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,

SECOND BRIEF OF APPELLANT-CROSS-APPELLEE 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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SECOND BRIEF OF APPELLANT-CROSS APPELLEE WYETH

REPLY BRIEF IN APPEAL NO. 17 EAP 2011

Plaintiff has waived her purported "negligent design defect" claim and nothing she argues in her response changes that fact. It is not enough to say she *would have* argued the claim on summary judgment if Wyeth referenced it more specifically in its moving papers; it is not enough to say that a "negligent design defect" claim was "encompassed" in another claim.

Moreover, even if Plaintiff had asserted such a claim, it should be rejected because it is inconsistent with decades of Pennsylvania jurisprudence regarding prescription drugs and would contravene the clearly expressed policies underlying that jurisprudence. Plaintiff's brief, which relies on cases involving products other than prescription drugs, and relies on non-Pennsylvania cases, fails to acknowledge that Pennsylvania, unlike some other states, treats product liability claims involving prescription drugs differently than claims involving ordinary products. Plaintiff's misplaced reliance on inapposite cases, as well as her failure to address the authority cited by Wyeth, highlights the absence of support for such a novel claim in Pennsylvania.

A. PLAINTIFF REPEATEDLY WAIVED ANY CLAIM FOR "NEGLIGENT DESIGN DEFECT."

The Superior Court *sua sponte* created a novel cause of action for "negligent design defect" of a prescription drug. This theory was never discussed by the trial court because it was never presented to that court, never listed in Plaintiff's Rule 1925(b) Statement, and never raised in the Questions Presented to the Superior Court. Waiver exists so that opposing parties and trial judges are not ambushed by unasserted arguments and claims. This Court has repeatedly stressed the importance of issue preservation:

> Issue preservation is foundational to proper appellate review. Our rules of appellate procedure mandate that "[i]ssues not raised in the lower court are waived and cannot be raised for the first time on appeal." By requiring that an issue be considered waived if raised for the first time on appeal, our courts ensure that the trial court that initially hears a dispute ***has had an opportunity to consider the issue***. This jurisprudential mandate is also grounded upon the principle that a trial court . . . must be given the ***opportunity to correct its errors as early as possible***. Related thereto, we have explained in detail the importance of this preservation requirement as it ***advances the orderly and efficient use of our judicial resources***. Finally, concepts of ***fairness*** and expense to the parties are implicated as well.

In re F.C. III, 2 A.3d 1201, 1211-12 (Pa. 2010) (citations omitted) (emphases added). *Accord e.g.*, *Commonwealth, Dept. of General Services v. U.S. Mineral Products Co.*, 598 Pa. 331, 347, 956 A.2d 967, 976 (2008) (waiver "afford[s] the trial judge the contemporaneous opportunity to take corrective action"); *Harman v. Borah*, 562 Pa. 455, 471, 756 A.2d 1116, 1124-25 (2000) (waiver "ensures that the trial court has a chance to correct alleged trial errors," "is indispensable to the orderly functioning of our judicial process, and developed out of a sense of fairness to an opposing party and as a means of promoting jurisprudential efficiency"). Thus, it is undisputed that this Court has consciously "taken a stricter approach to waiver than many other jurisdictions." *Schmidt v. Boardman Co.*, 11 A.3d 924, 942 (Pa. 2011).

The record below establishes waiver on multiple occasions, as set forth in Wyeth's Opening Brief. *See* Brief of Appellant Wyeth, at 11-16 (hereafter "Opening Br."). In response, Plaintiff first argues that the "Long Form" Complaint evidences an intent to assert a "negligent design defect" claim, and that Plaintiff's "incorporation" of those allegations in her opposition to summary judgment was sufficient to preserve a purported "negligent design defect" claim. Brief for Appellee/Cross-Appellant Patsy Lance, at 12-13 (hereafter "Pl. Br."). But the "Long Form" Complaint was an administrative document, and was not intended to reflect the limited claims available to Diet Drug plaintiffs under Pennsylvania law. Thus, for example, the "Long Form" Complaint included strict liability claims that are undeniably barred under Pennsylvania law. (R.

47a-50a). Each Diet Drug plaintiff had to file an additional "Short Form" Complaint identifying which of the "Long Form" claims were being asserted in an individual case. As Wyeth demonstrated, Plaintiff abandoned any "negligent design defect" claim from the outset of her case, when she filed a "Short Form" Complaint that characterized her claims as being for "negligent marketing" and "negligent failure to withdraw," and failed to plead any "negligent design defect" claim. Opening Br. at 12. Thus, Plaintiff's generalized reference to the "Long Form" Complaint was insufficient to raise or preserve any issue regarding "negligent design defect." Indeed, a few passing references in an administrative "Long Form" Complaint, never affirmatively argued before the trial court,[1] gave neither that court nor Wyeth any "fair" opportunity to address the novel theory the Superior Court has invented.[2]

Plaintiff next argues that she did not waive any "negligent design defect" claim when responding to Wyeth's summary judgment motion in the Court of Common Pleas. Yet, as Plaintiff's response acknowledges, Wyeth argued to the trial court precisely what Wyeth argues here: "[t]he ***only*** negligence claim that may be brought against the manufacturer of a prescription drug under Pennsylvania law is a claim for negligent failure to warn." Pl. Br. at 14 (citing (R. 75a-79a)) (emphasis added). Plaintiff's only response is to claim that Wyeth's argument below was not a sufficiently "direct[] challenge" to Plaintiff's purported "negligent design defect" claim, and thus did not require any specific response to the trial court regarding the viability of

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[1] *See* (R.19a) (Short Form Complaint: one mention of "defective in design" (¶14) as part of description of Plaintiff's "unreasonable marketing" and "failure to remove the drug from the market" claims); (R. 45a-47a) (Master Complaint: two mentions of "design/designing" in laundry lists of negligence allegations (¶¶64, 67(a))); (R. 134a) (Plaintiff's Common Pleas Brief: reciting Master Complaint laundry list in brief containing no design defect argument).

[2] Plaintiff's response states that design defect claims are "commonly asserted in prescription drug personal injury cases filed in Pennsylvania and throughout the Nation." Pl. Br. at 12. But Plaintiff does not cite any reported decision in Pennsylvania recognizing such claims, other than the present case.

that claim. Pl. Br. at 14. This is clear waiver. To oppose Wyeth's summary judgment motion, Plaintiff was obliged to come forward with "specific" evidence and arguments. *E.g.*, *Marks v. Tasman*, 527 Pa. 132, 135, 589 A.2d 205, 206 (1991). Plaintiff's failure to do so denied the trial court the opportunity to consider and rule specifically on any "negligent design defect" claim in the first instance. The trial court's opinion is silent as to "negligent design defect" because that undeveloped claim was abandoned and never before the court.

Third, Plaintiff cannot identify any specific reference to "negligent design defect" in either her Rule 1925(b) Statement or her Questions Presented to the Superior Court, as is required to preserve an issue under Pennsylvania's strict waiver rules. Nonetheless, Plaintiff now seeks to be excused for that repeated waiver. She argues that "negligent design defect" is "encompassed" or "fairly suggested" as a subsidiary question within a question that ***was*** presented to the Superior Court: whether the trial court erred by failing to recognize Plaintiff's claim that "Wyeth was negligent in bringing Redux to the market." Pl. Br. at 16. Plaintiff's brief to the Superior Court, however, undermines that *post-hoc* interpretation. In fact, Plaintiff's Superior Court brief clarifies that "[t]he negligent marketing claim that plaintiff is asserting here is essentially identical to the negligent failure-to-test claim..." (R. 598a).[3]

Therefore, under Pennsylvania Rule of Appellate Procedure 2116(a), Plaintiff waived any "negligent design defect" claim because she failed specifically to raise its dismissal as a claimed error. Although Plaintiff argues that she preserved the issue simply because her brief below "mentioned" the words design defect "a total of five times," Pl. Br. at 18, such "mentions" do not rise to the level of substantive "discussions" sufficient to preserve an issue. Mere "passing

[3] *See also* (R. 599a) ("Plaintiff's negligent marketing claim asserts that Wyeth was negligent in bringing Redux to market because, had Wyeth tested the medication in advance of bringing it to market, Wyeth would have concluded (as the FDA later concluded) that Redux's risks outweighed its benefits as to all possible classes of users of that medication.").

reference in [a] brief" does not "properly raise[]" an issue so as to avoid waiver. *Commonwealth v. Martorano*, 535 Pa. 178, 194-95, 634 A.2d 1063, 1071 (1993).

