In The

Supreme Court of Pennsylvania

Nos. 17 EAP 2011; 18 EAP 2011

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

Plaintiff-Appellee/Cross-Appellant,

v.

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

Defendant-Appellant/Cross-Appellee,

BRIEF OF APPELLANT WYETH

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

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BRIEF OF APPELLANT WYETH, f/k/a AMERICAN HOME PRODUCTS CORPORATION

I. STATEMENT OF JURISDICTION

This Court has jurisdiction pursuant to 42 Pa. C.S. § 724(a):

> Except as provided by section 9781(f) (relating to limitation on additional appellate review), final orders of the Superior Court . . . may be reviewed by the Supreme Court upon allowance of appeal by any two justices of the Supreme Court upon petition of any party to the matter. If the petition shall be granted, the Supreme Court shall have jurisdiction to review the order in the manner provided by section 5105(d) (relating to scope of appeal).

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. STATEMENT OF SCOPE AND STANDARD OF REVIEW

This case presents pure questions of law. Questions of law are subject to *de novo* review, and the Court's scope of review is plenary. *See Philomeno & Salamone v. Bd. of Suppliers of Upper Merion Twp.*, 600 Pa. 407, 411, 966 A.2d 1109, 1111 (2009).

IV. STATEMENT OF THE QUESTIONS INVOLVED

1. Whether the Superior Court erred in creating a new claim for "negligent design defect" of a prescription drug, despite Plaintiff-Appellee Patsy Lance's repeated waiver of that claim?

Suggested Answer: The Superior Court erred in considering a claim that Plaintiff repeatedly waived.

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?

Suggested Answer: The Superior Court erred in creating a new cause of action for "negligent design defect" in a case involving prescription drug product liability.

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?

Suggested Answer: The Superior Court erred in creating a new cause of action for "negligent design defect" of a prescription drug, because the claim ignores the Pennsylvania requirement that plaintiffs plead and prove a feasible alternative design, and fails to appropriately defer to the FDA, as the authority with regulatory oversight concerning prescription drugs.

V. STATEMENT OF THE CASE

A. Background

This is a prescription drug negligence case involving the diet drug Redux, which was approved by the FDA and sold by Appellant Wyeth, Inc. ("Wyeth"). This Court has long recognized that prescription drugs are unlike any other products, and that their unique nature has resulted in the application of different legal standards than those applied to other products. In that regard, Pennsylvania has repeatedly made clear that negligent failure to warn is the only available liability theory against a seller of a properly manufactured prescription drug. Pennsylvania, like many other states, follows Comment k of §402A of the Restatement (Second) of Torts, and recognizes all prescription drugs as "unavoidably unsafe." Thus, Pennsylvania does not recognize strict liability design defect claims against prescription drug manufacturers. Similarly, before the Superior Court's opinion here, Pennsylvania courts had never recognized "negligent design defect" claims against prescription drug manufacturers. Pennsylvania's treatment of prescription drugs as "unavoidably unsafe" is inconsistent with any claim for strict liability or "negligent design defect," because the risks associated with prescription drugs are unavoidable. The concept of feasible alternative design, an essential proof in a negligent design defect claim involving an ordinary product, is simply unworkable in a prescription drug case. A prescription drug is not like a lighter or SUV that could be made safer by adding a safety feature while at the same time remaining the same product. A redesign of a prescription drug would result in a completely different compound with different properties and its own unique benefits and risks – *i.e.*, a totally new product. Moreover, the FDA requires each prescription drug to undergo rigorous review and testing before it can be approved as "safe and effective" and prescribed by doctors. Given this lengthy regulatory process, it is very difficult to predict if or when a particular drug will even be approved. Therefore, the feasibility of any purported

"alternative design" would be speculation unless and until it was actually approved by the FDA. It is against this backdrop that this case must be examined.

B. Procedural History

Plaintiff-Appellee Patsy Lance ("Plaintiff") claimed her daughter, Catherine Ruth Lance, died from primary pulmonary hypertension ("PPH") after taking the diet drug Redux (dexfenfluramine), a prescription medication sold by Wyeth.

Plaintiff did *not* claim that Wyeth negligently failed to warn of the risks associated with Redux, but instead that Wyeth was negligent in: (1) unreasonably marketing the drug; and (2) unreasonable "failure to remove" the drug from the market. These claims were properly dismissed by the trial judge, and their dismissal was affirmed by the Superior Court. However, the Superior Court reversed the grant of summary judgment based on a theory of "negligent design defect" that was *never* presented to the lower court.

The FDA approved Redux 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, when new, preliminary information emerged concerning the risk of valvular heart disease (VHD), which is unrelated to PPH. (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 drug carried a conspicuous, FDA-approved warning about the risks of PPH potentially associated with Redux, and the FDA viewed Redux as "safe and effective." (R. 82-95a). 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. 94-95a, 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 described Plaintiff's negligence claim as "Unreasonable Marketing of a Dangerous Drug and Unreasonable Failure to Remove the Drug from the Market before January 1997." Thus Plaintiff asserted only two negligence claims: (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 negligence-based design claim, as would be expected, because it was not an issue before the court. *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 denied*, No. 459 EAL 2010 (April 18, 2011); and *Owens v. Wyeth*, No. 185 EDA 2009, 2010 WL

2965014 (Pa. Super. Ct. July 26, 2010) (unpublished opinion), *pet. for allocatur reserved*, No. 572 EAL 2010 (April 11, 2011). 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. The panel crafted this claim by reference to a general negligence paragraph of the standard "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. In so ruling, the Superior Court addressed an issue that Plaintiff waived on at least three separate occasions: (1) in Plaintiff's trial court briefing in opposition to Wyeth's motion for summary judgment; (2) in Plaintiff's Pa. R.A.P. 1925(b) statement of issues, which did not mention any "negligent design defect" theory; and (3) in Plaintiff's Pa. R.A.P. 2116 Statement of Questions Presented to the Superior Court. The Superior Court not only created a claim that was never asserted, but it also decided that the claim existed by reliance on two inapposite non-Pennsylvania cases, and on Restatement (Second) of Torts § 395 (1965) – none of which was discussed or cited in the parties' briefing.

[1] The court also correctly rejected any purported independent claim for negligent failure to test. *Id.* at 168-69.

Because neither party had briefed and argued 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 timely sought this Court's review of the Superior Court's decision to create a new cause of action for "negligent design defect" in prescription drug product liability cases. Plaintiff cross-appealed, seeking review of the Superior Court's order affirming summary judgment on Plaintiff's "unreasonable marketing" and "failure to remove" claims. This Court accepted the Cross-Petitions for review on March 15, 2011, deeming Wyeth the Appellant.

VI. SUMMARY OF ARGUMENT

The Superior Court committed multiple reversible errors when it took the unprecedented step of *sua sponte* creating a new cause of action for "negligent design defect" of a prescription drug. The Superior Court crafted a new cause of action with no record and minimal argument.

Procedurally, Plaintiff's case should fail and the Superior Court erred because Plaintiff repeatedly waived any design defect claim in both the trial court and the Superior Court. The Superior Court's decision should be reversed on this ground alone because it violated Pennsylvania's carefully defined limits on the proper scope of appellate review and based its decision on a ground that was not advanced by the parties.

On the merits, the Superior Court's new "negligent design defect" claim for prescription drugs is a radical departure from existing Pennsylvania prescription drug jurisprudence, for a number of reasons:

(1) The decision conflicts with this Court's settled precedent limiting the claims that may properly be brought against prescription drug sellers. In *Incollingo v. Ewing*, 444 Pa. 263, 287-

88, 282 A.2d 206, 219-20 (1971),[2] *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 confirmed that negligent failure to warn is the only available liability theory against a seller of a properly manufactured drug. No other 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.

(2) The decision conflicts with this Court's careful balance of the policy considerations implicated by prescription drug tort claims. This Court has established a tort regime that attempts to balance the need for compensating injured plaintiffs against the need to ensure the public continued access to affordable and beneficial prescription drugs. The Court has struck this balance by appropriately focusing the inquiry on whether the risk information conveyed to prescribing physicians was sufficient to permit them to conduct an individualized risk-benefit analysis and determine the appropriate course of treatment for a particular patient. The Superior Court has upset this balance, by allowing injured plaintiffs to pursue claims that an FDA-approved prescription drug was "defectively designed" and thus should not have been approved by the FDA or prescribed by physicians to their patients. In effect, this threatens to turn prescription drug manufacturers into insurers for their products, and specifically upsets the liability limitations set forth in Comment k of Restatement (Second) of Torts and adopted by this Court.

(3) The decision rests on two inapplicable and distinguishable cases from other jurisdictions, and a Restatement (Second) of Torts provision that has never been adopted by this Court. This cannot withstand scrutiny, and as a result, the Superior Court's new claim lacks principled underpinnings. The Superior Court's decision, if not reversed, would make

[2] *Overruled on other grounds*, *Kaczkowski v. Bolubasz*, 491 Pa. 561, 421 A.2d 1027 (1980).

Pennsylvania law depart from the law in the other jurisdictions that have adopted comment k with respect to all prescription drug cases. The overwhelming majority of those comment k states have not recognized prescription drug "negligent design defect" claims.

Finally, the Superior Court's expansion of Pennsylvania law also cannot be harmonized with Pennsylvania's general requirement that plaintiffs asserting negligent design defect claims plead and prove the existence of a feasible alternative design, and Pennsylvania law that gives deference to the FDA's considered judgments about the safety and efficacy of prescription medical products. Plaintiff's failure to put forth any feasible alternative design makes clear that her "negligent design defect" cause of action is nothing more than disguised claims that Redux should never have been approved by the FDA, or should have been withdrawn sooner than it was – claims that even the Superior Court recognized are not cognizable under Pennsylvania law. *Lance*, 4 A.3d at 166-67 ("Consistent with the practice of other courts, we defer to the federal regulatory scheme and the FDA's decision as to whether a drug should lawfully remain on the market.").

VII. ARGUMENT

A. PLAINTIFF REPEATEDLY WAIVED ANY CLAIM FOR "NEGLIGENT DESIGN DEFECT," AND THE SUPERIOR COURT ERRED BY CREATING A NEW CAUSE OF ACTION WITHOUT THE BENEFIT OF BRIEFING AND ARGUMENT.

As a threshold matter, the Superior Court's recognition of a new cause of action for "negligent design defect" should be reversed because Plaintiff waived any such claim, and thus the issue was not properly before the court. *See* Pa. R.A.P. 302 ("Issues not raised in the lower court are waived and cannot be raised for the first time on appeal."). Indeed, the abandonment of any "negligent design defect" claim was so unequivocal that the parties did not brief and argue the issue before the trial court or the Superior Court. Notwithstanding this repeated waiver, the Superior Court *sua sponte* delved into this issue and found that Plaintiff had a claim for

"negligent design defect," becoming the first court in this Commonwealth to recognize such a claim in a prescription drug case. This was clear error. *See Riedel v. Human Relations Comm'n*, 559 Pa. 34, 41, 739 A.2d 121, 125 (Pa. 1999) ("[W]e find that the Commonwealth Court improperly reversed the trial court's order on the basis of a waived issue that the court raised *sua sponte*."); *In re J.M.*, 556 Pa. 63, 83 n.15, 726 A.2d 1041, 1051 n.15 (Pa. 1999) (finding it "improper for the Superior Court to raise and decide the issue *sua sponte*" of whether appellee's due process rights were violated, where appellee failed to raise issue before trial court or Superior Court); *Arthur v. Kuchar*, 546 Pa. 12, 21, 682 A.2d 1250, 1254 (Pa. 1996) (concluding that "[i]ssues not preserved for appellate review may not be considered by an appellate court....[W]e cannot permit the Superior Court to raise issues *sua sponte*."); *see generally In re F.C. III*, 2 A.3d 1201, 1211–12 (Pa. 2010) ("Issue preservation is foundational to proper appellate review.").

Here, the Superior Court erred at the outset in considering a "negligent design defect" claim that Plaintiff had waived on three separate occasions. She did so in her Opposition to summary judgment before the trial court; again in her Rule 1925(b) Statement; and finally in her Statement of Questions Presented to the Superior Court. Indeed, Plaintiff consistently presented her negligence claims as being for negligent marketing and negligent failure to withdraw – not "negligent design defect." She described them that way in her "Short Form" Complaint and in her subsequent papers, and argued to both the trial court and the Superior Court that the "claims against Wyeth are for negligently marketing Redux and for negligently failing to remove Redux from the market." (R. 125a).[3] Plaintiff never identified any additional stand-alone claim for

[3] *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. 134-35a) (summarizing arguments in support of

"negligent design defect." Nor did Plaintiff explain to the trial court why such a novel claim was cognizable. It was not until *after* the Superior Court created the "negligent design defect" claim for Plaintiff that she belatedly sought to rely on it.

