *dictum* that California might recognize a claim for "negligent design" of a medical device, not a prescription drug, *Artiglio v. Superior Court*, 27 Cal. Rptr. 2d 589, 591 (Cal. App. 1994).

Thus, the Superior Court expanded Pennsylvania law only by following three questionable, non-binding sources, which the parties did not raise in their briefs. The Superior Court's resulting decision conflicts with this Court's precedent, as well as a number of the Superior Court's own prior decisions, including the panel's own decision in *Owens* just one week prior. Accordingly, the Court should grant review because of this conflict. *See* Supreme Court Internal Operating Procedures §5(A)(1-2).

[5] Indeed, the Superior Court cited only comment f to §395. This comment at most suggests that reasonable care may require the adoption of a "formula or plan" for manufacturing that, "if followed," will produce a safe product. The comment has no bearing on this case because Plaintiff does not allege that Wyeth failed to follow its "formula or plan" for manufacturing Redux.

C. The Superior Court's Creation Of A New Cause Of Action For "Negligent Design Defect" In Prescription Drug Cases May Affect Hundreds Or Thousands Of Cases In The Commonwealth And Raises Questions Of First Impression That Are Properly For This Court To Resolve.

As the Superior Court itself recognized, "[i]t is not the prerogative of an intermediate appellate court to enunciate new precepts of law or to expand existing legal doctrines. Such is a province reserved to the Supreme Court." 4 A.3d at 169 (quoting *Moses v. T.N.T. Red Star Express*, 725 A.2d 792, 801 (Pa. Super. Ct. 1999)). The new "negligent design defect" claim upset decades of settled precedent. Indeed, the Superior Court's decision strikes at the foundation of prescription drug product liability in Pennsylvania. This Court has repeatedly applied comment k to Restatement (Second) of Torts § 402A in *all* cases involving prescription drugs. *See Hahn*, 543 Pa. at 563, 673 A.2d at 891; *Baldino*, 505 Pa. at 244, 478 A.2d at 810; and *Incollingo*, 444 Pa. at 288 n.8, 282 A.2d at 220 n.8. This represents a policy judgment by this Court that prescription drugs, as a category, are "unavoidably unsafe." Put simply, prescription drugs are different from other products – drugs inevitably carry some risk accompanying the benefits they provide, which is why they require a physician's prescription. Thus, as comment k and this Court recognize, a prescription drug, "properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous." *Baldino*, 543 Pa. at 560 n.2, 673 A.2d at 890 n.2 (quoting comment k) (emphasis in original).

Only this Court, rather than the Superior Court, has the power to decide whether Pennsylvania should now recognize a new cause of action that conflicts with the categorical policy judgments this Court has made with respect to prescription drug liability. The Superior Court's decision potentially radically expands Pennsylvania law by creating a cause of action in prescription drug cases even where the plaintiff does not challenge the adequacy of the drug's warnings, or where the prescribing physician was adequately warned of any risks posed by the

allegedly "defective" drug. Such a decision should only emanate from this Court, and review is appropriate on this basis alone.

Further, the Court should review the Superior Court's decision because it created an ill-defined cause of action. Plaintiff's repeated waiver of any "negligent design defect" claim led the Superior Court to act without the benefit of full briefing and argument on the issue. As a result, this Court should address a number of important questions of first impression.

1. "Feasible Alternative Design"

Most significantly, the Superior Court left unanswered how any plaintiff can plead and prove the existence of a safer "feasible alternative design" in a prescription drug case, as Pennsylvania law requires for any other claims of negligent design defect. Ordinary negligent design defect cases require proof that the harm caused by the product at issue – for example, a car, machine, or lighter – could have been avoided by adding a feasible alternative design or safety feature such as a redesigned frame, a safety throttle, or a child-proof lock. Thus, every court considering the question has found feasible alternative design to be an essential element of negligent design defect under Pennsylvania law. *See, e.g., Kosmack v. Jones*, 807 A.2d 927, 931 (Pa. Cmwlth. 2002) ("a plaintiff bears the burden of establishing that there is an alternative design" in negligent design defect cases), *allocatur denied*, 577 Pa. 728, 847 A.2d 1289 (2003); *Smith v. Yamaha Motor Corp.*, ___ A.3d ___, 2010 WL 3239476, at *8 (Pa. Super. Ct. Aug. 18, 2010) (requiring proof of alternative design for all-terrain vehicle); *Berrier v. Simplicity Manufacturing, Inc.*, 563 F.3d 38, 64 (3d Cir. 2009) ("The determination of whether a product was negligently designed turns on whether an alternative, *feasible*, safer design would have lessened or eliminated the injury plaintiff suffered.") (emphasis in original) (applying Pennsylvania law); *Aaron*, 2010 WL 653984, at *11 (negligent design defect claim fails where

"[p]laintiff failed to provide any record evidence that there was an alternate, feasible, safer design").