Plaintiff's fallback arguments are also meritless. Plaintiff suggests that the Court should excuse her repeated waiver because the Court will have to "readdress" the question in a future case. Pl. Br. at 20. But this Court recently concluded in *Schmidt* that the value provided by the waiver rules outweighs any burden on future courts. 11 A.3d at 942 (finding argument waived and noting that burden on future courts was "modest" compared with waiver rule's "salutary effect" "to put the court and all parties on appropriate notice and to facilitate informed decision making").

Finally, Plaintiff argues that Wyeth itself waived the right to argue Plaintiff's waiver. Pl. Br. at 19. But in the Superior Court, Wyeth, "as the appellee, did not bear the burden of issue preservation." *Heim v. Medical Care Availability and Reduction of Error Fund*, ___ A.3d ___, 2011 WL 1588219, at *5 (Pa. April 28, 2011). Wyeth thus had no obligation to anticipate or guess at arguments and theories that Plaintiff never clearly asserted or pursued.

Plaintiff's repeated failure to raise any "negligent design defect" claim has resulted in waiver under Pennsylvania's strict rules. The Superior Court erred in *sua sponte* reaching out and deciding that waived issue. Accordingly, that portion of the court's opinion should be reversed.

B. PRECEDENT AND POLICY PRECLUDE "NEGLIGENT DESIGN DEFECT" CLAIMS IN PRESCRIPTION DRUG LITIGATION.

Plaintiff concedes that Pennsylvania has recognized that prescription drugs, as a class of product, are "unavoidably unsafe" under Restatement (Second) of Torts §402A, comment k (1965). *See* Pl. Br. at 22. This point is critical because it is the very basis of this Court's adoption of comment k in all prescription drug cases, and its limitation of the scope of permissible claims against prescription drug manufacturers. Opening Br. at 16-20 (discussing

Hahn v. Richter, 543 Pa. 558, 560, 673 A.2d 888, 889-90 (1996); *Baldino v. Castagna*, 505 Pa. 239, 244, 478 A.2d 807, 810 (1984); and *Incollingo v. Ewing*, 444 Pa. 263, 287-88, 282 A.2d 206, 219-20 (1971)). Plaintiff "does not challenge" this precedent. Pl. Br. at 41. Instead, her brief largely ignores it, and wholly fails to address the numerous lower court cases cited by Wyeth that apply this Court's precedent and thereby limit a plaintiff's claims in a prescription drug case to negligent failure to warn and negligent manufacture. *See* Opening Br. at 19-20 (collecting cases).

Plaintiff also ignores the Superior Court's improper reliance on Restatement (Second) of Torts §395 and two non-Pennsylvania cases to create a claim for "negligent design defect." Opening Br. at 25-29 (discussing Restatement (Second) of Torts §395; *Artiglio v. Superior Court*, 27 Cal. Rptr. 2d 589 (Cal. App. 1994); and *Toner v. Lederle Laboratories*, 732 P.2d 297 (Idaho 1987)). Plaintiff does not even cite §395 or *Artiglio*, and makes only passing reference to *Toner* without addressing the deficiencies raised by Wyeth. *See* Pl. Br. at 26.[4] Yet although Plaintiff has abandoned the Superior Court's opinion, she continues to pursue an amorphous and radical "negligent design defect" claim that is improper as a matter of Pennsylvania law and sound policy.

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[4] Wyeth demonstrated in its initial brief that: (1) Pennsylvania has never adopted §395, and (2) §395 addresses negligence in manufacturing, not design, of products. Opening Br. at 25-27. Although Plaintiff does not respond to those arguments herself, Plaintiff's *amici* implicitly concede that the Superior Court's citation is erroneous by offering a different section – Restatement (Second) of Torts §398 (1965) – not previously relied on by any party or court. Brief of *Amici Curiae* The American Association For Justice And Pennsylvania Association For Justice, at 6 (hereafter "Pl. *Amici* Br."). But §398 has never been adopted by this Court. Nor has it been applied to prescription drugs, or any other unavoidably unsafe product, by any Pennsylvania court. Even if §398 had been adopted by the Court, Restatement "language is not to be considered controlling in the manner of a statute." *Coyle v. Richardson-Merrell, Inc.*, 526 Pa. 208, 212, 584 A.2d 1383, 1385 (1991). In any event, "it is settled that an *amicus* cannot raise issues that have not been preserved by the parties." *Alliance Home v. Board of Assessment Appeals*, 591 Pa. 436, 461 n.8, 919 A.2d 206, 221 n. 8 (2007) (citation omitted).

1. Plaintiff's Novel "Negligent Design Defect" Claim Is Contrary To Settled Pennsylvania Law.

Plaintiff fails to acknowledge the numerous Pennsylvania cases cited by Wyeth that expressly limit prescription drug plaintiffs to two claims: (1) negligent failure to warn; and (2) negligent manufacture. Plaintiff also fails to cite ***any*** Pennsylvania cases that establish the viability of a "negligent design defect" claim in the context of a prescription drug or other "unavoidably unsafe" product. Rather, Plaintiff relies on cases involving products other than prescription drugs and cases outside of Pennsylvania that are not relevant to the analysis.

For example, Plaintiff relies on this Court's plurality decision in *Phillips v. Cricket Lighters*, 576 Pa. 644, 841 A.2d 1000 (2003), which involved strict liability and negligence claims against the manufacturer of a cigarette lighter. *Phillips* merely stands for the proposition that a claim for negligent design defect may be viable in a case involving an ordinary product – a fact Wyeth does not dispute. Plaintiff also relies on *Wright v. Aventis Pasteur, Inc.*, 14 A.3d 850 (Pa. Super. 2011) (en banc), a vaccine case that is of questionable precedential value after the United States Supreme Court's subsequent ruling that the National Childhood Vaccine Act preempts all "negligent design defect" claims in putative vaccine cases. *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068, 1075, 1082 (2011). *Wright* simply predicted (wrongly) that "negligent design defect" claims are not preempted, and does not stand for the more general proposition that Pennsylvania courts recognize "negligent design defect" claims in prescription drug cases.[5] Indeed, *Wright* has no applicability in this prescription drug case, because the *Wright* court based its preemption

[5] On page 26 of her brief, Plaintiff provides a partial quotation from *Wright*, suggesting that the court stated unequivocally, "comment k [to Restatement (Second) of Torts § 402A] does not outright bar all design defect claims against FDA-approved drugs." Plaintiff omitted a critical part of the quotation, which in full states: "***In a majority of states***, we note that Comment K does not outright bar all design defect claims against FDA-approved drugs." *Wright*, 14 A.3d at 874 (emphasis added). Thus, this quotation is not describing the state of Pennsylvania law, as Plaintiff appears to suggest. Rather, it simply reflects that the majority of states – unlike Pennsylvania – have not adopted comment k to apply categorically to all prescription drugs.

decision in part on the conclusion that Congress had not deemed all vaccines as a class to be "unavoidably unsafe." *See Wright*, 14 A.3d at 874, 878-80. In Pennsylvania, by contrast, this Court has continually affirmed that all prescription drugs are "unavoidably unsafe" and thus subject to comment k.