1. Plaintiff Waived Any "Negligent Design Defect" Claim By Failing To Specifically Identify It As An Asserted And Cognizable Claim When Opposing Wyeth's Summary Judgment Motion.

This Court has consistently recognized that grounds "not raised initially before the trial court in opposition to summary judgment cannot be raised for the first time on appeal." *Krentz v. Consolidated Rail Corp.*, 589 Pa. 576, 604, 910 A.2d 20, 37 (2006); *see also Kimmel v. Somerset Cty. Comm'rs*, 460 Pa. 381, 384, 333 A.2d 777, 779 (1975) ("It is a fundamental principle of appellate review that we will not reverse a judgment or decree on a theory that was not presented to the trial court."). Plaintiff never offered any substantive briefing or argument in the trial court concerning a "negligent design defect" claim. But Plaintiff now insists she "expressly noted" that claim to the trial court, simply because she "made clear" that she was incorporating the master "Long Form" Complaint used by Diet Drug plaintiffs. Respondent's Answer In Opposition To Wyeth's Petition For Allowance Of Appeal, at 8 (citing (R. 134-135a)). As described above, however, her "Short Form" Complaint clarified that she was asserting only negligent marketing and negligent failure to remove claims. (R. 18a). Furthermore, the word "design" appeared only once in Plaintiff's Opposition to Summary Judgment, as part of the recitation of the vague allegations contained in the Long Form

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"Plaintiff's claims of negligent marketing of Redux and negligent failure to withdraw Redux from the market"); (R. 139a) ("Plaintiff has cognizable claims against Wyeth for negligent marketing of Redux and for negligent failure to withdraw Redux from the market"). In fact, Plaintiff identified the precise scope of her negligence claims in the Opposition's core argument heading: "Plaintiff has cognizable claims for negligent marketing and negligent failure to withdraw from market, without making a claim for failure to warn." (R. 129a). This heading is consistent with how she clarified the negligence claims in her "Short Form" Complaint. (R. 18a).

Complaint. *See* (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). Plaintiff wrongly claims this language is sufficient to establish that "a design defect claim has been asserted by each and every plaintiff in the Fen-Phen mass tort proceedings." Respondent's Answer In Opposition To Wyeth's Petition For Allowance Of Appeal, at 7. But as this Court said in *Commonwealth v. Shaw*, where appellant's papers "fail[] to elaborate upon [a] mere assertion, this claim has been waived." 494 Pa. 364, 370 n.3, 431 A.2d 897, 900 n.3 (1981).

It is also notable that Judge Allan Tereshko, in his opinion granting summary judgment and dismissing Plaintiff's claims in their entirety, never mentioned "negligent design defect." *See Lance v. Wyeth, Inc.*, Nov. Term 2006, No. 0926, 2010 WL 497387 (Pa. Com. Pl. Jan. 7, 2010) (Appendix A). Of course, this is because Plaintiff never told the trial court that she was pursuing a "negligent design defect" claim. Rather, time and again, Plaintiff explained the limited basis of her negligence claims: unreasonable marketing and failure to remove Redux from the market. Plaintiff thus waived any "negligent design defect" claim by failing to specifically identify it or otherwise argue for its viability to the trial court.

2. Plaintiff Waived Any "Negligent Design Defect" Claim By Failing To Specifically Raise Its Dismissal As A Claimed Error In Her Rule 1925(b) Statement.

Plaintiff's Rule 1925(b) Statement further waived any "negligent design defect" claim. The Statement neither mentioned "design" nor identified 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 (R. 578-81a). Rather, Plaintiff once again made clear the limited scope of her negligence claims, contending 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.* (R. 579a ¶1). Under this Court's "bright-line rule," Plaintiff waived any "negligent design defect" claim by failing even to specifically 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, 22, 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.").

3. Plaintiff Waived Any "Negligent Design Defect" Claim By Failing To Specifically Raise Its Dismissal As A Claimed Error In Her Statement Of Questions Presented To The Superior Court.

Pa. R.A.P. 2116 required Plaintiff to identify any claimed error concerning 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." (R. 588a). And again, there was no specific mention of error relating to any "negligent design defect" claim. The failure to raise any claimed error with respect to this purported claim constitutes a third independent instance of 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*, 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).

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Any of these waivers, standing alone, was sufficient to bar the Superior Court from considering a "negligent design defect" claim. Instead, the Superior Court took the extraordinary step of creating a new cause of action, and did so without the benefit of briefing and argument from the parties. Although Plaintiff now claims "negligent design defect" has been a part of this case from the outset, she can point to nothing more than a few passing mentions of the word "design." Nor can Plaintiff identify a single instance where she specifically argued that the trial court erred by dismissing a purported "negligent design defect" claim as such. Put simply, this claim was not before either the trial court or the Superior Court, and thus the Superior Court erred by adjudicating a waived issue. This Court should 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. And if the Court finds that Plaintiff waived any "negligent design defect" claim, the Court need not even address the merits.

B. 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.

1. Settled Pennsylvania Law Recognizes Failure To Warn And Manufacturing Defect As The Only Cognizable Claims Against The Manufacturers Of Prescription Drugs.

On three separate occasions over the past forty years, this Court has recognized negligent failure to warn as the "only" cognizable claim against a seller of a properly manufactured drug. *Hahn*, 543 Pa. 558, 673 A.2d 888; *Baldino*, 505 Pa. 239, 478 A.2d 807; *Incollingo*, 444 Pa. 263, 282 A.2d 206. This is because the Court has adopted Restatement (Second) of Torts § 402A, comment k (1965), deciding that all prescription drugs are "unavoidably unsafe," and thus "quite incapable of being made safe for their intended and ordinary use." *Hahn*, 543 Pa. at 561, 673 A.2d at 890 (quoting comment k). The adoption of comment k: (1) barred strict liability claims

against prescription drug manufacturers; (2) left no room for design defect claims of any kind, whether "strict liability" or "negligence;" and (3) signaled a clear policy decision that prescription drugs are different from ordinary products.

As a result, this Court has never expressly nor impliedly held that a plaintiff may pursue a "negligent design defect" claim against a prescription drug manufacturer, and to do so is at odds with this Court's consistent application of the "unavoidably unsafe" rationale of comment k. Moreover, prior to the panel's decision in this case, the Superior Court had never recognized a "negligent design defect" claim against a prescription drug manufacturer. The Superior Court's "negligent design defect" cause of action thus conflicts with the well-settled prescription drug tort framework established by this Court, and heretofore respected by every other court in this Commonwealth. It represents a significant expansion of potential liability, and a departure from the settled principles that have been Pennsylvania law for nearly forty years.

In *Incollingo*, this Court disapproved of strict liability claims against prescription drug manufacturers and left no room for design-related claims against an FDA-approved and properly labeled drug. Rather, the question in prescription drug cases is "whether the warning that was given to the prescribing doctors was proper and adequate." 444 Pa. at 288, 282 A.2d at 220. The Court relied upon the comments to Restatement § 402A, including comment k:

> The Restatement reaches the same conclusion as to a product which is incapable of being made safe for its intended use, such as new or experimental drugs. . . . "The seller of such products," concludes this comment (comment k), "again with the qualification that they are properly prepared and marketed and proper warning is given . . . 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."

Incollingo, 444 Pa. at 287-88, 282 A.2d at 219-20 (quoting comment k).

The *Incollingo* Court recognized that warning claims may be successful in two instances: where a prescription drug manufacturer provides inadequate warnings; or where otherwise

adequate warnings are "canceled out" or rendered "meaningless" by subsequent affirmative promotional activity. 444 Pa. at 288-89, 282 A.2d at 220. *Incollingo* thus delineated the scope of a prescription drug manufacturer's liability; this delineation reflected a careful balancing, taking into account the unique nature of prescription drugs, while at the same time providing prescription drug plaintiffs with more limited remedies, as recognized by the Restatement. At the same time, *Incollingo* did not expand prescription drug manufacturer liability beyond the boundaries of negligent failure to warn. In particular, the Court did not recognize any theory of liability based on "design defect" theories – whether grounded in strict liability or negligence.

In *Baldino*, the Court revisited *Incollingo*, again rejecting strict liability claims, and again relying on comment k:

> Where warning is given . . . a product bearing such a warning, which is safe for use if it is followed, is not in defective condition nor is it unreasonably dangerous. . . . [T]he Restatement reaches the same conclusion as to drugs which serve a useful purpose notwithstanding a medically recognizable risk.

505 Pa. at 247, 478 A.2d at 811-12 (following Restatement §402A, comments j-k). The Court reiterated that failure to warn is the only allowable claim against a seller 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). Again, the Court neither recognized a design defect claim, nor any other claim inconsistent with the principle that prescription drugs are "unavoidably unsafe."

Finally, in *Hahn v. Richter*, the Court reaffirmed both the applicability of Restatement § 402A, comment k to all prescription drugs, and the limited scope of liability in prescription drug cases, which was originally established by *Incollingo* and *Baldino*. 543 Pa. at 562, 673 A.2d at 890-91; *see also id.* at 563, 673 A.2d at 891 (rejecting strict liability in prescription drug cases).

Hahn did not expand the permitted theories of liability set out in *Incollingo* and *Baldino*, but rather reinforced them. *Id.* at 563, 673 A.2d at 891 ("*Incollingo* and *Baldino*, as well as comments j and k, make it clear that where the adequacy of warnings associated with prescription drugs is at issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, i.e., the manufacturer's negligence, is the only recognized basis of liability."). Nor did *Hahn* suggest that Pennsylvania would recognize a "negligent design defect" claim despite adequate warnings accompanying the prescription drug at issue. *See also Coyle v. Richardson-Merrell, Inc.*, 526 Pa. 208, 212-13, 584 A.2d 1383, 1385 (1991) (recognizing applicability of comment k exception in prescription drug case).

The Court's precedent establishes the contours of permissible claims against prescription drug manufacturers under Pennsylvania law. The Superior Court, in reliance on this Court's guidance, had previously consistently acknowledged the limited scope of permissible negligence claims in prescription drug cases. *Cochran v. Wyeth, Inc.*, 3 A.3d at 676-77 ("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"); *Lineberger v. Wyeth*, 894 A.2d 141, 150 (Pa. Super. Ct. 2006) (same); *Brecher v. Cutler*, 396 Pa. Super. 211, 219, 578 A.2d 481, 485 (1990) (same); *White v. Weiner*, 386 Pa. Super 111, 123, 562 A.2d 378, 384 (1989) (same), *aff'd per curiam*, 525 Pa. 572, 583 A.2d 789 (1991); *Leibowitz v. Ortho Pharm. 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) ("[T]he 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.").[4]

In sum, until the panel's decision in this case, Pennsylvania law had been consistent as to the permitted claims against prescription drug manufacturers. For forty years courts in this Commonwealth, whether expressly or by implication, have limited prescription drug claims to one of two theories of liability: (1) failure to warn, the core theory in virtually every prescription drug case; or (2) manufacturing defect. In the face of this history, Plaintiff argues that an amorphous "negligent design defect" claim has somehow survived, unnoticed, at the fringe of prescription drug litigation and has thus avoided appellate review by any court of this Commonwealth until now. *See* Respondent's Answer In Opp. To Wyeth's Pet. For Allowance of Appeal, at 11-14.

That argument is belied by the entire history of prescription drug litigation in Pennsylvania – a history notable for inadequate warning claims in prescription drug cases, and devoid of any "negligent design defect" cases. In fact, neither Plaintiff nor the *Lance* panel identified a single Pennsylvania state court decision that recognized – or even discussed – a "negligent design defect" claim against a prescription drug manufacturer. *Lance* departed from the consistent precedent of this Court and the Superior Court, and in the process disregarded Pennsylvania law recognizing that prescription drugs are different from ordinary products, which makes design defect claims inappropriate. The Superior Court's decision to recognize a "negligent design defect" claim should thus be overturned. *See Moses v. T.N.T. Red Star*

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[4] In *Aaron*, the district court properly acknowledged the limited scope of permissible negligence claims against prescription drug manufacturers under Pennsylvania law, and also concluded that the plaintiff abandoned his purported claim for design defect. The court further noted in *dicta* that even if a "design defect" claim were otherwise allowed, it would also fail because the plaintiff did not plead or prove a feasible alternative design. *Aaron*, 2010 WL 653984, at *11. The same is true here. *See infra* Section C.1.