Plaintiff did not plead an alternative design here. (R. 44a-47a) (Count I "Negligence"). Nor has Plaintiff ever explained how such an alternative could possibly exist where redesign of a prescription drug would lead to a completely different molecule – and thus a different drug with different properties. *See, e.g.*, Bernard D. Goldstein & Mary Sue Henifin, "Reference Guide on Toxicology," at 421 n.51, *Reference Manual on Scientific Evidence* (Fed. Judicial Center 2d ed. 2000) ("molecules with minor structural differences can produce very different biological effects"). A prescription drug, because it has no possible safer alternative design, is not negligently designed, but rather is "unavoidably unsafe" within the meaning of this Court's precedent adopting Restatement §402A, comment k.

Because the Superior Court's precedential opinion is silent as to how a prescription drug "negligent design defect" claim may coexist with Pennsylvania's requirement of proving "feasible alternative design," review is appropriate to address this important question of first impression.

2. Deference To Regulatory Authority

The Superior Court also left unanswered how a prescription drug "negligent design defect" claim is consistent with Pennsylvania's policy of deference to regulatory decisions. Compliance with governmental regulations is evidence of due care in negligence. *E.g., Groh v. Philadelphia Electric Co.*, 441 Pa. 345, 349-50, 271 A.2d 265, 267 (1970); *Brogley v. Chambersburg Engineering Co.*, 306 Pa. Super. Ct. 316, 319-20, 452 A.2d 743, 745 (1982) (collecting cases). In the specific context of prescription drugs, "[o]ur legislature unequivocally has expressed a policy of deference" to FDA regulatory decisions "and we can ascertain no reason not to extend that policy to civil cases." *White v. Weiner*, 386 Pa. Super 111, 119-20, 562

A.2d 378, 383 (1989). This Court summarily affirmed *White*. *White v. Weiner*, 525 Pa. 572, 583 A.2d 789 (1991) (per curiam). Indeed, the Superior Court acknowledged this fundamental principle of Pennsylvania law in this case, recognizing that it should "defer to the federal regulatory scheme and the FDA's decision as to whether a drug should lawfully remain on the market." *Lance*, 4 A.3d at 167.

Plaintiff's purported "negligent design defect" claim necessarily conflicts with the deference recognized under Pennsylvania law to FDA-approved designs. Plaintiff argued that, despite FDA approval, Redux should never have been marketed at all. Appellant's Br., at 6, 8, 14-17. Plaintiff's failure to plead or prove any feasible alternative design for Redux makes clear that the "negligent design defect" claim in this case is nothing more than a repackaged claim for "negligent marketing" and/or "negligent failure to remove," *i.e.*, a claim that Wyeth should never have introduced Redux in the first place, even though it was FDA-approved, or that Wyeth should have withdrawn Redux from the market notwithstanding its FDA approval because there was no "alternative" that would make it safer. Plaintiff pursued these "negligent marketing" and "failure to recall" claims in both the trial court and Superior Court, and the panel correctly rejected them. 4 A.3d at 166-67.

Allowing *Lance* to stand would inevitably unleash a host of claims that, notwithstanding an FDA approval of a drug's risk-benefit profile as "safe and effective," its manufacturer was nevertheless "negligent" in placing and keeping the drug on the market. Such claims are the antithesis of deference, and are internally inconsistent with other portions of the panel's opinions in *Lance* and *Owens*. The Court should take review to address as a matter of first impression how a plaintiff could ever assert a "negligent design defect" claim in a prescription drug case consistent with Pennsylvania's policy of deference to the decisions of the FDA.