Plaintiff's reliance on non-Pennsylvania cases is similarly misplaced. Plaintiff cites *Feldman v. Lederle Laboratories*, 479 A.2d 374, 385 (N.J. 1984), for the proposition that Pennsylvania recognizes design defect claims. Pl. Br. at 22. But *Feldman* was a New Jersey case applying New Jersey law, and pre-dated New Jersey's adoption of the Products Liability Act that now governs all New Jersey product liability claims. Unlike Pennsylvania, New Jersey does not apply comment k categorically to bar strict liability claims against all prescription drug manufacturers. *See Feldman*, 479 A.2d at 385 (discussing plaintiff's strict liability claims against drug manufacturer).[6]

Plaintiff also relies on *Brown v. Superior Court*, 751 P.2d 470, 483 n.12 (Cal. 1988), for the faulty proposition that California, another jurisdiction that applies comment k to all prescription drugs, recognizes negligent design defect claims against prescription drug manufacturers. Pl. Br. at 25. The language cited by Plaintiff is *dicta*, and no subsequent reported California case has applied *Brown*'s *dicta* to permit a "negligent design defect" claim against a prescription drug manufacturer.[7]

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[6] For similar reasons, Plaintiff's reliance on *Insolia v. Philip Morris Inc.*, 216 F.3d 596 (7th Cir. 2000), is unpersuasive. *Insolia* involved cigarettes, not "unavoidably unsafe" prescription drugs, and applied Wisconsin law, which recognizes both strict liability and negligent design defect claims against manufacturers of ordinary products. *Id.* at 599, 606.

[7] The *Latex Glove* case cited by Plaintiff, Pl. Br. at 25-26, involved a medical device. *See In re Coordinated Latex Glove Litig.*, 121 Cal. Rptr. 2d 301, 312 (Cal. App. 2002) ("Of course, latex gloves, even as used in the health care field as this plaintiff did, are not prescription drugs...").

Finally, Plaintiff makes passing reference to *Toner v. Lederle Laboratories*, 732 P.2d 297 (Idaho 1987). Pl. Br. at 26. As discussed in Wyeth's Opening Brief, *Toner* stands on questionable footing in the wake of the United States Supreme Court's *Bruesewitz* decision, and Idaho, unlike Pennsylvania, does not apply comment k to all prescription drugs as a class. Opening Br. at 27. Plaintiff fails to offer any response to these points.

Nothing cited by Plaintiff affects the key points demonstrated by Wyeth in its Opening Brief:

(1) This Court has determined that all prescription drugs are "unavoidably unsafe," and consistent with that settled precedent, negligent failure to warn is the only available liability theory against a seller of a properly manufactured prescription drug;

(2) Numerous Pennsylvania lower court opinions have followed this Court's guidance and allowed only negligent failure to warn and negligent manufacturing claims to proceed against prescription drug manufacturers; and

(3) The overwhelming majority of "comment k states," like Pennsylvania prior to *Lance*, have not recognized prescription drug "negligent design defect" claims. Contrary to Plaintiff's claim, Pl. Br. at 27, Wyeth's Opening Brief cited cases from Utah and Massachusetts – two other "comment k states" – that expressly declined to recognize "negligent design defect" claims against prescription drug manufacturers. *See* Opening Br. at 32, 34. Plaintiff's brief, by contrast, cites no cases from "comment k states" expressly recognizing such claims. *See supra* at 8 (discussing *dicta* in *Brown*). Moreover, the lack of significant precedent merely underscores the radical nature of Plaintiff's "negligent design defect" claim.

2. Plaintiff's Ill-Defined "Negligent Design Defect" Claim Is Contrary To Sound Policy And Ignores Bedrock Principles Of Pennsylvania Product Liability Law.

As Wyeth showed in its Opening Brief, comment k's "unavoidably unsafe" concept, as applied by Pennsylvania courts, is fundamentally at odds with a design defect claim; the theoretical basis of a design defect claim is that the danger presented by the allegedly defective design can be avoided. Thus, imposing liability for not redesigning a product which, by definition "in the present state of human knowledge, [is] quite incapable of being made safe," amounts to absolute liability. Restatement (Second) of Torts § 402A, comment k. This result is inconsistent with long-standing Pennsylvania precedent and sound public policy. *See generally* Opening Br. at 23-24. Plaintiff does not respond to these points.

Rather, Plaintiff contends that she should be permitted to assert a "negligent design defect" claim because Redux was subsequently withdrawn from the market, well after Ms. Lance had stopped using it. This voluntary withdrawal, Plaintiff claims, conclusively establishes that Redux was defectively designed – even though Wyeth withdrew Redux because of emerging risk information regarding valvular heart disease (VHD). That condition is irrelevant in this case, where Ms. Lance allegedly developed primary pulmonary hypertension (PPH). The withdrawal of Redux had nothing to do with the well-known and conspicuously warned-of risk of PPH. Wyeth's withdrawal thus involved a risk/benefit analysis for a condition that is not at issue in this case (VHD), and it is too remote to be proximately related to the harm alleged here (PPH). The Superior Court rightly rejected an identical theory when it was asserted in a recent Diet Drug case involving negligent failure to warn claims, and this Court denied allocatur. *Cochran v. Wyeth, Inc.*, 3 A.3d 673, 680-81 (Pa. Super. 2010) ("[T]he relationship between the legal wrong (the failure to disclose the risk of VHD) and the injury (PPH) is not directly correlative and is too remote for proximate causation."), *allocatur denied*, 20 A.3d 1209 (Pa. 2011).

The same sound jurisprudential policy should apply here. If Plaintiff's theory were correct and her claim were allowed to survive, it would undeniably give rise to absolute liability any time a manufacturer voluntarily withdrew a product from the market for whatever reason. In that circumstance, a plaintiff suffering any injury from use of the withdrawn product could assert a "negligent design defect" claim, even if that plaintiff's injury had nothing to do with the reason the product was withdrawn, thereby converting manufacturers into insurers for their products.

Because Plaintiff's "negligent design defect" claim here depends on Wyeth's voluntary withdrawal of Redux after Ms. Lance stopped using the product, *see* Pl. Br. at 34, recognizing such a claim would also be contrary to Pennsylvania's well-established state of the art defense in prescription drug cases – that the defendant's conduct should be judged in relation to the state of existing knowledge at the time the plaintiff took the product, and not on subsequent scientific developments and advances.[8] Creating a tort regime that punishes manufacturers for voluntarily withdrawing products would also run counter to the longstanding rule that subsequent remedial measures, such as Wyeth's voluntary post-use withdrawal, "are inadmissible for the purpose of proving antecedent negligence." *Incollingo*, 444 Pa. at 294, 282 A.2d at 222-23.[9] Establishing a wide-ranging tort regime that is tantamount to absolute liability following a product recall, as proposed by Plaintiff, would run counter to the public policy underlying the subsequent remedial measure rule, and could discourage product withdrawals and harm the public good.

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[8] *See 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 v. Ortho Pharmaceutical Co.*, 224 Pa. Super. 418, 433-35, 307 A.2d 449, 458-59 (1973); *Mazur v. Merck & Co.*, 964 F.2d 1348, 1366-67 (3d Cir. 1992) (applying Pennsylvania law).

[9] *Accord, e.g., Duchess v. Langston Corp.*, 564 Pa. 529, 538-49, 769 A.2d 1131, 1137-42 (2001); *Pressler v. City of Pittsburgh*, 419 Pa. 440, 443-44, 214 A.2d 616, 618 (1965). Recalls, including voluntary recalls of FDA-approved products, constitute inadmissible subsequent remedial measures in negligence cases. *E.g., Pusey v. Becton Dickinson & Co.*, ___ F. Supp.2d ___, 2011 WL 2200144, at *7 (E.D. Pa. June 7, 2011) (applying Federal Rules of Evidence); *Hardin v. Upjohn Co.*, 47 Pa. D. & C. 3d 66, 68-70 (Pa. C.P. Philadelphia Co. 1986).

3. Plaintiff's Ill-Defined "Negligent Design Defect" Claim Is Inconsistent With Pennsylvania's Requirement That Plaintiffs Alleging Design Defect Plead And Prove A Feasible Alternative Design.

One of the checks on absolute liability, as established in Wyeth's Opening Brief, is Pennsylvania's requirement that plaintiffs plead and prove a feasible alternative design in design defect cases. Opening Br. at 29-33. The requirement is intended to prevent vague claims that a product must be defectively designed simply because it caused harm, which would give rise to an absolute liability regime. It also requires plaintiffs to offer more than mere speculation that the product could have been designed "better" or "safer." In the context of prescription drug litigation, however, the feasible alternative design requirement is impractical, illogical, and speculative, and provides further reason why Plaintiff's "negligent design defect" claim is contrary to Pennsylvania law. Opening Br. at 29-33.