Express, 725 A.2d 792, 801 (Pa. Super. Ct. 1999) ("It 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") (quoted in *Lance*, 4 A.3d at 169); *see also Foflygen v. Zemel*, 420 Pa. Super. 18, 34, 615 A.2d 1345, 1353 (Pa. Super. Ct. 1992) (refusing to recognize negligence-based "informed consent" cause of action because "this Court is obligated to follow the precedent set down by our Supreme Court."). But the panel's ground-breaking opinion is flawed for additional reasons, to which Wyeth now turns. The panel not only undermined the policy judgments undergirding this Court's prescription drug jurisprudence, but it also relied on inapplicable, non-binding precedent that does not provide a reasoned basis for creating a new cause of action and potentially dramatically expanding the scope of prescription drug litigation in Pennsylvania.

2. The Limitation On Allowable Claims Against Prescription Drug Manufacturers Represents A Sound Policy Judgment By This Court That Should Not Be Disturbed.

In *Incollingo*, *Baldino*, and *Hahn,* this Court struck an appropriate balance between the need to compensate injured plaintiffs and the need to limit liability against prescription drug manufacturers, who provide socially valuable medicine for the public's benefit. This Court has uniformly held that prescription drugs, as a class, are "unavoidably unsafe" under Restatement § 402A, comment k, because they are not without unavoidable "medical risks." *Hahn*, 543 Pa. at 560, 673 A.2d at 889-90; *see also Incollingo*, 444 Pa. at 287, 282 A.2d at 219 (recognizing that comment k applies to a product that is "incapable of being made safe for its intended use"). Put simply, prescription drugs are different from other products. Indeed, as FDA informs consumers, "[a]ll medicines have benefits and risks."[5]

[5] http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm196029.htm.

Because the risks that all prescription drugs carry are "unavoidably unsafe" attributes, a patient must obtain a prescription from a doctor – who weighs the benefits and risks for the particular patient – before gaining access to the medicine. In essence, by recognizing prescription drugs as "unavoidably unsafe" and therefore exempted from strict liability, this Court made a policy determination arising out of the fact that all prescription drugs require complicated risk-benefit determinations that should be made on a patient-by-patient basis in consultation with a "learned intermediary" – the prescribing physician. *See, e.g.*, *Coyle*, 526 Pa. at 216, 584 A.2d at 1387 (prescription drug is "product whose distribution is limited precisely because its benefits and risks are to be assessed only by licensed physicians acting on behalf of particular patients whose individual physical condition and circumstances are known to them"); *see also Makripodis v. Merrell-Dow Pharms., Inc.*, 361 Pa. Super. 589, 594, 523 A.2d 374, 376-77 (1987) ("[S]uch drugs are not available to the public but may be obtained only upon the prescription of a licensed physician. This restriction upon the availability of such drugs has been imposed because of the inherently dangerous properties of such drugs."). This individualized decision-making process is, and should be, at the heart of prescription drug product liability cases decided under Pennsylvania law. Assuming the drug is properly manufactured, Pennsylvania courts, applying a negligence standard, only impose liability when a manufacturer improperly alters that risk-benefit analysis – either by providing inadequate warnings or by affirmatively "nullifying" otherwise adequate warnings.

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." *Hahn*, 543 Pa. at 560 n.2, 673 A.2d at 890 n.2 (quoting comment k) (emphasis in original). Comment k's "unavoidably unsafe" concept is inherently incompatible with the notion of a design defect, because the theoretical basis of a design defect claim is that a product is

avoidably unsafe. This is equally true whether the prescription drug plaintiff pursues a design claim in strict liability or negligence, as the core questions in either type of claim would be the same: whether the product was "unreasonably dangerous" as designed, and whether there existed a feasible alternative design.

A "negligent design defect" claim also implicates broader, longstanding policies favoring access to beneficial medicines and guarding against unduly deterring prescription drug manufacturers from developing and marketing beneficial new drugs. Even before *Incollingo*, this Court recognized the importance of preserving a balance between the interest in holding prescription drug manufacturers to a "high degree of responsibility" against the public interest in ensuring that those same manufacturers continue to develop and sell beneficial drugs. *See Henderson v. National Drug Co.*, 343 Pa. 601, 610, 23 A.2d 743, 748 (1942) (finding that "the making and selling" of prescription drugs "would be a most peculiarly hazardous enterprise" if liability attached any time a drug caused "harmful results"). *Incollingo*, when citing *Henderson* with approval, recognized this balance. Expanding liability now to permit an amorphous "negligent design defect" claim would upset the balance this Court has struck between allocating responsibility for injury and safeguarding development of valuable pharmaceutical products.

In fact, because prescription drugs are, as this Court has repeatedly recognized, "unavoidably unsafe," imposition of design-based liability amounts to absolute liability, since a drug's FDA-approved design cannot be changed to eliminate an unavoidable risk. This Court has never approved categorical liability in any circumstance, let alone against potentially life-saving products such as prescription drugs. *See, e.g., Schmidt v. Boardman Co.*, ___ Pa. ___, 11 A.3d 924, 939 n.14 (Pa. 2011) ("design" claims present "a particular problem" because of the "risk of creating an absolute liability regime"); *Coyle*, 526 Pa. at 217, 584 A.2d at 1387 (finding "[r]eliance on cost-shifting as the only factor to be considered" was insufficient to support

liability because it "would result in absolute liability rather than strict liability"); *Estate of Witthoeft v. Kiskaddon*, 557 Pa. 340, 353, 733 A.2d 623, 630 (1999) ("we will not countenance" tort theories that make defendants "absolutely liable").

Allowing recovery under a "negligent design defect" theory could disrupt the development and distribution of new drugs, which would affect the public's access to beneficial medicine. This is contrary to the policies underlying *Henderson* and *Incollingo*, and undermines the Court's judgment that prescription drug manufacturers cannot be "insurers" or "guarantors" of safety given that their products are "unavoidably unsafe." *See Hahn*, 543 Pa. at 562, 673 A.2d at 890-91; *Leibowitz*, 224 Pa. Super. at 433, 307 A.2d at 458 (rejecting expansion of tort liability against prescription drug manufacturer, because expansion would "fatally choke the industry in its marketing and development procedures," and a manufacturer "would virtually become an insurer against all possible consequences"); s*ee also White v. Weiner*, 386 Pa. Super. 111, 123-24, 562 A.2d 378, 385 (1989) (rejecting expansion of tort liability against prescription drug manufacturer, and noting, "[i]t is illusory to believe that the public does not pay for tort recoveries, or that resources for such are limitless. As it is with everything, a balance must be struck – certain limits drawn") (quoting Pennsylvania Supreme Court concurrence), *aff'd per curiam* 525 Pa. 572, 583 A.2d 789 (1991).

Finally, courts and litigants have relied on the guidance of *Hahn* and its predecessors for years. As a result, the overwhelming majority of prescription drug cases in Pennsylvania involve allegations of failure to warn, with numerous trial court and appellate decisions developing the law in that area over the past forty years. By contrast, there has been no prescription drug design defect claim litigated in the Pennsylvania appellate courts. Allowing such a novel claim now could not only dramatically alter the landscape of prescription drug litigation in this Commonwealth, but it could also risk importing into the prescription drug arena the difficulties

that have plagued strict liability and negligent design defect claims generally. *See, e.g., Schmidt*, 11 A.3d at 940 (noting "material ambiguities and inconsistencies" in Pennsylvania design defect jurisprudence).

3. The Superior Court Misapplied Settled Precedent And Instead Crafted A New Cause Of Action By Relying On Inapplicable, Non-Binding, And Unpersuasive Sources.

The panel's decision was also error because it based its new cause of action on an inapplicable section of the Restatement (Second) of Torts and two inapposite out-of-state cases. Thus, the analytical underpinnings of any new "negligent design defect" cause of action are without proper basis, and cannot withstand scrutiny.

Restatement (Second) of Torts §395 (1965) is the cornerstone of the panel's decision. This Court has neither cited nor adopted § 395. Rather, this Court has consistently looked solely to Restatement §§ 388 and 402A to determine the appropriate scope of prescription drug product liability. Without guidance from this Court, or briefing from the parties, the panel misinterpreted § 395 to allow design defect claims, when in reality the section applies to "Negligent *Manufacture* of Chattel Dangerous Unless Carefully Made," not negligent *design defect*. Nor does the plain text of § 395 support a design defect claim:

> A manufacturer who fails to exercise reasonable care in the *manufacture* of a chattel which, unless carefully made, he should recognize as involving an unreasonable risk of causing physical harm . . . is subject to liability for physical harm caused to [users] by its lawful use in a manner and for a purpose for which it is supplied.
>
> Restatement (Second) of Torts § 395 (1965) (emphasis added).

Notwithstanding the facial inapplicability of this section, the Superior Court erroneously concluded that § 395 "addresses a manufacturer's negligent design of products." *Lance*, 4 A. 3d at 166. The Superior Court cited no cases from Pennsylvania or elsewhere applying § 395 to

support such a claim in a prescription drug case, *id.*, and instead simply cited comment f, which again confirms that § 395 applies to negligent manufacture, not design:

> f. *Particulars which require care.* A manufacturer is required to exercise *reasonable care in manufacturing* any article which, if *carelessly manufactured*, is likely to cause harm to those who use it in the manner for which it is manufactured. The particulars in which reasonable care is usually necessary for protection of those whose safety depends upon the character of chattels are (1) the adoption of a formula or plan which, if properly followed, will produce an article safe for the use for which it is sold, (2) the selection of material and parts to be incorporated in the finished article, (3) the fabrication of the article by every member of the operative staff no matter how high or low his position, (4) the making of such inspections and tests during the course of manufacture and after the article is completed as the manufacturer should recognize as reasonably necessary to secure the production of a safe article, and (5) the packing of the article so as to be safe for those who must be expected to unpack it.

(Emphases added). The Superior Court again failed to identify a single case, in Pennsylvania or elsewhere, applying this comment to allow for design defect claims in a prescription drug case – not surprising, since the comment, like the entire Restatement section, applies to negligent manufacturing claims. *See Lance*, 4 A. 3d at 166; *see also Sykes v. Bayer Pharms. Corp.*, 548 F. Supp. 2d 208, 215 and n.5 (E.D. Va. 2008) (citing § 395 as support for potential manufacturing-defect claim in prescription drug case). A negligent manufacturing claim is distinct from a negligent design claim. A product is negligently manufactured when it departs from its intended design, whereas a product is negligently designed when its intended design is unreasonably dangerous in the first instance. *Stecher v. Ford Motor Co.*, 779 A.2d 491, 502 (Pa. Super. Ct. 2001) ("Liability for manufacturing defects involves discrepancies between the nature and quality of a product intended by the manufacturer and the product as produced, where liability for design defects involves discrepancies between the design of a product causing injury and an alternative specification that would have avoided the injury."), *rev'd on other grounds*, 571 Pa. 312, 812 A.2d 553 (2002).

At most, the comment suggests that reasonable care may require the adoption of a "formula or plan" for *manufacturing* that, "if followed," will produce a safe product. In other words, the focus is on the execution of a plan through the manufacturing process, not the design of the product in the first instance. Finally, as a factual matter Plaintiff does not allege that Wyeth failed to follow any "formula or plan" for manufacturing Redux. The Superior Court's reliance on § 395 was therefore misplaced.

The panel's reliance on two non-Pennsylvania cases is similarly misguided. The older case, *Toner v. Lederle Laboratories*, 732 P.2d 297 (Idaho 1987), involved design defect claims against a vaccine manufacturer. That *Toner* involved vaccines is significant for two reasons. First, *Toner* is of questionable precedential value after the United States Supreme Court's ruling that the National Childhood Vaccine Injury Act preempts all negligent design claims in putative vaccine cases. *See generally Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068, 1075, 1082 (2011). Second, as a factual matter, the plaintiff in *Toner*, unlike Plaintiff here, had alleged the existence of a feasible alternative design. *Toner*, 732 P.2d at 300 (discussing defendant's use of killed "whole-cell" rather than "fractionated cell" pertussis bacteria in the vaccine). *Toner* is distinguishable for another reason as well – Idaho, unlike Pennsylvania, has not adopted comment k in all prescription drug cases. Rather, Idaho applies comment k on a case-by-case basis, allowing every court and every jury to reassess the risk-benefit calculation that led to a drug's approval. *Toner*, 732 P.2d at 305, 309. Thus, unlike Pennsylvania, Idaho has not determined that all prescription drugs are "unavoidably unsafe," and an Idaho court could allow strict liability claims if comment k were found inapplicable in a particular case.