* * * *

There can be no doubt that the Superior Court took a momentous step in this case. The legal press correctly described this theory as "new" and "of first impression." *See* "Superior Court Recognizes New Pharma Cause of Action," *The Legal Intelligencer*," at 1 (Aug. 4, 2010).[6] In the same article Plaintiff's trial counsel labeled the Superior Court's decision "seminal" – precisely because "plaintiffs have a cognizable claim, irrespective of whether . . . the warning label was inadequate." *Id.* at 8.[7] Liability despite the presence of adequate prescription drug warnings would be, of course, a drastic departure from and radical expansion of this Court's decisions in *Incollingo*, *Baldino*, and *Hahn*.

This expansion could flood Pennsylvania courts with more prescription drug product liability claims, and subject the many Pennsylvania manufacturers of prescription drugs to liability even where there is no claim that the drug was improperly manufactured or that the accompanying warnings were inadequate in any way.

For this reason as well, the Superior Court's decision qualifies for this Court's review. It raises questions of first impression that are of substantial importance and in need of prompt and definitive resolution by the Court. *See* Supreme Court Internal Operating Procedures §5(A)(3). As a result of the Superior Court's unprecedented ruling, there are thousands of prescription drug plaintiffs with cases pending throughout Pennsylvania who may now seek to advance a "negligent design defect" claim that has never been recognized or examined by this Court.

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[6] Available at < http://www.law.com/jsp/pa/PubArticlePA.jsp?id=1202464224040 >. *See also* "Pfizer Appeals Court's Recognition of New Pharma Cause of Action," *The Legal Intelligencer* Available at < http://www.law.com/jsp/pa/PubArticlePA.jsp?id=1202470979976 > (Aug. 24, 2010).

[7] Quoting Tobias Millrood of Pogust, Braslow & Millrood. The Pogust Firm's website similarly "hail[s] the [Lance] opinion as an important victory that will expand" liability. http://www.druginjurylawyerblog.com/2010/08/pennsylvania_recognizes_neglig.html.

VI. CONCLUSION

For the reasons set forth above, Defendant-Petitioner Wyeth respectfully requests the Court to allow this appeal and to decide the important questions of prescription drug product liability that this case presents.

Respectfully submitted,

ROBERT C. HEIM, I.D. No. 15758
JUDY L. LEONE, I.D. No. 41165
WILL W. SACHSE, I.D. No. 84097

Dechert LLP
Cira Centre
2929 Arch Street
Philadelphia, PA 19104-2808
(215) 994-2570

Attorneys for Defendant-Petitioner

Dated: November 1, 2010

PROOF OF SERVICE

The undersigned hereby certifies that on this day I caused a true and correct copy of the foregoing Petition for Allowance of Appeal of Wyeth, f/k/a American Home Products Corporation to be served upon the following counsel via first-class mail:

Howard Jonathan Bashman, Esq.
2300 Computer Ave., Suite G 22
Willow Grove, PA 19090
(215) 830-1458
Attorney for Respondent Patsy Lance

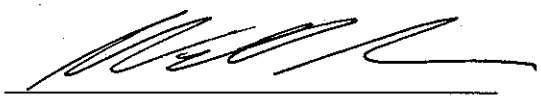
Tobias Lael Millrood
Pogust, Braslow & Millrood, L.L.C.
161 Washington St., Suite 1520
Conshohocken, PA 19428
(610) 941-4204
Attorney for Respondent Patsy Lance

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
Attorneys for Respondent Patsy Lance

Michael T. Scott, Esq.
Henry F. Reichner, Esq.
Barbara R. Binis, Esq.
Ira Steven Lefton, Esq.
Reed Smith, LLP
2500 One Liberty Place
1650 Market Street
Philadelphia, PA 19103-7301
(215) 851-8100
Attorneys for Respondent Wyeth

Raymond M. Williams, Esq.
DLA Piper LLP (US)
One Liberty Place
1650 Market Street – Suite 4900
Philadelphia, PA 19103
(215) 656-3368
Attorneys for Respondent Wyeth

November 1, 2010



WILL W. SACHSE, I.D. No. 84087
Dechert LLP
Cira Centre
2929 Arch Street
Philadelphia, PA 19104-2808
(215) 994-2570
Attorneys for Defendant-Petitioner Wyeth, f/k/a American Home Products Corporation