In response, Plaintiff initially claims that Wyeth somehow waived this issue. But Wyeth, as Appellee below, did not bear the burden of issue preservation; nor did it have an obligation to guess that the Superior Court would *sua sponte* craft a novel cause of action never before recognized in Pennsylvania jurisprudence. *See Heim,* 2011 WL 1588219, at *5; *see generally supra* at 5 (discussing Plaintiff's argument that Wyeth waived issues). In fact, as soon as the Superior Court took that momentous step, Wyeth immediately raised below the same legal errors that are now on appeal to this Court. (R. 664a-668a) (arguing that court failed to consider Pennsylvania product liability principles including feasible alternative design and deference to FDA authority).

On the merits, Plaintiff argues that she has no burden to demonstrate a feasible alternative design because Redux was voluntarily withdrawn from the market after Ms. Lance stopped taking the drug, and therefore, according to Plaintiff, Redux's risks outweighed its benefits for all patients. Thus, Plaintiff contends, she bears no burden to address any specific alleged design

flaw that led to Plaintiff's alleged injury, or how that flaw could have been improved. To support the viability of this novel claim, Plaintiff cites the negligent design defect standard articulated in § 6(c) of the Restatement (Third) of Torts: Products Liability (1998). *See* § 6(c) (prescription drug not "reasonably safe due to defective design" only where reasonable health-care providers "would not prescribe the drug...for any class of patients"). But as Plaintiff explicitly acknowledges, "Section 6(c) does not accurately reflect existing Pennsylvania law, nor does plaintiff herein urge its adoption in Pennsylvania." Pl. Br. at 28. The Superior Court reached the same conclusion. *Lance v. Wyeth*, 4 A.3d 160, 169 (Pa. Super. 2010) (rejecting application of § 6(c)). Plaintiff's simultaneous reliance on and disavowal of Restatement (Third) underscores the amorphous and ill-defined nature of her "negligent design defect" claim, and further demonstrates that such a claim is contrary to Pennsylvania law.

Even in strict liability, Pennsylvania courts have refused to impose liability on the bare assertion that a product's risks outweigh its benefits – unless the plaintiff can also prove a feasible alternative design. *Goldstein v. Philip Morris Inc.*, 854 A.2d 585, 589 (Pa. Super. 2004) (no liability "merely for manufacturing a legal and regulated product with inherent risks"); *Dauphin Deposit Bank & Trust Co. v. Toyota Motor Corp.*, 408 Pa. Super. 256, 265, 596 A.2d 845, 849 (1991) ("expressly reject[ing] the application of a risk-utility approach to design-defect cases"); *Hite v. R.J. Reynolds Tobacco Co.*, 396 Pa. Super. 82, 89, 578 A.2d 417, 420 (1990) ("Pennsylvania courts have refused to recognize causes of action for products which are legal and not defectively manufactured, but inherently dangerous, except in those cases in which there has been a failure to warn"), *allocatur denied*, 527 Pa. 666, 593 A.2d 842 (1991). Thus, an alternative design "is ***an essential*** element of the plaintiff's liability case predicated on a theory of design defect." *Duchess v. Langston Corp.*, 564 Pa. 529, 559 n.24, 769 A.2d 1131, 1149 n.24 (2001) (emphasis added).

The same is true in negligent design defect cases. *See* Opening Br. at 30-31 (collecting Pennsylvania precedent holding feasible alternative design to be an essential element of negligent design in cases involving ordinary products). As Wyeth's Opening Brief established, the feasible alternative design requirement renders prescription drug "negligent design defect" claims impractical, unwarranted, and unduly speculative. Opening Br. at 30-33. Prescription drugs are different from ordinary products because the active ingredient cannot be redesigned without changing the fundamental nature of the drug and requiring renewed FDA approval. *Id.*[10] Moreover, altering the drug gives rise to a new and unique risk/benefit profile, which may have different effects on different patients. *Id.*[11]

Thus, in this context, negligent design litigation would degenerate into lengthy and expensive generalized trials of any and all product risks, regardless of whether those risks caused harm to a particular plaintiff. This is an exercise that, in the prescription drug field, and within the confines of a trial, would futilely try to duplicate and usurp the overall risk/benefit analysis conducted by FDA. *See* Brief of *Amicus Curiae* Product Liability Advisory Council, Inc., at 9-13 (hereafter "PLAC Br."). Courts and lay juries are ill-suited to adjudicate drug design claims, because it would require a wholesale, sweeping re-examination of the lengthy, technical FDA

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[10] On pages 24-25 of her brief, Plaintiff offers hypothetical design claims that she argues would be viable against prescription drug manufacturers. None of the hypotheticals resembles her claim here. Pl. Br. at 24-25. Rather, both hypotheticals involve a claim that the drug was defectively designed because of a harmful inactive ingredient. *See id.* (hypotheticals discussing unidentified "inactive ingredient," and "capsule" made from "harmful material"). Here, by contrast, Plaintiff claims that it was the active ingredient of Redux that caused injury. Wyeth could not change that active ingredient without changing the molecule itself.

[11] Plaintiff relies on *Brown*, a California case, to suggest that Wyeth is "unnecessarily restrictive" in its application of Pennsylvania's feasible alternative design standard. Pl. Br. at 35-36 (quoting *Brown v. Superior Court*, 751 P.2d 470 (Cal. 1988)). In fact, apart from being a statement on California law, as opposed to Pennsylvania law, *Brown* ultimately ***rejected*** the "risk/benefit analysis" described in the passage quoted by Plaintiff. *See id.* at 480 ("[w]e decline to hold, therefore, that a drug manufacturer's liability for injuries caused by the defective design of a prescription drug should be measured by the [risk/benefit] standard set forth in *Barker*").

approval process and the underlying studies leading to approval. *See* James A. Henderson, Jr. and Aaron D. Twerski, *Drug Designs Are Different*, 111 YALE LAW J. 151, 161 n.40 (2001) ("[I]t is beyond the competence of courts to litigate drug designs because to do so would require them to replicate the FDA approval process that stretches over many years," and because drug design "requires prolonged testing to deal with the interaction between drug toxicity and the human body and cannot be replicated in the courtroom"); *see also id.* at 167 n.71 (preapproval drug testing "require[s] extremely sophisticated and subjective interpretation and thus could present difficult inquiries beyond 'the institutional competence of common law courts'") (citation omitted). Nor can litigation experts solve these intractable problems of proof. Given the intricacies and uncertainties of FDA approval, experts cannot offer an opinion that a particular drug would or would not have been approved "without engaging in rank speculation." *Id.* at 167. Particularly here, where Plaintiff's "negligent design" theory broadly delves into all risks – including risks related to VHD, which is not at issue – such a claim would be unprecedented and unworkable, and for this reason, deference to FDA is appropriate.[12]

Moreover, deference to FDA should be at its strongest here, because Plaintiff's wide-ranging and ill-defined claim implicates FDA's basic decision of whether a drug can "lawfully" be sold. *Lance*, 4 A.3d at 167; *see also* Opening Br. at 33-36; PLAC Br. at 15-20. Safety testing and licensing of prescription medical products "is a responsibility specifically undertaken by the

[12] Plaintiff suggests that such deference is somehow contrary to *Wyeth v. Levine*, 129 S. Ct. 1187 (2009). Pl. Br. at 31. *Levine*, however, was a much different case – solely involving preemption of warning claims that this Plaintiff specifically "disclaimed any intention to assert." Pl. Br. at 7. The Supreme Court specifically limited *Levine* to the narrow question of "adequate warning," 129 S. Ct. at 1194, and based its result on the absence of any FDA preapproval requirement. *Id.* at 1198 (the "regulation permitted [defendant] to provide such a warning before receiving the FDA's approval"). Similarly, although Plaintiff cites *Tobin v. Astra Pharmaceutical Products, Inc.*, 993 F.2d 528 (6th Cir. 1993), that case involved strict liability design defect claims – which this Court has repeatedly rejected, and Plaintiff does not advocate.

federal government." *Cafazzo v. Central Medical Health Services, Inc.*, 542 Pa. 526, 535, 668 A.2d 521, 526 (1995).