The Superior Court's reliance on an intermediate appellate court decision from California is even further afield. *Artiglio v. Superior Court*, 27 Cal. Rptr. 2d 589 (Cal. App. 1994), held only that *strict liability* design defect claims are not available against *medical device*

manufacturers. *Id.* at 593. The Superior Court lifted from *Artiglio* a single sentence of *dictum* that, if there could be design liability, it "would require proof of negligence." 27 Cal. Rptr. 2d at 591. There is no subsequent published California appellate decision, however, adopting this *dictum* and recognizing a negligent design defect claim in a prescription drug case. *Cf. In re Coordinated Latex Glove Litig.*, 99 Cal. App. 4th 594, 609 (Cal. Ct. App. 2002) (quoting *Artiglio*).

The failure of the Superior Court to find any meaningful guidance from other jurisdictions is unsurprising, for most states have not recognized a "negligent design defect" claim in the prescription drug context. In fact:

> [A] majority of American jurisdictions recognize that special problems attend design defect litigation with respect to prescription drugs. Different drugs provide benefits to various subgroups of patients. It is normally the decision of the prescribing physician, who has received adequate warnings of the drug's benefits and detriments, whether or not to prescribe the drug. Thus, the only basis on which courts traditionally have held drug manufacturers liable is unreasonable failure to warn of known or knowable risks.
>
> On occasion, however, drug designs are attacked as unsound on the ground that the harms they cause outweigh their overall benefit to society. A majority of courts have taken the position that drug design litigation is unwise, and that a drug manufacturer has a duty only to warn prescribing physicians of foreseeable risks.

James A. Henderson, Jr. & Aaron D. Twerski, *A Proposed Revision Of Section 402A Of The Restatement (Second) Of Torts*, 77 CORNELL L. REV. 1512, 1522-23 (1992); *see also* James A. Henderson, Jr. & Aaron D. Twerski, *Drug Designs Are Different*, 111 YALE LAW J. 151, 178 (2001) (hereafter "Drug Designs Are Different") ("[N]o matter what standard for defective drug design is employed, design-based liability plays a relatively minor role with regard to prescription products .... [F]ailure to warn is by far the more important basis of drug companies' exposures to liability."); AMERICAN LAW OF PRODS. LIAB. 3D, § 17:43 (2011) (noting "traditional refusal by courts to impose tort liability for defective designs of prescription drugs").

In sum, 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 therefore rests on a distinguishable and infirm foundation – and one that is inconsistent with this Court's precedent as well as the policies underlying those decisions. It would also be out of step with the overwhelming majority of those jurisdictions that categorically apply comment k to all prescription drugs. Accordingly, the Superior Court's decision should be reversed for this reason as well.

C. THE SUPERIOR COURT'S CREATION OF A NEW CAUSE OF ACTION FOR "NEGLIGENT DESIGN DEFECT" CANNOT BE HARMONIZED WITH: (1) EXISTING PENNSYLVANIA LAW REQUIRING DESIGN DEFECT PLAINTIFFS TO PLEAD AND PROVE A FEASIBLE ALTERNATIVE DESIGN; AND (2) THE PENNSYLVANIA POLICY OF DEFERENCE TO REGULATORY AUTHORITIES.

The Superior Court's decision in *Lance* is inconsistent with all prior Pennsylvania cases addressing prescription drug product liability. As discussed above, 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 principle represents a forty-year policy judgment by this Court that prescription drugs, as a category, are "unavoidably unsafe." The Superior Court's decision is unsettling because it ignored that guiding principle. It instead created a novel, ill-defined cause of action that is out of step with prescription drug jurisprudence in Pennsylvania, and that should therefore be reversed.

The Superior Court's decision is also alarming because, if left undisturbed, courts throughout this Commonwealth will be faced with the challenge of attempting to harmonize the novel cause of action with existing Pennsylvania jurisprudence regarding negligent design defect

claims generally. The history of negligent design defect – in particular the requirement that plaintiffs plead and prove a feasible alternative design – is at odds with the special nature of prescription drugs, which are "unavoidably unsafe" products precisely because they cannot be redesigned without creating a wholly new product. Moreover, the Superior Court's decision is inconsistent with long-standing Pennsylvania policy affording deference to regulatory agencies such as the FDA. It is impossible to reconcile the Superior Court's new "negligent design defect" cause of action with these long-standing principles of Pennsylvania jurisprudence. These circumstances provide another set of compelling reasons to reverse the Superior Court's decision and restore the *status quo* of Pennsylvania prescription drug jurisprudence.

1. The Superior Court Failed To Consider How A Prescription Drug Plaintiff Could Ever Plead And Prove The Essential Element Of Feasible Alternative Design.

In crafting its new cause of action, the Superior Court ignored that Plaintiff neither pleaded nor ever offered evidence of an alternative design. (*See* R. 44a-47a) (Count I "Negligence"). Ordinary negligent design defect cases in Pennsylvania require proof that the harm caused by the product at issue could have been avoided by adding a feasible alternative design or safety feature. Feasible alternative design has therefore been considered an essential element of negligent design defect under Pennsylvania law. *See, e.g., Kosmack v. Jones*, 807 A.2d 927, 931 (Pa. Commw. Ct. 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); *see also Smith v. Yamaha Motor Corp.*, 5 A.3d 314, 322-23 (Pa. Super. Ct. 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").[6]

Plaintiff's failure to plead a feasible alternative design is not surprising, given the special nature of prescription drugs. What 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"). Because a prescription drug cannot have a safer alternative design without rendering it a new drug subject to new FDA review and approval, a prescription drug "negligent design defect" claim is incompatible with Pennsylvania's general requirement of proving feasible alternative design. This rigorous and lengthy FDA review process also means that any claim based on a hypothetical, unapproved "alternative" or allegedly "safer" product should not survive: "Given that a manufacturer cannot market a drug in the United States without FDA approval, for a court to find that an alternative drug should have been developed would require it to predict with confidence that the alternative drug would have actually been approved. No expert could honestly opine that approval would have been granted without engaging in rank speculation." Drug Designs Are Different, 111 YALE LAW J. at 167.

[6] This Court has never considered the question of feasible alternative design in a negligent design defect case, but has required that a plaintiff prove the existence of such an alternative design in strict liability actions. *See, e.g., Duchess v. Langston Corp.*, 564 Pa. 529, 559 n.24, 769 A.2d 1131, 1149 n.24 (2001) (finding evidence of feasible alternative design "is *an essential* element of the plaintiff's liability case predicated on a theory of design defect") (emphasis original). In *Duchess* the Court further observed that "design defect cases employ risk-utility balancing similar to that utilized in negligence." *Id.* at 547, 769 A.2d at 1141.

Commentators and courts have acknowledged the difficulties attendant to pleading and proving a feasible alternative design in the prescription drug context, which makes design defect claims impractical and unwarranted. As explained by Professors Henderson and Twerski, "[i]n cases involving drugs, the claim of defective design is much more difficult to sustain. Different drugs provide different benefits to patients. What may be beneficial to one group of patients may be less so for another, who may in turn benefit from a drug with a slightly different composition." *See* James A. Henderson, Jr. & Aaron D. Twerski, *A Proposed Revision Of Section 402A Of The Restatement (Second) Of Torts*, 77 CORNELL L. REV., at 1538; *accord* AMERICAN LAW OF PRODS. LIAB. 3D, § 17:43 (2011) ("The traditional refusal by courts to impose tort liability for defective designs of prescription drugs ... is based on the fact that a prescription drug ... entails a unique set of risks and benefits; what may be harmful to one patient may be beneficial to another.").

On those rare occasions when plaintiffs have pursued "negligent design defect" claims in a prescription drug case, the impossibility of proving feasible alternative design for pharmaceutical products has led to rejection of the claim:

> To alter the chemistry of the Triazolam molecule, would be to create a new compound and a new product. There does not exist a mixture of ingredients capable of alternative design and, consequently, plaintiff's claim of negligent design must, as a matter of law, be dismissed [because] Halcion is created from a single, active ingredient and only has one possible formulation. Furthermore, under these circumstances, plaintiff's defective design claim is actually a claim that Halcion should never have been designed or manufactured at all.

Sprague v. Upjohn Co., 1995 WL 376934, at *1-2 (D. Mass. May 10, 1994); *accord Brockert v. Wyeth Pharms., Inc.*, 287 S.W.3d 760, 771 (Tex. App. 2009) (dismissing negligent design claim and stating that, "[i]n essence, Brockert argues that the [medication] should have been a different product .... Texas law does not recognize this sort of categorical attack on a product"); *see also Godoy ex rel. Gramling v. E.I. du Pont de Nemours & Co.*, 768 N.W.2d 674, 685-86 (Wis. 2009)

("A claim for defective design cannot be maintained where . . . the alleged defect in design . . . is a characteristic of the product itself.").

Given the impossibility of proving a feasible alternative design, the Superior Court erred by recognizing a vague "negligent design defect" claim that is impractical, unworkable, and inconsistent with general design defect principles. This Court should therefore reverse, thereby recognizing, consistent with other courts, the fundamental incompatibility of "negligent design defect" claims in the prescription drug context.

2. The Superior Court Failed To Appropriately Defer To The FDA's Regulatory Authority Concerning Prescription Drugs.

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. *See, 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); *see also Joint Bargaining Comm. of the Pa. Soc. Services Union v Pa. Labor Rel. Bd.*, 503 Pa 236, 241, 469 A.2d 150, 152 (1983) ("This Court 'will not lightly substitute its judgment for that of a body selected for its expertise whose experience and expertise make it better qualified than a court of law to weigh facts within its field'.") (citation omitted). With respect to 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 at 119-20, 562 A.2d at 383. This Court summarily affirmed *White*. 525 Pa. 572, 583 A.2d 789 (1991) (per curiam). In fact, the Superior Court acknowledged this fundamental principle 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. But the recognition of a "negligent design defect"

claim is inconsistent with a policy of deference to the FDA's regulatory authority and its decisions regarding prescription drug approvals.

To be clear, Wyeth is not arguing in this case that the FDA's regulatory scheme and oversight resulted in preemption of state-law claims. Rather, Pennsylvania's long-standing policy of deference to regulatory authorities is in conflict with the recognition of a cause of action that specifically undertakes to re-evaluate those regulators' decisions and predict what they might do differently. In the guise of "negligent design defect" claims, prescription drug plaintiffs would seek to have individual courts and juries second-guess the FDA's decision that the health benefits of a drug's "design" outweigh its overall risks.

The Utah Supreme Court, in rejecting design defect claims, observed that the FDA's "extensive regulatory scheme is capable of and appropriate for making the preliminary determination regarding whether a prescription drug's benefits outweigh its risks....Allowing individual courts and/or juries to continually reevaluate a drug's risks and benefits ignores the processes of this expert regulatory body and the other avenues of recovery available to plaintiffs." *Grundberg v. Upjohn Co.*, 813 P.2d 89, 97 (Utah 1991). The court further explained the complications that necessarily arise when a plaintiff seeks to assert a design-defect claim fundamentally clashing with the risk-benefit judgments of FDA, which is better suited to undertake that analysis:

> [W]e do not believe that a trial court in the context of a products liability action is the proper forum to determine whether, as a whole, a particular prescription drug's benefits outweighed its risks at the time of distribution. In a case-by-case analysis, one court or jury's determination that a particular drug is or is not "defectively designed" has no bearing on any future case. As a result, differences of opinion among courts in different jurisdictions leaves unsettled a drug manufacturer's liability for any given drug. Although the FDA may have internal differences of opinion regarding whether a particular new drug application should be approved, the individuals making the ultimate judgment will have the benefit of years of experience in reviewing such products, scientific experience in the area, and access to volumes of data they can compel manufacturers to produce.