This appeal presents no preemption issues, but among the considerations in deciding whether to recognize a novel negligence theory are "the consequences of imposing a duty" and "the overall public interest in the proposed solution." *Atcovitz v. Gulph Mills Tennis Club, Inc.*, 571 Pa. 580, 587, 812 A.2d 1218, 1223 (2002). That a government agency, such as FDA, has already evaluated the overall risks and benefits of a product reduces any "public interest" in having common-law juries vainly try to duplicate and second-guess that effort. Likewise the potential for conflicting risk/benefit determinations inherent in such a duplicative theory is a "consequence" that strongly counsels against its adoption.

In sum, Plaintiff's brief makes clear that her "negligent design defect" claim is very different than the typical negligent design claim asserted in an ordinary products case. In such a case, the plaintiff points to a specific error in the design of the product which, if fixed, increases the safety of that product. Here, by contrast, Plaintiff does not claim that Wyeth could have done anything to make Redux safer. Instead, Plaintiff claims that Wyeth should have simply stopped selling Redux, notwithstanding FDA approval. In this circumstance, deference to the FDA is appropriate, to prevent a wide-ranging re-examination of FDA's risk/benefit analysis and its decision to approve Redux for sale.

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For all of the foregoing reasons, as well as those stated in Wyeth's Opening Brief, the *sua sponte* decision of the Superior Court erroneously created a new "negligent design defect" theory of liability against a prescription drug manufacturer that contravenes decades of Pennsylvania jurisprudence. The Court should therefore reverse in Appeal 17 EAP 2011 and reinstate summary judgment.

APPELLANT'S BRIEF IN APPEAL NO. 18 EAP 2011

I. COUNTER-STATEMENT OF SCOPE AND STANDARD OF REVIEW

Plaintiff's appeal presents two pure questions of law. "Questions of law are subject to *de novo* review, and our scope of review is plenary." *Philomeno & Salamone v. Board of Supervisors*, 600 Pa. 407, 411, 966 A.2d 1109, 1111 (2009). The scope of review encompasses "the entire record." *Summers v. Certainteed Corp.*, 606 Pa. 294, 307, 997 A.2d 1152, 1159 (2010).

II. COUNTER- STATEMENT OF THE QUESTIONS INVOLVED

1. Did the Superior Court appropriately refuse to create a novel, independent claim, never before recognized in Pennsylvania, for "negligent failure to test" a prescription drug?

Suggested Answer: Yes.

2. Did the Superior Court appropriately refuse to create a novel, independent claim, never before recognized in Pennsylvania, for "failure to properly market" or "negligent failure to withdraw" a prescription drug?

Suggested Answer: Yes.

III. COUNTER-STATEMENT OF THE CASE

Wyeth incorporates, as its counter-statement of the case in Appeal No. 18 EAP 2011, its statement of the case in its Opening Brief in Appeal No. 17 EAP 2001, filed on May 2, 2011. *See* Opening Br. at 5-9. The following facts, however, are particularly pertinent to Plaintiff's cross-appealed claims.

FDA approved Redux as "safe and effective" for the entire time it was used by Ms. Lance. (R. 82a-95a). After three years of study, FDA "concluded that the drug product is safe and effective for use as recommended in the draft labeling," and Redux received FDA approval "for the use of this drug in the management of obesity." (R. 83a). Ms. Lance was treated with Redux between January and April 1997. (R. 17a ¶5). At all relevant times prior to and during Ms. Lance's Redux treatment, the FDA-approved labeling featured an "all capitals and bolded" warning:

> **DEXFENFLURAMINE IS AN APPETITE SUPPRESSANT, AND APPETITE SUPPRESSANTS INCREASE THE RISK OF DEVELOPING PRIMARY PULMONARY HYPERTENSION** [("PPH")], **AN OFTEN FATAL DISORDER.**

(R. 91a).

Four months after Ms. Lance discontinued Redux treatment, FDA decided against recalling Redux, denying a citizen's petition that demanded its withdrawal, and reaffirming the agency's view that Redux was safe and effective. (R. 94a-95a, 97a).

Wyeth voluntarily removed Redux from the market in September 1997. (R. 100a-01a). That action was taken in response to "new, preliminary information" concerning valvular heart

disease ("VHD"). *Id.* But Ms. Lance never developed VHD. Rather, Plaintiff claims that Ms. Lance developed PPH as a result of her treatment with Redux. (R. 18a ¶¶7-8).[13]

[13] Redux was Wyeth's trade name for the drug dexfenfluramine. (R. 83a). Although Plaintiff persists in calling it "Fen-phen," Pl. Br. at 4, that characterization is untrue, as Fen-phen was a combination of two different substances, fenfluramine and phentermine.

IV. SUMMARY OF ARGUMENT

Unable to dispute the adequacy of the explicit – in all capitals and bolded – PPH warning that accompanied Redux, Plaintiff instead asserts novel theories of liability that have never been recognized by Pennsylvania courts: for alleged "negligent failure to test" and "negligent marketing/failure to withdraw" the drug. Plaintiff states that these claims are viable under Pennsylvania law only because Redux has been withdrawn and is no longer approved by FDA. *See* Pl. Br. at 11.[14] Because Plaintiff ties her novel claims to the withdrawal of Redux, neither novel theory is based on the PPH risk that Plaintiff alleges caused injury in this case. Rather, Plaintiff's novel theories are both related to the alleged risk of VHD, a different medical condition not related to the alleged injury in this case, and the condition for which Redux was withdrawn. Thus, Plaintiff's novel theories are not properly presented in this case.

Moreover, under Pennsylvania law a manufacturer of a properly manufactured prescription drug is not liable if the manufacturer adequately warns of the risk that the plaintiff alleges caused her injury. Wyeth clearly and undeniably warned of the precise medical condition suffered by Plaintiff. Thus, the Superior Court properly affirmed dismissal of the novel theories Plaintiff advances. Those rejected theories would impose liability notwithstanding Wyeth's undisputedly adequate warnings. Overwhelming precedent rejects any separate cause of action based solely on alleged failure to test a product. While deficient testing can be evidence in support of traditional claims involving negligent warnings, manufacture, or design (in the case of a non-prescription drug), a lack of testing, standing alone, does not cause compensable injury or state a legally cognizable claim. Thus, courts correctly treat allegations concerning testing procedures as "subsumed" by traditional product liability claims.

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[14] Plaintiff thus concedes that any "negligent failure to test" or "negligent marketing/failure to withdraw" claim cannot be viable where the prescription drug remains on the market and approved by FDA. Pl. Br. at 11, 40, 45.

Finally, no jurisdiction recognizes Plaintiff's claim that would impose liability simply because Wyeth continued to market its FDA-approved drug. This Court has previously held that a claim for "negligent marketing" is a variation of a traditional failure to warn claim; it is cognizable only where the plaintiff alleges that the defendant engaged in "overpromotion" so as to negate otherwise sufficient warnings. *Baldino v Castagna*, 505 Pa. 239, 244, 478 A.2d 807, 810 (1984); *Incollingo v. Ewing*, 444 Pa. 263, 288, 282 A.2d 206, 220 (1971). Plaintiff does not raise any such allegations in this case. Rather, she claims Wyeth was "negligent" for ever manufacturing and marketing Redux at all. Pennsylvania product liability law has rightly rejected any form of absolute liability.

For many of the same reasons, no jurisdiction has imposed a common-law duty to remove or recall a legal product from the market – much less a prescription drug enjoying FDA approval. In addition to being a transparent form of absolute liability, failure to withdraw/recall claims exceed the proper function of the tort system by trying to regulate what products can be legally sold. Courts throughout the nation correctly recognize that product liability amounting to a product ban would be an unwise intrusion into policy-laden questions better left to other branches of government. With respect to prescription drugs, courts have deferred to FDA on the question of whether or not such drugs should be made available to the public.