> Nor is the FDA subject to the inherent limitations of the trial process, such as the rules of evidence, restrictions on expert testimony, and scheduling demands.
>
> . . . .
>
> To determine whether a drug's benefit outweighs its risks is inherently complex because of the manufacturer's conscious design choices regarding the numerous chemical properties of the product and their relationship to the vast physiologic idiosyncracies of each consumer for whom the drug is designed. Society has recognized this complexity and in response has reposed regulatory authority in the FDA.

Id. at 98-99.

Whether sounding in strict liability or negligence, the undeniable result of a design defect claim is the same – the prescription drug plaintiff is in effect asking the court and the jury to re-evaluate and second-guess the FDA's risk-benefit analysis.

This case is the perfect example. Plaintiff's purported "negligent design defect" claim necessarily conflicts with the deference afforded under Pennsylvania law to FDA-approved designs, because, as noted above, Plaintiff did not even attempt to plead a feasible alternative design. As such, what Plaintiff passes off as a "negligence" theory is in reality more onerous even than strict liability, which requires proof of alternative designs. *See supra* n.5. Plaintiff has argued that, despite FDA approval, Redux should never have been marketed at all, or should have been removed from the market. (R. 591a, 593a, 599-602a). Because these allegations now serve as the sole basis of Plaintiff's newfound "negligent design defect" claim in this case, this is simply an attempt to resuscitate and repackage Plaintiff's improper "negligent marketing" and/or "negligent failure to remove" claims. According to Plaintiff, Wyeth should never have introduced Redux in the first place, even though it was FDA-approved, or 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.[7]

Allowing the Superior Court's decision 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. The Court should not permit those claims, which are the antithesis of the deference that should be afforded the FDA.

[7] Plaintiff now argues that Wyeth's decision to voluntarily withdraw Redux confirms the correctness of Plaintiff's position that Redux should never have been on the market, and thus was "negligently designed." Respondent's Answer In Opp. To Wyeth's Pet. For Allowance Of Appeal, at 16-17. This argument ignores the "state of the art" principle applied in Pennsylvania prescription drug litigation – the defendant's product must be evaluated in light of the "state of the art" information that was known or reasonably knowable at the time the plaintiff used the product, rather than using hindsight to evaluate the benefits and risks of a particular product. *Hahn v. Richter*, 427 Pa. Super. 130, 145-46, 628 A.2d 860, 867-68 (1993) (*en banc*), *aff'd*, 543 Pa. 558, 673 A.2d 888 (1996); *Leibowitz*, 224 Pa. Super. at 433-35, 307 A.2d at 458-59; *Mazur v. Merck & Co.*, 964 F.2d 1348, 1366-67 (3d Cir. 1992) (applying Pennsylvania law).

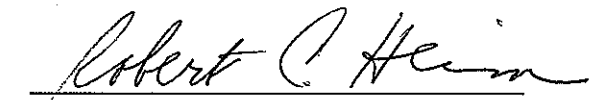
VIII. CONCLUSION

The Superior Court created a novel cause of action that is out of step with Pennsylvania jurisprudence, was not argued by Plaintiff, and was therefore waived. Given this waiver, the Court need not even consider the merits of this novel claim. Should the Court do so, however, the Superior Court ignored the fundamental differences separating prescription drugs from other products. Liability despite the presence of adequate prescription drug warnings would be a drastic departure from and radical expansion of this Court's decisions in *Incollingo*, *Baldino*, and *Hahn*, and would also be out of step with the law in an overwhelming majority of the jurisdictions that have applied comment k to all prescription drugs.

This expansion could flood Pennsylvania courts with more prescription drug product liability claims. It would undoubtedly put Pennsylvania at the extreme of prescription drug litigation, allowing a claim that few others have, and a claim that is rife with the potential for abuse given its vagaries.

For the reasons set forth above, Appellant Wyeth respectfully requests the Court to reverse the Superior Court's decision creating a new cause of action for "negligent design defect."

Respectfully submitted,



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Attorneys for Defendant-Appellant

Dated: May 2, 2011

APPENDIX A

THE FIRST JUDICIAL DISTRICT OF PENNSYLVANIA, PHILADELPHIA COUNTY
IN THE COURT OF COMMON PLEAS

PATSY LANCE, ADMINSTRATRIX FOR THE ESTATE OF CATHERINE RUTH LANCE,	:	TRIAL DIVISION - CIVIL
	:	NOVEMBER TERM 2006
Plaintiff	:	NO. 0926
V.	:	
WYETH, INC., et al.	:	SUPERIOR COURT NO. 2905 EDA 2008
Defendants	:	

OPINION

PROCEDURAL HISTORY

Plaintiff, Patsy Lance ("Plaintiff"), Administratrix for the Estate of Catherine Ruth Lance ("Lance"), appeals this Court's Order granting Summary Judgment in favor of Defendant Wyeth[1], due to Plaintiff's failure to present a cognizable claim under Pennsylvania law and dismissing with prejudice Plaintiff's claims. For the following reasons, this Court's Order should be affirmed.

FACTUAL BACKGROUND

Plaintiff, Patsy Lance ("Plaintiff"), is a resident of the State of Ohio who alleges her daughter, decedent Catherine Ruth Lance ("Lance"), ingested Defendant's diet drug, Redux, from approximately January 15, 1997 to April 1997. (Short Form of Complaint, ¶¶ 1, 5). Redux is prescribed to treat cases of obesity. (Plaintiff's Opposition in Response to Wyeth's Motion for Summary Judgment, Exhibit 30). The physicians who prescribed Redux to Lance for her obesity were Dr. John Imm, M.D. and Jim Doone, M.D. from

[1] Defendants Wyeth, formerly known as American Home Products Corporation, Wyeth-Ayerst Pharmaceuticals, Inc., Wyeth-Ayerst Laboratories, Co., and Wyeth-Ayerst Laboratories, Division of American Home Products Corporation will be collectively addressed as "Wyeth".

Community Health Partners in Fremont, Ohio. (Short Form Complaint, ¶6). The FDA approved Redux as "safe and effective" on April 29, 1996, and the FDA continued to approve Redux after Ms. Lance stopped using it. (Wyeth's Motion for Summary Judgment, Exhibits A-C). Lance ingested the drug for approximately three (3) months before discontinuing its use.

On or around November 15, 2004, more than seven (7) years after Lance discontinued using Redux, she was diagnosed with Primary Pulmonary Hypertension ("PPH")[2] by Dean M. Bernardo, M.D. At that time Lance first suspected that her ingestion of diet drugs was related to her diagnosis. *Id.* ¶¶ 7-8. Although Lance died in December 2004, the cause of her death is at issue and contested by the parties.

Plaintiff instituted the within Phen-Fen Mass Tort action by Short Form Complaint filed on November 13, 2006. Plaintiff alleged that on November 15, 2004, Lance was diagnosed with PPH as a result of her ingestion of Defendant's diet drug, Redux. (Short Form Complaint, ¶¶ 5-8).

Plaintiff included in her Short Form Complaint an "Addendum of Additional Allegations" for "clarification of her claims." (Short Form of Complaint, ¶ 12-13). Plaintiff stated that her negligence claim was based on "Unreasonable Marketing of a Dangerous Drug and Unreasonable Failure to Remove the Drug from the Market before January 1997.[3]" *Id.* Additionally, Plaintiff explicitly stated that she was making "No Inadequate Labeling Claims." *Id.* at ¶ 17.

On March 6, 2008, Defendant Wyeth filed its Motion for Summary Judgment asserting that Plaintiff had no cognizable claim under Pennsylvania law and that the action must therefore be dismissed. (Wyeth's Motion for Summary Judgment, p. 1). Plaintiff filed a response to Defendant's Motion on April 21, 2008. On May 14, 2008, Defendant filed its reply.

Plaintiff asserts that her claim for negligent marketing is within the purview of pharmaceutical negligence claims recognized in Pennsylvania. (Plaintiff's Response in

---

[2] Primary Pulmonary Hypertension is a rare, progressive disorder characterized by high blood pressure (hypertension) of the main artery of the lungs (pulmonary artery). *See* Mosby's Medical Dictionary, 6th Edition.

[3] Plaintiff's Complaint, although alleging Wyeth was negligent in marketing Redux, fails to allege that any marketing of Redux by Wyeth was relied upon by Plaintiff and influenced her to decision to request that she be prescribed Redux from her physicians. (Complaint, ¶¶12-17).

On October 10, 2008, Plaintiff timely filed her appeal and on October 29, 2008, filed her 1925(b) Statement of Matters, in response to this Court's Order. Plaintiff raises the following issues for review:

1. Whether the trial Court abused its discretion or committed an error of law in granting the Wyeth's Motion for Summary Judgment, where plaintiff has failed to prove an impurity or an inadequacy in labeling.

See Plaintiff Concise of Errors Complained of on Appeal, November 5, 2008.

LEGAL ANALYSIS

"After the relevant pleadings are closed, but within such time as not to unreasonably delay trial, any party may move for summary judgment in whole or in part as a matter of law." Pa.R.C.P. 1035.2. "A proper grant of summary judgment depends upon an evidentiary record that either (1) shows the material facts are undisputed or (2) contains insufficient evidence of facts to make out a *prima facie* cause of action or defense and, therefore, there is no issue to be submitted to the jury." *Biernacki v. Presque Isle Condos. Unit Owners Ass'n*, 828 A.2d 114, 115-116 (Pa.Super. 2003) (quoting *Grandelli v. Methodist Hospital*, 777 A.2d 1138, 1143-44 (Pa.Super. 2001)). Where a Motion for Summary Judgment is based upon insufficient evidence of a material fact, the adverse party must come forward with evidence to preserve the cause of action and if he fails to do so, the moving party is entitled to judgment as a matter of law. *Id.*

In reviewing a Trial Court's grant of Summary Judgment, the "scope of review is plenary." *Harber Philadelphia Center City Office Ltd. V. LPCI Ltd. Partnership*, 764 A.2d 1100, 1103 (Pa.Super. 2000). The same standard implemented by the Trial Court is applied by the reviewing court, "reviewing all the evidence of record to determine whether there exists a genuine issue of material fact." *Id.* The reviewing court must "view the record in the light most favorable to the non-moving party and resolve all doubts as to the existence of a genuine issue of material fact in its favor." *Haney v. Pagnanelli*, 830 A.2d 978, 980 (Pa.Super. 2003) (quoting *Juniata Valley Bank v. Martin Oil Co.*, 736 A.2d 650, 655 (Pa.Super. 1999)). "In reviewing a grant of summary judgment, the appellate Court may disturb the trial court's order only upon an error of law or an abuse of discretion." *Biernacki*, 828 A.2d at 116.

The purpose of Summary Judgment under Rule 1035.2 is "to eliminate cases prior to trial where a party cannot make out a claim or a defense after relevant discovery has been completed."*Miller v. Sacred Heart Hosp.*, 753 A.2d 829, 833 (Pa.Super. 2000) (quoting *Eaddy v. Hamaty*, 694 A.2d 639, 643 (Pa.Super. 1997). A plaintiff "must state a *prima facie* case before he will be allowed to proceed to trial." *Eaddy*, 694 A.2d at 643.

At issue in the instant case is whether Plaintiff in fact presented a cognizable claim for negligence under Pennsylvania law. Wyeth argues Plaintiff has not pled a cognizable negligence claim under Pennsylvania law because she did not allege harm from the adverse effects of using this prescription drug while proving (1) "an impurity" in the drug or (2) a failure to adequately warn. Wyeth's Motion for Summary Judgment, p. 6 (citing *Leibowitz v. Ortho Pharmaceutical Corp.*, 307 A.2d 449, 458 (Pa.Super. 1973)). The Supreme Court in *Leibowitz* more specifically stated:

> Because of the desirability of permitting drugs of proven value to be marketed despite known or suspected risks in said drugs, courts have uniformly held that 'a drug, properly tested, labeled with appropriate warnings, approved by the Food and Drug Administration, and marketed properly under federal regulation, is, as a matter of law, a reasonably safe product. Accordingly, 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 against the seller.

Id. at 307 A.2d at 458.

Pennsylvania courts have consistently refused to impose strict liability on manufacturers of prescription drugs. *Demmler v. SmithKline Beecham Corp.*, 671 A.2d 1151, 1154 (Pa.Super. 1996); *Baldino v. Castagna*, 478 A.2d 807, 810 (Pa. 1984) ("[A]ssuming proper preparation and warning, a manufacturer of drugs is not strictly liable for unfortunate consequences attending the use of otherwise useful and desirable products which are attended with a known but apparently reasonable risk"); *Incollingo v. Ewing*, 282 A.2d 206, 219 (Pa. 1971). ([N]either the law of Pennsylvania, nor, so far as we are aware, the law of other states has imposed strict liability upon a drug manufacturer merely because of dangerous propensities of the product."). Plaintiff does not allege any impurity or negligent manufacture of Redux in her Complaint.