This Court's forty-plus years of precedent in prescription drug product liability cases has gotten it right. Where, as here, a manufacturer has adequately warned of the inherent risks of its "unavoidably unsafe," prescription-only product, it is not subject to liability simply because those inherent risks exist.

V. ARGUMENT

A. THE SUPERIOR COURT CORRECTLY REFUSED TO EXPAND PENNSYLVANIA LAW AND RECOGNIZE "NEGLIGENT FAILURE TO TEST" AS A SEPARATE CAUSE OF ACTION INDEPENDENT OF A CLAIM FOR FAILURE TO WARN OR NEGLIGENT MANUFACTURE.

Pennsylvania law has never allowed an independent cause of action for "failure to test," and Plaintiff provides the Court with no sound grounds for expanding product liability law and creating that novel cause of action in cases involving a prescription drug that has been withdrawn or recalled from the market.[15] Pennsylvania is squarely in the legal mainstream in refusing to recognize a testing-related theory of liability separate from traditional product liability claims.

This Court previously considered an independent "failure to test" claim in *Viguers v. Philip Morris USA, Inc.*, 584 Pa. 120, 881 A.2d 1262 (2005), in which it unanimously affirmed the Superior Court's refusal to recognize such a theory in a *per curiam* order. *See Viguers v. Philip Morris USA, Inc.*, 837 A.2d 534 (2003).[16]

The Superior Court in *Viguers* explicitly rejected any separate duty to test, holding that "the claim for 'negligent failure to test' is not a viable cause of action recognized by our courts[.]" 837 A.2d at 541. "Failure to test" allegations, instead of being an independent tort, are entirely "subsumed" within other recognized legal theories, such as negligent failure to warn.

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[15] Plaintiff does not advocate for the creation of a "negligent failure to test" cause of action in all prescription drug cases, but only in those cases where the drug at issue has been withdrawn or recalled. *See* Pl. Br. at 40 ("[T]his Court should hold that a plaintiff may assert a negligent failure to test claim under Pennsylvania law as the result of having been injured by ingesting a drug that the FDA later determined was too unsafe to be offered for sale to anyone.").

[16] While a *per curiam* affirmance is not binding precedent as to "the rationale employed by the lower court," it does signify the Court's agreement with the Superior Court's "final disposition of the matter" in *Viguers* – which included the outright dismissal of an identical "failure to test" theory as a matter of law. *See Commonwealth v. Tilghman*, 543 Pa. 578, 588-89, 673 A.2d 898, 903-04 (1996) (explaining precedential value of the Court's *per curiam* orders of affirmance).

Lance, 4 A.3d at 169. The Superior Court correctly followed existing Pennsylvania law when it refused to expand liability and create a new cause of action for "negligent failure to test."

Plaintiff does not address or cite *Viguers*. Instead, she relies on a 1973 Third Circuit decision that sought to predict Pennsylvania law. Pl. Br. at 37-38. That case, *Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132 (3d Cir. 1973), is not binding on any Pennsylvania court and does not create a "conflict" with settled Pennsylvania law. *See Kapres v. Heller*, 536 Pa. 551, 557 n.6, 640 A.2d 888, 891 n.6 (1994).

Moreover, *Hoffman* did not consider and did not recognize a novel ***independent*** tort of "negligent failure to test," as Plaintiff contends. *See* 485 F.2d at 134 (testing allegations made in support of broader failure-to-warn claim). Rather, *Hoffman* stands for the unremarkable proposition that a manufacturer may be liable for failure to warn where "adequate testing would have disclosed potentially harmful side effects," and thus those risks should have been known to the manufacturer and conveyed to the doctor as learned intermediary. *Hoffman*, 485 F.2d at 141; *see also id.* at 140 n.26 (defendant's knowledge of risk but failure "to use reasonable care to warn of the danger, is most persuasive"). Unlike *Hoffman*, where the plaintiff claimed the manufacturer failed to disclose potentially harmful side effects, Plaintiff here, faced with an explicit, all-caps PPH warning (R. 91a), deliberately refrained from asserting any warning claim at all.

Since *Hoffman*, the Third Circuit has predicted that Pennsylvania law would ***not*** recognize an independent "negligent failure to test" claim because "no authority . . . establishes the principle that a manufacturer has a general duty to test its product." *Oddi v. Ford Motor Co.*, 234 F.3d 136, 143-44 (3d Cir. 2000). A failure to test claim cannot exist independently from a claim for failure to warn, negligent manufacture, or, in a case involving an ordinary product, design defect, because the cause of injury is not the lack of testing, but rather some condition in

the product that adequate testing allegedly would have prevented. All recent Pennsylvania precedent is in accord. *See Ashton v. Aventis Pasteur, Inc.*, 2003 WL 21361355, at *6 (Pa. C.P. Philadelphia Co. May 22, 2003) ("negligent failure to test is not an independent tort under Pennsylvania law"), *aff'd mem.*, 851 A.2d 908 (Pa. Super. 2004); *In re N Phenylpropanolamine Litigation*, 2002 WL 244858, at *1 (Pa. C.P. Philadelphia Co. Feb. 5, 2002) ("[n]o such independent tort [for negligent failure to test] exists"); *Wolfe v. McNeil-PPC, Inc.*, 773 F. Supp. 2d 561, 570 (E.D. Pa. 2011) ("Pennsylvania does not recognize a tort for negligent failure to test," and testing claims "are subsumed within" traditional defect theories); *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 318 n.32 (E.D. Pa. 2007) ("[u]nder Pennsylvania law, an inadequate testing claim does not support an independent claim for relief . . . under a negligence theory."); *Stitt v. Philip Morris Inc.*, 245 F. Supp. 2d 686, 694 (W.D. Pa. 2002) ("Pennsylvania law . . . does not recognize an independent cause of action for negligent testing"); *LaBelle v. Philip Morris Inc.*, 243 F. Supp. 2d 508, 519 n.12 (D.S.C. 2001) ("Pennsylvania law has not explicitly recognized an independent tort for 'negligent failure to test'"); *Shires v. Celotex Corp.*, 1988 WL 1001970, at *2 (E.D. Pa. March 30, 1988) ("[a]ny duty defendants may have had to test their [product] would appear to be logically subsumed within plaintiff's defective design or defective manufacture claims").

Plaintiff's brief fails even to cite – let alone address – any of this on-point precedent, even though it forms the foundation of the Superior Court's correct decision. Pl. Br. at 36-40. Instead, Plaintiff relies primarily on the Third Circuit's inapposite *Hoffman* decision. The other authority advanced by Plaintiff and her *amici* similarly did not involve the novel, stand-alone "failure to test" claim Plaintiff advocates. *Leibowitz v. Ortho Pharmaceutical Corp.*, 224 Pa. Super. 418, 307 A.2d 449 (1973), was, like *Hoffman*, a failure-to-warn case. *Id.* at 430, 307 A.2d at 457 (1973) (the "gravamen" of plaintiff's case was that the defendant "failed to

adequately warn"). Nothing in *Leibowitz* created a freestanding cause of action for "failure to test." *Id.* at 434-35, 307 A.2d at 459. *Foley v. Pittsburgh-Des Moines Co.*, 363 Pa. 1, 68 A.2d 517 (1949), cited only by *amici*, applied Ohio substantive law, not Pennsylvania substantive law, *id.* at 9-10, 32, 68 A.2d at 521-22, 532, and was a negligence action in which "responsibility for the design of the tank" that ruptured was established by the defendant's failure to test the tank's steel for suitability under cryogenic conditions. *Id.* at 15-16, 68 A.2d at 524. Again, there was no separate cause of action for "failure to test" in *Foley*. And *Romah v. Hygienic Sanitation Co.*, 705 A.2d 841 (Pa. Super. 1997), *aff'd per curiam*, 558 Pa. 378, 737 A.2d 249 (1999), cited by Plaintiff, is not relevant. While a separate testing-related claim may have been pleaded in *Romah*, the only issue on appeal was federal preemption. *Romah* did not address the viability of such a claim under Pennsylvania law, and pre-dated the Superior Court's specific rejection of a "failure to test" claim in *Viguers*. Finally, Restatement (Second) of Torts §395, comment e (1965), only discusses testing in terms of "failure to exercise care in manufacture."

Taken together, *Foley*, *Leibowitz*, *Hoffman*, *Romah* and Restatement §395, comment e, do not advance in the slightest Plaintiff's advocacy of a ***separate*** cause of action for "negligent failure to test." To the contrary, they illustrate the correctness of the points Wyeth has made throughout this litigation: Allegations of inadequate testing are evidentiary. Such evidence may be used in prescription drug cases to support claims for inadequate warning or inadequate manufacturing. Inadequate testing does not alone create liability, nor does it comprise a legally cognizable cause of action. Lack of testing does not cause harm. Rather, the potential for harm – and thus the claim available to a plaintiff – occurs only if inadequate tests allow some inadequacy in warning or manufacture to persist when proper product testing would have prevented it. As the Superior Court correctly concluded, any allegations of inadequate testing are "subsumed within [Plaintiff's] other claims." *Lance*, 14 A.3d at 169.

In not allowing an independent cause of action for "negligent failure to test," Pennsylvania law is squarely in the mainstream of modern product liability jurisprudence. Numerous courts in literally dozens of states have determined separate testing claims to be superfluous because lack of testing only causes injury if giving rise to warning, design, or manufacturing defects. For example, the Supreme Court of South Carolina recently rejected independent "failure to test" claims in *Branham v. Ford Motor Co.*, holding:

> [Defendant] asserts there is no separate "failure to test claim" apart from the duty to design and manufacture a product that is not defective and unreasonably dangerous. We agree, for if a product is not in a defective condition unreasonably dangerous to the user, an alleged failure to test cannot be the proximate cause of an injury.

701 S.E.2d 5, 9 (S.C. 2010); *see also Moore v. Ford Motor Co.*, 332 S.W.3d 749, 761 (Mo. 2011) ("What tests [the defendant] may or may not have run . . . would not have provided an alternative theory of recovery."); *Oxford v. Foster Wheeler LLC*, 99 Cal. Rptr. 3d 418, 435 (Cal. App. 2009) ("[e]ven if defendant failed in this respect, there could be no causation of injury or recovery for such failure if there was no defect in the product"), *review denied* (Cal. Dec 2, 2009); *Green v. General Motors Corp.*, 709 A.2d 205, 216 (N.J. Super. App. Div. 1998) ("a failure to test or of inadequate testing may be evidential . . . but it is not in itself proof of a separate basis for liability"), *certif. denied*, 718 A.2d 1210 (N.J. 1998); *Pennington v. Vistron Corp.*, 876 F.2d 414, 419 n.6 (5th Cir. 1989) (negligent failure to test "is . . . not actionable per se, but instead is a variation of the failure to warn theory") (applying Louisiana law). Thus, the Superior Court's rejection of a separate claim for "negligent failure to test" conforms to a nationwide legal consensus.[17]

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[17] *See, e.g., Theriot v. Danek Medical, Inc.*, 168 F.3d 253, 256 (5th Cir. 1999) (plaintiff "is arguing that he should be permitted to proceed to trial if [defendant] cannot demonstrate that it adequately tested its product"; "no basis in [Louisiana] law for such a rule"); *Skotak v. Tenneco Resins, Inc.*, 953 F.2d 909, 912 n.5 (5th Cir. 1992) ("negligence claims, such as the alleged failure to adequately test [the product], are subsumed within" a failure to warn claim) (applying

Under the law of Pennsylvania, which in this respect is entirely consistent with overwhelming precedent from around the country, the Superior Court was manifestly correct in concluding that no separate, free-standing product liability claim for "negligent failure to test"

Texas law), *cert. denied*, 506 U.S. 832 (1992); *Rodriguez v. Stryker Corp.*, 2011 WL 31462, at *9-10 (M.D. Tenn. Jan. 5, 2011) ("it is clear that there is no broadly recognized 'duty to test' in Tennessee"); *Torkie-Tork v. Wyeth*, 757 F. Supp. 2d 567, 572 (E.D. Va. 2010) ("a manufacturer's duty to warn of a product's dangers imposes no underlying duty to conduct additional studies or tests"); *Sykes v. Bayer Pharmaceuticals Corp.*, 548 F. Supp. 2d 208, 215 (E.D. Va. 2008) (entering judgment on the pleadings against failure to test claim as not recognized under Virginia law); *Vanderwerf v. SmithKlineBeecham Corp.*, 529 F. Supp. 2d 1294, 1305 n.15 (D. Kan. 2008) ("plaintiffs' testing claims are subsumed in plaintiffs' warning claims because their theory is that proper testing would have resulted in more adequate warnings"), *appeal dismissed*, 603 F.3d 842 (10th Cir. 2010); *Latiolais v. Merck & Co.*, 2007 WL 5861354, at *3 n.1 (C.D. Cal. Feb. 6, 2007) (failure to test "liability theory is subsumed by the manufacturer's duty to warn"), *aff'd*, 302 Fed. Appx. 756 (9th Cir. 2008); *Graham v. Medtronic, Inc.*, 2006 WL 2194012, at *2 (M.D. Fla. Aug. 2, 2006) (dismissing claims that "attempt to assert a cause of action for negligent failure to inspect and test the device"); *In re Prempro Prods. Liab. Litig.*, 2006 WL 1981902, at *4 (E.D. Ark. July 13, 2006) ("'failure to test' claim is simply a component of [plaintiff's] failure to warn and negligence claims," not an "independent cause of action"); *Miller v. Pfizer Inc.*, 196 F. Supp. 2d 1095, 1124 n.97 (D. Kan. 2002) ("duty to warn and the duty to test are, for all practical purposes, coextensive"), *aff'd*, 356 F.3d 1326 (10th Cir.), *cert. denied*, 543 U.S. 917 (2004); *Linsley v. C.R. Bard, Inc.*, 2000 WL 343358, at *6 (E.D. La. Mar. 30, 2000) (plaintiff's "only . . . argument [is] that [defendant] did not adequately test its product"; summary judgment granted); *Clark v. Danek Medical, Inc.*, 1999 WL 613316, at *3 n.4 (W.D. Ky. March 29, 1999) ("inadequate testing" claim is "subsumed" by warning claim).

Accord Patton v. Country Condo Ass'n, 2000 WL 33728374, at *4 (Ill. App. July 7, 2000) ("[w]here plaintiffs alleged a failure to test, they have alleged an incomplete tort. The failure to test is not a negligent act in itself"), *appeal denied*, 742 N.E.2d 330 (Ill. 2000); *Smith v. Daimlerchrysler Corp.*, 2002 WL 31814534, at *5 (Del. Super. Nov. 20, 2002) ("[i]n Delaware, there is no separate cause of action for failure to test or inspect in a products action"); *Villegas v. Deere & Co.*, 135 Fed. Appx. 279, 281 (11th Cir. 2005) ("Georgia does not recognize a cause of action for negligent testing"); *McSwain v. Sunrise Medical, Inc.*, 689 F. Supp. 2d 835, 848 (S.D. Miss. 2010) ("the negligence claim for failure to conduct adequate testing . . . would be subsumed"); *Tuosto v. Philip Morris USA Inc.*, 672 F. Supp. 2d 350, 354 n.2 (S.D.N.Y. 2009) ("'failure to test' is not a cognizable claim under New York products liability law"); *Solo v. Trus Joist MacMillan*, 2004 WL 524898, at *13 n.26 (D. Minn. March 15, 2004) ("duty to test . . . is not a separate cause of action under Minnesota law"); *Messer v. Amway Corp.*, 210 F. Supp. 2d 1217, 1234 (D. Kan. 2002) (negligent testing claim is variant of failure to warn), *aff'd* 106 Fed. Appx. 678 (10th Cir. 2004); *McClain v. Metabolife International, Inc.*, 193 F. Supp. 2d 1252, 1257 (N.D. Ala. 2002) ("[p]laintiffs have not directed the Court's attention to a single authority supporting the maintenance of such a [duty to test] claim under Alabama law"); *Neri v. R.J. Reynolds Tobacco Co.*, 2000 WL 33911224, at *19 (N.D.N.Y. Sept. 28, 2000) ("no case law to support the existence of a separate claim for negligent testing").

exists. Rather, inadequate testing allegations are subsumed within a negligent failure to warn claim – which in this case, Plaintiff declined to pursue because at all relevant times, Redux contained a conspicuous warning about the risk of PPH. Thus, this Court should affirm. Plaintiff's final argument, Pl. Br. at 39-40, seeks to use testing-related allegations to support a purported claim for "negligent marketing/failure to withdraw" (Redux should "not [be] offered for sale"), so Wyeth now turns to that ostensible claim.