In *Hahn v. Richter*, 628 A.2d 860, 866; 427 Pa.Super. 130 (Pa.Super. 1993), our Superior Court rejected strict liability claims for prescription drugs and held that "prescription drugs, which, although dangerous in that they are not without medical risks, are not deemed defective and unreasonably dangerous when marketed with the proper warnings."

Because Plaintiff does not present any evidence that Redux was defective in its manufacture, her Complaint must be based on alleged negligent failure to warn in order to have a sustainable claim. *Incollingo*, 282 A.2d at 219. However, Plaintiff admits in her Complaint that she is not making "any claim that the Redux FDA-approved warnings were inadequate, or that defendants failed to adequately warn about the risks of Redux, other than their failure to remove Redux from the market sooner than they did." (Complaint, ¶17).

Instead, Plaintiff alleges that Wyeth had a duty to protect her from "unreasonable risks" and "owed a duty to her not to introduce onto the market a drug that was unreasonably dangerous for any person to use." (Complaint, ¶12-13). No Pennsylvania court has recognized a claim for negligently putting an FDA-approved prescription drug on the market, or, for failing to withdraw it. In addition, the FDA approved Redux as "safe and effective" on April 29, 1996, and the FDA continued to approve Redux after Ms. Lance stopped using it. On September 3, 1997, the FDA again reaffirmed that Redux "is safe and effective for use." (Wyeth's Motion for Summary Judgment, Exhibit D). Redux was eventually withdrawn from the market on September 15, 1997, not because of risk of PPH, rather because of new, preliminary information related to risk of valvular heart disease, which Plaintiff never had. Id.

According to the caselaw, Plaintiff's assertion that Redux is "unreasonably dangerous" has not been recognized to support a negligence claim if it is not brought within a claim that the FDA approved warnings that were also inadequate. The fact that the FDA approved Redux is further evidence that this claim is unsustainable.

Had Plaintiff pled a negligent failure to warn claim she would be required to prove that the manufacturer failed to exercise reasonable care to inform those for whose use the article is supplied of the facts which make it likely to be dangerous. *Baldino*, 478 A.2d at 810 (emphasis added) (citing *Incollingo*, 282 A.2d at 220). This duty to warn

runs not to the patient or the general public, however, but to the prescribing physician. *See Incollingo*, 282 A.2d at 220 ("Since the drug was available only upon prescription of a duly licensed physician, the warning required is not to the general public or to the patient, but to the prescribing doctor"); *Demmler v. SmithKline Beecham Corp.*, 671 A.2d 1151, 1154 (Pa.Super. 1996) ("a prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient" and weigh "the benefits of any medication against its potential dangers."); *Leibowitz*, 307 A.2d at 457 ("It is for the prescribing physician to use his own independent medical judgment, taking into account the data supplied to him from the drug manufacturer, other medical literature, and any other source available to him, and weighing that knowledge against the personal medical history of his patient, whether to prescribe a given drug."); *see also Lineberger v. Wyeth*, 894 A.2d 141, 149-50 (Pa.Super. 2006) (discussing learned intermediary doctrine for failure to warn prescription drug case law).

In evaluating case law under what has come to be known as the "learned intermediary" doctrine, the *Incollingo* Court looked at "whether the warning that was given to the prescribing doctors was proper and adequate" and "whether, if the printed warning was proper and adequate, it was in effect nullified by the representations of the so-called 'detail men'." *Id.* at 220; *see also Baldino*, 478 A.2d at 811 ("[A] drug manufacturer can be held to have breached his duty of reasonable care by promoting its product in such a way as to nullify printed warnings."). A plaintiff must prove the manufacturer knew or should have known of the risk and failed to take the precautions that a reasonable person would take in presenting the drug to the public. *See Hahn*, 628 A.2d at 867-68. Plaintiff fails to meet her burden set forth in *Hahn* because the FDA approved Redux and the PPH warnings that Wyeth provided to Lance's prescribing physician. *Incollingo*, 282 A.2d at 220.

Plaintiff characterizes her claim in her Short Form Complaint as "Negligence – [in the] Unreasonable Marketing of a Dangerous Drug and Unreasonable Failure to Remove the Drug from the Market before January 1997." (Short Form Complaint, ¶¶12-13). Neither of these claims is cognizable under Pennsylvania law. *See Leibowitz*, 307 A.2d at 458; *Hahn v. Richter*, 628 A.2d at 866. According to Pennsylvania law, the only cognizable claims against a manufacturer of prescription drugs are claims of (1)

manufacturing defect or (2) failure to warn. *See Letbowitz*, 307 A.2d at 458. Plaintiff's complaint did not allege a manufacturing defect regarding Redux. Also, Plaintiff's Complaint expressly stated "Plaintiff does not make any claim that the Redux FDA-approved warnings were inadequate, or that defendants failed to adequately warn about the risks of Redux..."). (Short Form Complaint, ¶17).

Pennsylvania has not recognized claims of "unreasonable" or negligent marketing as a stand alone claim, but rather it has been required to have been brought within a failure to warn claim. The marketing and promotional practices of drug manufacturers are taken into consideration when determining the adequacy of a warning in a failure to warn claim. *Incollingo*, 282 A.2d at 220. A drug manufacturer's marketing practices are a necessary factor for determining the reasonableness of the manufacturer's actions and the adequacy of the warning accompanying the drug. *See Id.*; *Baldino*, 478 A.2d at 811; *Hahn*, 628 A.2d at 867-68. In some instances a drug manufacturer has been held to have breached its duty of reasonable care by promoting a drug in such a way as to nullify warnings; however this is not the case here. *See Incollingo*, 282 A.2d at 220; *Baldino*, 478 A.2d at 811; *Hahn*, 628 A.2d at 867-68. In addition, other jurisdictions have not recognized "unreasonable" or negligent marketing as a cause of action separate from failure to warn. *See Laisure-Radke v. Par Pharmaceutical, Inc.*, 426 F.Supp.2d 1163, 1168-69 (W.D.Wash. 2006) (plaintiff alleged "negligent marketing of a defective product with inadequate and/or legally defective labeling" but not as separate claims); *McClain v. Metabolife International, Inc.*, 193 F.Supp.2d 1252, 1257 (N.D.Ala. 2002) (no separate cause of action for negligent marketing under Alabama law).

Pennsylvania's recognition of the learned intermediary doctrine nullifies this novel claim by Plaintiff that this prescription drug was unreasonably dangerous and unfit to be prescribed to anyone. In acknowledging the inherent risks that come along with the benefits of prescription drugs, Pennsylvania law holds that drugs "properly tested, labeled with appropriate warnings, approved by the Food and Drug Administration, and marketed properly under federal regulation" are reasonably safe products as a matter of law. *Leibowitz*, 307 A.2d at 458. The learned intermediary doctrine provides further protection from the dangerous propensities of prescription drugs by requiring drug manufacturers to supply adequate warnings to the physicians who ultimately make the decision to

prescribe a potentially dangerous drug to the consumer. *See Demmler*, 671 A.2d at 1154 ("a prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient" and weigh "the benefits of any medication against its potential dangers."). Therefore, so long as a prescription drug has the appropriate FDA approved labeling found to sufficiently warn prescribing physicians of the risks of such a drug, the drug cannot be found unreasonably dangerous. Plaintiff's claim that Redux was an unreasonably dangerous drug that should not have been marketed to anyone nor been available on the market is not a sustainable claim.

CONCLUSION

For the foregoing reasons, this Court concludes that Plaintiff has failed to present a cognizable claim under Pennsylvania law. Therefore, this Court's Order granting Summary Judgment in Defendant Wyeth's favor should be AFFIRMED.

BY THE COURT:

Jan 7th, 2010
DATE

Tereshko
ALLAN L. TERESHKO, J.

cc:

Tobias Lael Millrood
Barbara R. Binis
Michael T. Scott
Ira Steven Lefton

COPIES SENT
PURSUANT TO Pa.R.C.P. 236(b)
JAN 7 2010
FIRST JUDICIAL DISTRICT OF PA
USER I.D.:

030418

PATSY LANCE,
ADMINISTRATRIX FOR THE
ESTATE OF CATHERINE LANCE

Plaintiff,

v.

WYETH, INC., et al.,

Defendants.

COURT OF COMMON PLEAS
COUNTY OF PHILADELPHIA

November Term 2006,

No. 000926

ORDER

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

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

BY THE COURT:

TERESHKO, J.

COPIES SENT
PURSUANT TO Pa.R.C.P. 236(b)
SEP 19 2008
FIRST JUDICIAL DISTRICT OF PA
USER I.D.:

SEP 19 2008

L. MARIE DAVIS

Lance Vs Wyeth Etal-ORDRF

APPENDIX B

J. A21017-10

2010 PA Super 137

PATSY LANCE, Administratrix for the Estate of CATHERINE RUTH LANCE, Deceased,	:	IN THE SUPERIOR COURT OF PENNSYLVANIA
Appellant	:	
v.	:	
WYETH, f/k/a, AMERICAN HOME PRODUCTS CORPORATION,	:	
Appellee	:	No. 2905 EDA 2008

Appeal from the Judgment entered September 19, 2008,
Court of Common Pleas, Philadelphia County,
Civil, at No. 926, November Term 2006

BEFORE: STEVENS, GANTMAN and ALLEN, JJ.

Petition for Reargument Filed August 16, 2010

OPINION BY ALLEN, J.: Filed: August 2, 2010

Petition for Reargument Denied October 1, 2010

¶ 1 Plaintiff, Patsy Lance ("Appellant"), Administratrix for the Estate of Catherine Ruth Lance ("Lance"), appeals from the trial court's order granting summary judgment in favor of Wyeth, formerly known as American Home Products Corporation ("Wyeth"). We affirm in part and reverse in part.

¶ 2 In her short form complaint, Appellant alleged that Wyeth was negligent in placing an unreasonably dangerous prescription drug on the market and in failing to withdraw it upon discovering that it was unsuitable for public consumption. R.R. at 18. Appellant also asserted that Wyeth breached the standard of care in designing, developing, inspecting, testing

and preparing the drug. R.R. at 45. The trial court concluded that Appellant failed to present a cognizable claim under Pennsylvania law.

¶ 3 The trial court set forth the facts and procedural history of this case as follows.

> [Appellant] is a resident of the State of Ohio who alleges her daughter, decedent [Lance], ingested [Wyeth's] diet drug, Redux, from approximately January 15, 1997 to April 1997. Redux is prescribed to treat cases of obesity. The physicians who prescribed Redux to Lance for her obesity were Dr. John Imm, M.D., and Jim Doone, M.D., from Community Health Partners in Fremont, Ohio. The [Food and Drug Administration] ("FDA") approved Redux as "safe and effective" on April 29, 1996, and the FDA continued to approve Redux after [Lance] stopped using it. Lance ingested the drug for approximately three (3) months before discontinuing its use. [On September 15, 1997, Wyeth voluntarily withdrew Redux from the market because of the risk that the drug may cause valvlular heart disease.]
>
> On or around November 15, 2004, more than seven (7) years after Lance discontinued using Redux, she was diagnosed with Primary Pulmonary Hypertension ("PPH") by Dean M. Bernardo, M.D. At that time[,] Lance first suspected that her ingestion of diet drugs was related to her diagnosis. Although Lance died in December 2004, the cause of her death is at issue and contested by the parties.
>
> [Appellant] instituted the within Phen-Fen Mass Tort action by Short Form Complaint filed on November 13, 2006. [Appellant] alleged that on November 15, 2004, Lance was diagnosed with PPH as a result of her ingestion of . . . Redux.
>
> [I]n her Short Form Complaint, [Appellant included] an "Addendum of Additional Allegations" for "clarification of her claims." [Appellant] stated that her negligence claim was based on "Unreasonable Marketing of a Dangerous Drug and Unreasonable Failure to Remove the Drug from the Market before January 1997." Additionally, [Appellant] explicitly stated that she was making "No Inadequate Labeling Claims."

> [Appellant's] Complaint, although alleging Wyeth was negligent in marketing Redux, faile[d] to allege that any marketing of Redux by Wyeth was relied upon by [Lance] and influence[d] her decision to request that she be prescribed Redux from her physicians.
>
> [As part of her short from complaint, Appellant also adopted the negligence count of the master complaint. R.R. at 17. In particular, Appellant alleged that Wyeth breached the standard of care in designing, developing, inspecting, testing and preparing Redux. R.R. at 45.]

Trial Court Opinion (T.C.O.), 1/07/10, at 1-2 (citations and footnotes omitted).

¶ 4 On March 6, 2008, Wyeth filed a motion for summary judgment, contending that as a matter of law, Appellant did not assert a cognizable claim. In particular, Wyeth argued that in Pennsylvania, a plaintiff can only recover from a drug manufacturer by proving either that the drug had a manufacturing defect or an inadequate warning. Wyeth maintained that because Appellant did not aver a manufacturing defect claim and admitted that her negligence claim was not based on a failure to warn, Appellant failed to plead a valid cause of action.

¶ 5 In opposition, Appellant conceded that she was not asserting a failure to warn claim. Appellant, however, argued that Wyeth was negligent in placing an unreasonably dangerous product into the market. Appellant further asserted that Wyeth was negligent in failing to properly test Redux before the FDA approved the drug and in failing to withdraw Redux from the market after discovering that it was unreasonably dangerous. Finally,

Appellant proposes that she advanced a viable negligent design defect claim. On these grounds, Appellant submitted that her claims were actionable under Pennsylvania law.

¶ 6 On September 19, 2008, the trial court granted summary judgment in favor of Wyeth. The trial court concluded that as a matter of law, Appellant failed to plead a cognizable cause of action. This appeal ensued.

¶ 7 Appellant raises the following issue for review:

> 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, [] Lance?

Brief for Appellant at 3.

¶ 8 We review a grant of summary judgment under the following well-settled standards:

> Pennsylvania law provides that summary judgment may be granted only in those cases in which the record clearly shows that no genuine issues of material fact exist and that the moving party is entitled to judgment as a matter of law. The moving party has the burden of proving that no genuine issues of material fact exist. In determining whether to grant summary judgment, the trial court must view the record in the light most favorable to the non-moving party and must resolve all doubts as to the existence of a genuine issue of material fact against the moving party. Thus, summary judgment is proper only when the uncontraverted allegations in the pleadings, depositions, answers to interrogatories, admissions of record, and submitted affidavits demonstrate that no genuine issue of material fact exists, and that the moving party is entitled to judgment as a matter of law. In sum, only when the facts are so clear that reasonable minds cannot differ, may a trial court properly enter summary judgment.

Wright v. Allied Signal, Inc., 963 A.2d 511, 514 (Pa. Super. 2008) (citation omitted).

¶ 9 Here, Wyeth did not claim that Appellant was unable to adduce evidence sufficient to establish a *prima facie* case. Rather, Wyeth argued that as a matter of law, Appellant failed to allege a cognizable cause of action in her complaint. As such, this Court is presented with a pure question of law, *i.e.*, whether Appellant pursued a viable cause of action.[1]

¶ 10 According to the short form complaint, Appellant asserted three legal claims. First, Appellant asserted a claim for "Negligence – Unreasonable Marketing of a Dangerous Drug." R.R. at 18. To support this claim, Appellant alleged, *inter alia*, that "Redux was so unreasonably dangerous and defective in design that it never should have been on the market." R.R. at 19. Second, Appellant averred a claim for "Negligence – Unreasonable Failure to Remove [Redux] from the Market before January 1997." R.R. at 18. In support of this claim, Appellant contended that Wyeth was negligent in failing to withdraw Redux after discovering in 1994 that the drug was associated with heart valve disease. R.R. at 19. Third, Appellant raised a

[1] We note that Wyeth filed its motion for summary judgment prior to filing an answer to Appellant's complaint. Indeed, because the trial court granted Wyeth summary judgment, Wyeth did not file an answer at all. Therefore, although this case was disposed of on summary judgment, the procedural posture indicates that Wyeth's motion for summary judgment was more akin to a preliminary objection in the nature of a demurrer, challenging the legal sufficiency of the complaint. ***See Reed v. Dupuis***, 920 A.2d 861, 864 (Pa. Super. 2007) (setting forth the standard of review from an order granting a preliminary objection in the nature of a demurrer).

standard negligence count; in this claim, Appellant alleged that Wyeth breached the standard of care in designing, developing, inspecting, testing and preparing Redux. R.R. at 45.

¶ 11 Appellant first argues that the trial court erred in granting summary judgment on her "Unreasonably Marketing of a Dangerous Drug" claim. Appellant maintains that Wyeth was negligent in placing an unreasonably dangerous drug on the market and contends that the overall risks of Redux outweighed the drug's benefits for any class of persons. In addition, Appellant asserts that Redux was unreasonably dangerous because it was defective in design and chemical composition. Appellant proposes that Pennsylvania law recognizes this type of claim as a legal basis for relief. Finding that Appellant's purported cause of action is a design defect claim sounding in products liability, we do not agree.

¶ 12 In ***Webb v. Zern***, 220 A.2d 853 (Pa. 1966), our Supreme Court adopted The Restatement (Second) of Torts § 402A. This section governs products liability claims and allows recovery where a product causes harm to a plaintiff and is in "a defective condition unreasonably dangerous to the consumer or user[.]" Restatement (Second) of Torts, § 402A(1). In general, there are three types of defective conditions which may give rise to strict liability: a manufacturing defect, a design defect, and a failure to warn defect. ***Phillips v. A-Best Products Co.***, 665 A.2d 1167, 1170 (Pa. 1995).

¶ 13 In Pennsylvania, however, products liability law is superseded as it applies to prescription drugs. In ***Hahn v. Richter***, 673 A.2d 888, 889-90 (Pa. 1996), our Supreme Court continued to "den[y] application of strict liability to products such as prescription drugs, which, although dangerous in that they are not without medical risks, are not deemed defective and unreasonably dangerous when marketed with proper warnings." ***Id.*** Relying on previous case law, our Supreme Court in ***Hahn*** adopted comment k of the Restatement (Second) of Torts, §402A. In pertinent part, comment k provides:

> *k. Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. . . . The seller of such products, 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 cmt. k (emphasis in original).

¶ 14 Due to the inherent risks and dangers associated with prescription drugs, our Supreme Court has limited the potential causes of action available to a plaintiff who alleges a strict liability claim against a drug manufacturer. In particular, a plaintiff may advance only two possible strict liability claims: (1) a manufacturing defect claim, or (2) a failure to warn

claim. ***Baldino v. Castagna***, 478 A.2d 807, 810 (Pa. 1984) ("[A]ssuming proper preparation and warning, a manufacturer of drugs is not strictly liable for unfortunate consequences attending the use of otherwise useful and desirable products which are attended with a known but apparently reasonable risk."). If a plaintiff asserts a failure to warn claim under §402A, strict liability will not be imposed upon the drug manufacturer. Rather, pursuant to ***Hahn***, the failure to warn claim will be analyzed and adjudicated in accordance with the negligence standard contained in the Restatement (Second) of Torts, § 388. ***Hahn***, 673 A.2d at 890-91.

¶ 15 Here, Appellant did not allege that Redux contained a manufacturing defect or inadequate warnings. Instead, Appellant argues that Redux was "unreasonably dangerous" and that the drug's "risks outweighed its benefits as to all possible classes of users of that medication." Brief for Appellant at 14. Although Appellant labels her claim as "negligent and unreasonable marketing," her proposed cause of action duplicates a design defect claim, seeking to impose strict liability on Wyeth because Redux was unreasonably dangerous. ***See Fitzpatrick v. Madonna***, 623 A.2d 322, 324-26 (Pa. Super. 1993) (discussing strict liability design defect claims). With our Supreme Court's adoption of comment k, a design defect claim for strict liability is not cognizable under Pennsylvania law when it is asserted against

a manufacturer of prescription drugs.[2] For purposes of strict liability and § 402A, a drug cannot be deemed unreasonably dangerous, even if it is defectively designed, so long as the drug is manufactured properly and contains adequate warnings. Restatement (Second) of Torts, § 402A cmt. k (stating that a prescription drug "properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous.") (emphasis in original).[3] As noted above, Appellant did not allege that Redux contained a manufacturing defect or inadequate warnings. The trial court, therefore, did not err in granting summary judgment in favor of Wyeth on Appellant's "Unreasonable Marketing" claim to the extent that it averred a strict liability design defect claim.

¶ 16 Appellant next argues that she asserted a cognizable negligent design defect claim. Here, in the incorporated long form complaint, Appellant included an allegation that Wyeth breached the standard of care in designing

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[2] Although some jurisdictions employ a case-by-case approach to decide whether to apply comment k to a particular drug, ***see, e.g., Castrignano v. E.R. Squibb & Sons, Inc.***, 546 A.2d 775 (R.I. 1988), Pennsylvania is one of the few jurisdictions that afford comment k protection to all prescription drugs as a matter of law. ***Castagna***, 478 A.2d at 810; ***Incollingo v. Ewing***, 282 A.2d 206, 220-21 (Pa. 1971).

[3] "By its own terms, comment k excepts 'unavoidably unsafe' products from liability for design defects. . . . Thus, once comment k is applied, all questions of a product's design become irrelevant and the focus shifts to the adequacy, or reasonableness, of the warning of the product's risks." Carla Herron and Kelli DeGeeter, *Can Texas Escape the Unavoidably Unsafe Medicine of Comment k by Adopting Section 8 of the Proposed Third Restatement of Torts?,* 49 Baylor L. Rev. 73, 78-79 (1997).

Redux. R.R. at 45. We agree with Appellant that notwithstanding comment comment k in § 402A, this claim is actionable under Pennsylvania law.

¶ 17 It is important to note that a negligent design claim is not foreclosed merely because summary judgment is granted in favor of a defendant on a plaintiff's strict liability claim. ***Phillips v. Cricket Lighters***, 841 A.2d 1000, 1008 (Pa. 2003) (plurality). This is because a strict liability design defect claim is distinct from a negligence design defect claim. ***Id.*** "Strict liability examines the product itself, and sternly eschews considerations of the reasonableness of the conduct of the manufacturer." ***Id.*** "In contrast, a negligence cause of action revolves around an examination of the conduct of the defendant." ***Id.***

¶ 18 The Restatement (Second) of Torts, §395 addresses a manufacturer's negligent design of products. Unlike comment k in § 402A, this provision contains no exemption or special protection for prescription drugs. ***See*** Restatement (Second) of Torts § 395 cmt. f (adopting rule of negligence liability for product design without any reference to drugs or comment k). In ***Toner v. Lederle Labs.***, 732 P.2d 297, 309-10 (Idaho 1987), the Supreme Court of Idaho aptly explained why a negligent design claim is not precluded by comment k:

> In a literal sense, comment k, when applicable, quite clearly does not act as a bar to negligence claims. By its own terms, the comment only bars claims that the product's design was 'defective' and '*unreasonably* dangerous' (emphasis original) -- in other words, strict liability claims. The comment expressly states that the seller of 'unavoidably unsafe' products 'is not to

> be held to strict liability for unfortunate consequences attending their use . . . .' The authorities universally agree that where a product is deemed unavoidably unsafe, the plaintiff is deprived of the advantage of a strict liability cause of action, but may proceed under a negligence cause of action.
>
> By denying plaintiffs recovery based on the dangerousness of the product and requiring plaintiffs to prove negligent conduct on the part of the defendants, comment k furthers the policy of encouraging the production and marketing of useful products. However, to immunize sellers of products deemed unavoidably unsafe pursuant to comment k from negligence claims would remove needed incentive for safe design.

Id. (citations omitted).

¶ 19 Likewise, in ***Artiglio v. Superior Court***, 22 Cal. App. 4th 1388, 1393 (Cal. Ct. App. 4th Dist. 1994), an intermediate court of appeals for the State of California concluded that under comment k, "[l]iability for defective design could not be premised on strict liability, but would require proof of negligence." Indeed, § 402A expressly limits its application to strict liability claims and does not bar negligence claims: "The rule [of strict liability] stated here is not exclusive, and does not preclude liability based upon the alternative ground of negligence of the seller, where such negligence can be proved." Restatement (Second) of Torts § 402A cmt. a.

¶ 20 Therefore, comment k is confined to strict liability claims and has no application to claims sounding in negligence. Pursuant to Pennsylvania law, a negligent design defect claim is considered to be distinct from, and not subsumed within, a strict liability design defect claim. Consequently, Appellant's negligent design claim is not precluded by comment k, and is a

valid cause of action upon which relief may be granted. The trial court thus erred in entering summary judgment in favor of Wyeth on Appellant's negligent design defect claim.

¶ 21 In addition, Appellant argues that her claim for negligent failure to withdraw/recall Redux from the market was cognizable under Pennsylvania law. According to Appellant, Wyeth did not adequately evaluate reports of health problems associated with Redux and should have withdrawn and/or recalled Redux from the market before it was prescribed to her. Appellant's assertion lacks merit.

¶ 22 In ***Lynch v. McStome & Lincoln Plaza Assoc.***,548 A.2d 1276, 1281 (Pa. Super. 1998), this Court refused to recognize a duty to retrofit a product. Following the natural direction of ***Lynch***, this Court is persuaded by the majority of modern jurisdictions that have decided not to impose a common law duty to recall on a manufacturer. ***See, e.g., Ford Motor Co. v. Reese***, 684 S.E. 2d 279, 283-85 (Ga. Ct. App. 4th Div. 2009); ***Stanger v. Smith & Nephew, Inc.***, 401 F. Supp. 2d 974, 982 (D. Mo. 2005); 47 ALR 5th 395, § 2 (a) (1997) (compiling cases and concluding that "[t]he majority of courts refuse to extend upon the manufacturer the duty to repair or remedy its product postsale."). As the court in ***Reese*** explained, public policy considerations weigh heavily against imposing a duty to recall on a manufacturer:

> Because the cost of locating, recalling, and replacing mass-marketed products can be enormous and will likely be passed on

> to consumers in the form of higher prices, the recall power should not be exercised without extensive consideration of its economic impact. Courts, however, are constituted to define individual cases, and their inquiries are confined to the particular facts and arguments in the cases before them. Decisions to expand a manufacturer's post-sale duty beyond making reasonable efforts to warn product users about newly discovered dangers should be left to administrative agencies, which are better able to weigh the costs and benefits of such action.

684 S.E. 2d at 285 (quoting Victor Schwartz, *The Post-Sale Duty to Warn: Two Unfortunate Forks in the Road to a Reasonable Doctrine*, 58 N.Y.U. L. Rev. 892, 901 (I) (1983)).

¶ 23 In the absence of a state statute or administrative directive mandating a recall, we decline to impose upon a drug manufacturer a common law duty to recall a drug. Although the FDA does not have the authority to recall prescription drugs, it is vested with the power to withdraw approval of prescription drugs, thus precluding the manufacturer from legally marketing a drug. 21 U.S.C.A. § 355(e). As such, the FDA's power to withdraw approval of a prescription drug is analogous to the power to recall.

¶ 24 Here, on April 29, 1996, the FDA approved Redux as "safe and effective." After Appellant stopped ingesting Redux in April 1997, the FDA continued to approve the drug. Consistent with the practice of other courts, we defer to the federal regulatory scheme and the FDA's decision as to whether a drug should lawfully remain on the market. ***See, e.g., Ramirez v. Plough, Inc.***, 863 P.2d 167, 177-78 (Cal. 1993) ("We conclude . . . that defendant may not be held liable for failing to withdraw its product from the

market . . . . Pending completion [of studies linking aspirin with Reye's syndrome], the FDA concluded that product warnings were an adequate public safety measure. Although the FDA's conclusion is not binding on us, we think it deserves serious consideration."). Therefore, during the time-frame in which Appellant ingested Redux, Wyeth did not have a duty to withdraw/recall Redux from the market, because the FDA did not withdraw its approval of Redux.

¶ 25 Moreover, a manufacturer has a post-sale duty to warn of "any dangerous side effects produced by its drugs of which it knows or has reason to know" as long as its drugs are sold on the market. ***Barson v. E.R. Squibb & Sons, Inc.***, 682 P.2d 832, 835 (Utah 1984). "The duty is a continuous one, requiring the manufacturer to keep abreast of the current state of knowledge of its products as gained through research, adverse reaction reports, scientific literature, and other available methods." ***Lindsay v. Ortho Pharmaceutical Corp.***, 637 F.2d 87, 91 (2d. Cir. 1980); ***see Schenebeck v. Sterling Drug, Inc.***, 423 F.2d 919, 922 (8th Cir. 1970); ***Wooderson v. Ortho Pharm. Corp.***, 681 P.2d 1038, 1050-51 (Kan. 1984); ***Feldman v. Lederle Laboratories***, 479 A.2d 374, 388-89 (N.J. 1984). Consequently, a drug manufacturer's post-sale duty to warn of dangerous propensities provides consumers with a remedy and sufficient protection against risks that a manufacturer discovers (or should have discovered) after

the drug was placed into the stream of commerce.[4] However, any decision to expand a drug manufacturer's post-sale duty to warn into the arena of a duty to recall/withdraw is left to the FDA, which is better equipped to weigh the benefits and risks associated with permitting a drug to remain on the market.

¶ 26 Given the FDA's regulatory authority and a drug manufacturer's post-sale duty to warn, we conclude that Wyeth did not have a common law duty to recall or withdraw Redux. The trial court did not err in granting summary judgment in favor of Wyeth on Appellant's claim for negligent withdraw and/or recall.

¶ 27 Appellant also maintains that her alleged her causes of action, including her claims for "unreasonable marketing" and "negligent failure to

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[4] In imposing a continuing, post-sale duty to warn on a drug manufacturer, we are cognizant that in ***Lynch v. McStome and Lincoln Plaza Associates***, 548 A.2d 1276 (Pa. Super. 1988) and ***DeSantis v. Frick***, 745 A.2d 624 (Pa. Super. 1999), this Court held that there is no post-sale duty to warn about technological advances when a defect did not exist in the product at the time of sale. ***Lynch*** and ***DeSantis***, however, did not address the special circumstances attendant to the marketing, labeling and distribution of prescription drugs. "The duty to warn assumes great significance in . . . a case involving pharmaceuticals," ***Baker v. St. Agnes Hosp.***, 70 A.D. 2d 400, 405 (N.Y. 1979), and "it is important to point out that the drug manufacturer is held to be an expert in its particular field." ***Barson***, 682 P.2d at 835. Moreover, the FDA's labeling rules require a prescription drug manufacturer to make any changes to its labels to add or strengthen a warning about a possible adverse reaction as soon it has reasonable evidence that the drug or device caused an adverse reaction. 21 C.F.R. § 314.70(c)(6)(iii)(A)-(E). We conclude that ***Lynch*** and ***DeSantis*** are inapplicable to the matter at hand, and confine the holdings in those cases to manufacturing operations that do not involve prescription drugs.

withdraw," are sustainable because they are akin to a failure to inspect and/or test claim. Citing ***Hoffman v. Sterling Drug, Inc.***, 485 F.2d 132, 140-41 (3d. Cir. 1973), Appellant argues that a failure to test claim is valid cause of action. We disagree.

¶ 28 In ***Hoffman***, the United States Court of Appeals for the Third Circuit applied Pennsylvania law and concluded that there was sufficient evidence for the jury to find that the manufacturer failed to adequately test its drug to discover potentially harmful side-effects. 485 F.2d at 140-41. Regardless of the ***Hoffman*** decision, which is not binding upon this Court, ***Trach v. Fellin***, 817 A.2d 1102, 1115 (Pa. Super. 2003) (*en banc*), Pennsylvania law has not recognized an independent tort for negligent failure to test. In fact, we have held that "the claim for 'negligent failure to test' is not a viable cause of action recognized by our courts[.]" ***Viguers v. Philip Morris USA, Inc.***, 837 A.2d 534, 541 (Pa. Super. 2003), *aff'd* 881 A.2d 1262 (Pa. 2005).

¶ 29 If there is a duty to test and/or inspect in Pennsylvania, it does not exist as an independent cause of action, but rather, is subsumed within Appellant's other claims. In ***Kociemba v. G.D. Searle & Co.***, 707 F. Supp. 1517, 1527 (D. Min. 1989), the court refused to permit a claim based solely on the failure to test. The court explained why the failure to test cannot stand alone as an independent cause of action:

> [T]he reason that manufacturers are under a duty to test their products is to discover defects or dangers associated with use of the products. Once the manufacturer has discovered a defect or danger the manufacturer should either change the product's

> design or manufacturing process, or warn consumers of the danger associated with using the product.
>
> Thus, unless the manufacturer's breach of its duty to test leads the manufacturer to produce a product that is defective in design, manufacture, or warning, no injury can result. If the manufacturer designs the product safely, manufactures the product safely, and provides an adequate warning of dangers inherent in the use of the product, then a failure to test the product cannot, standing alone, cause any injury. The duty to test is a subpart of the other three duties because a breach of the duty to test cannot by itself cause any injury.

Id.; ***accord Adams v. G.D. Searle & Co., Inc.***, 576 So. 2d 728, 730 (Fla. Ct. App. 2d Dist. 1999); ***Valentine v. Baxter Healthcare Corp.***, 68 Cal. App. 4th 1467, 1485-86 (Cal. Ct. App. 4th Div. 1999); ***see also Vassallo v. Baxter Heathcare Corp.***, 696 N.E. 2d 909, 921 (Mass 1998) (concluding that breach of duty to test does not create an independent cause of action).

¶ 30 Therefore, even if there is a general duty to inspect and/or test under Pennsylvania law, it would be subsumed within Appellant's design defect claims and/or any potential failure to warn claim that Appellant may have had. Because failure to test is not an independent cause of action in Pennsylvania, Appellant's arguments to the contrary fail.

¶ 31 Finally, Appellant argues that she averred an actionable claim under the Restatement (Third) of Torts: Products Liability § 6(c). Brief for Appellant at 15-16. Our Supreme Court has never adopted this provision, and it runs contrary to law as stated in ***Hahn*** and the Restatement (Second) of Torts, §402A. "As an intermediate appellate court, this Court is obligated to follow the precedent set down by our Supreme Court. It 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." ***Moses v. T.N.T. Red Star Express***, 725 A.2d 792, 801 (Pa. Super. 1999) (citations omitted). "Until and unless our Supreme Court alters its approach to strict liability, we will continue to adhere to established principles." ***Bugosh v. Allen Refractories Co.***, 932 A.2d 901, 911 (Pa. Super. 2007), *appeal dismissed as improvidently granted in* 971 A.2d 1228 (Pa. 2009) (declining to adopt a portion of the Restatement (Third) of Torts: Product Liability because our Supreme Court continues to apply the Restatement (Second) of Torts, § 402A). Because the Restatement (Second) of Torts, §402A remains the law in this Commonwealth, Appellant's contention does not merit relief.

¶ 32 For the above-stated reasons, we conclude that the trial court did not err in granting summary judgment against Appellant on her claims of "Unreasonable Marketing" and "Unreasonable Failure to Remove [Redux] from the Market." The trial court, however, erred in granting summary judgment in favor of Wyeth on Appellant's claim for negligent design defect. Accordingly, we affirm in part and reverse in part, and remand for further proceedings.

¶ 33 Order affirmed in part and reversed in part. Case remanded. Jurisdiction relinquished.

"Judge Gantman Concurs In Result."

APPENDIX C

J. A21017/10

PATSY LANCE, ADMINISTRATRIX FOR THE ESTATE OF CATHERINE RUTH LANCE, DECEASED,	:	IN THE SUPERIOR COURT OF PENNSYLVANIA
Appellant	:	
v.	:	
WYETH F/K/A AMERICAN HOME PRODUCTS CORPORATION,	:	
Appellee	:	No. 2905 EDA 2008

ORDER

AND NOW, this 1st day of October, 2010, IT IS HEREBY ORDERED:

THAT the application filed August 16, 2010, requesting reargument of the decision dated August 2, 2010, is DENIED.

PER CURIAM

PROOF OF SERVICE

The undersigned hereby certifies that on this day I caused a true and correct copy of the foregoing Brief of Appellant Wyeth to be served upon the following counsel via first-class mail:

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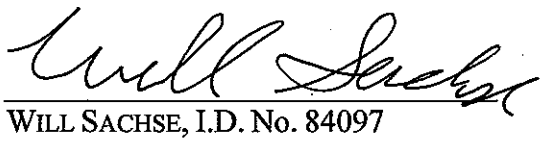
May 2, 2011



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