B. THE SUPERIOR COURT CORRECTLY REFUSED TO EXPAND PENNSYLVANIA LAW AND RECOGNIZE A NOVEL CAUSE OF ACTION FOR "NEGLIGENT MARKETING/FAILURE TO WITHDRAW."

Plaintiff also advocates creating a new cause of action that would impose absolute liability on Wyeth simply because it sold a prescription drug that Plaintiff claims should have been removed from the market altogether. Sometimes she describes this claim as "negligent marketing," Pl. Br. at 42-43; elsewhere she calls it "negligent failure to withdraw" Wyeth's drug from the market. *Id.* at 43-45. Any distinction is without a difference, because both theories seek the same radical result: imposition of blanket liability merely because Wyeth sold Redux, an FDA-approved drug that was later withdrawn from the market.[18]

Plaintiff wholly lacks support for her novel "negligent marketing/failure to withdraw" claim. Pennsylvania courts have never recognized a cause of action for "negligent failure to withdraw" a prescription drug, and Plaintiff cites no case from any jurisdiction that recognizes such a claim. The only case cited, *Wyeth v. Levine*, does not, as Plaintiff appears to suggest, recognize that a "negligent failure to withdraw" is cognizable. Pl. Br. at 44. *Wyeth* does not mention "negligent failure to withdraw" or "negligent marketing" claims at all, but rather

[18] Just as is the case with Plaintiff's "negligent design defect" and "negligent failure to test" claims, Plaintiff's "negligent marketing/negligent failure to withdraw" claim is dependent on the fact that Redux is no longer approved for sale. Pl. Br. at 41-46. Thus, this novel claim would not be available in those cases where the prescription drug was still approved by FDA.

analyzes the question of whether negligent failure to warn claims are preempted. The portion of the opinion cited by Plaintiff simply finds that state tort laws complement FDA's regulatory scheme, and does not support Plaintiff's argument that this Court should create a new "negligent failure to withdraw" claim. *See Wyeth v. Levine*, 129 S. Ct. 1187, 1202 (2009).

Further, this Court has already held that "negligent marketing" claims are cognizable in the prescription drug context only where the prescription drug seller "promoted its product in such a way to nullify printed warnings," and thus failed adequately to warn about the risks associated with the drug. *Baldino*, 505 Pa. at 244, 478 A.2d at 810. Plaintiff does not make any "overpromotion" claim in this case, and similarly does not assert a failure to warn claim.

Rather than acknowledging the express limitations placed on "negligent marketing" claims by this Court, Plaintiff instead cites an inapposite Sixth Circuit case, *Tobin v. Astra Pharmaceuticals*, 993 F.2d 528 (6th Cir. 1993). *Tobin* was a prediction of Kentucky law, and analyzed the viability of a strict liability claim against a prescription drug manufacturer. Therefore, *Tobin* had nothing to do with negligent marketing claims, and is not relevant in this case where strict liability claims are not available.[19]

Plaintiff's novel "negligent marketing/failure to withdraw" claim seeks to impose "absolute liability" on Wyeth simply for selling an FDA-approved drug that allegedly caused injury. This claim is contrary to Pennsylvania policy, contrary to the law of Pennsylvania, and out of step with the law across the country.

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[19] Moreover, subsequent to *Tobin*, the Kentucky Supreme Court interpreted comment k to bar strict liability in prescription drug cases where proper warnings are given. "[T]he fact that a particular drug might produce unfortunate side effects makes it 'unavoidably unsafe' but not '***unreasonably*** dangerous,' and strict liability will not obtain if proper warning is given, where the situation calls for it." *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 761 (Ky. 2004) (applying Restatement §402A, comment k) (emphasis original). *Tobin*'s analysis of a strict liability prescription drug claim thus does not reflect the current state of Kentucky law, as enunciated by that state's highest court.

1. Pennsylvania Law Does Not, And Should Not, Impose Liability For "Negligent Marketing" Where The Claim Asserts That The Product Should Not Be Marketed At All.

Plaintiff explains her "negligent marketing" theory: that a "prudent manufacturer knowing all of the risks would not market" its product. Pl. Br. at 43 (citation and quotation marks omitted). No matter what the stated theory, however, the liability of a product manufacturer in Pennsylvania has never amounted to "absolute" or "insurer" liability. Product liability, even in its strictest form, "was not intended to make [a manufacturer] an insurer of all injuries caused by the product." *Azzarello v. Black Brothers Co.*, 480 Pa. 547, 553, 391 A.2d 1020, 1024 (1978) (footnote omitted). The first time the Court ever encountered a product liability claim involving a prescription drug, it presciently stated:

> If those who make and compound drugs and medicines in packages or bottles, under the strict conditions prescribed by the [predecessor of the Food, Drug, and Cosmetic Act] for use by the public, can be ***mulcted in damages every time some person uses such drugs or medicines with harmful results***, the making and selling of such products would be a most pecuniarily hazardous enterprise.

Henderson v. National Drug Co., 343 Pa. 601, 610, 23 A.2d 743, 748 (1942) (rejecting strict liability in the guise of warranty law) (emphasis added). Since *Henderson*, this Court has reiterated its opposition to absolute product liability theories over and over again. *See* Opening Br. at 23-24 (collecting cases).

Plaintiff relies on comment k language to suggest that there exists an independent cause of action for "negligent marketing," Pl. Br. at 42, but does not acknowledge that this Court has already defined the limited nature of any such "overpromotion" claim. *See Baldino*, 505 Pa. at 244, 478 A.2d at 810 ("negligent marketing" cognizable only where the prescription drug seller "promot[ed] its product in such a way as to nullify printed warnings"); *Incollingo*, 444 Pa. at 289, 282 A.2d at 220 ("[a]ction designed to stimulate the use of a potentially dangerous product must be considered in testing the adequacy of a warning"). Plaintiff's novel "negligent

marketing" claim – a claim that Wyeth should never have sold Redux – is not a claim for overpromotion, it is a claim that Wyeth is liable simply because it chose to sell an FDA-approved drug.

Plaintiff's claim that ***any and all*** marketing of Redux was inherently "negligent" because the drug should not have been sold at all is entirely unprecedented. *See* Pl. Br. at 42-43. In fact, the Superior Court properly rejected it as an improper strict liability design defect claim in disguise. *Lance*, 4 A.3d at 165. There is no sound basis to disturb the Superior Court's correct ruling on this "negligent marketing" claim.

2. Pennsylvania Does Not, And Should Not, Impose Liability For Negligent Failure To Withdraw Or Recall A Product.

The Superior Court also correctly refused to credit Plaintiff's absolute liability arguments when presented in the guise of "negligent failure to withdraw from the market." *Lance*, 4 A.3d at 167. Neither Plaintiff nor her *amici* cite any precedent allowing a jury to impose liability upon an FDA-regulated manufacturer for not removing its FDA-approved product from the market.

This is the first case in Pennsylvania to litigate a pure "negligent failure to withdraw" claim. Pennsylvania courts have, however, repeatedly rejected a related "duty" involving failure to "retrofit" a product – that is, to remove existing products (or parts of them) and replace them with improved versions. In *Lynch v. McStome*, 378 Pa. Super. 430, 548 A.2d 1276 (1988), the plaintiff claimed that once an alternative safer design became available, the defendant manufacturer had a duty to remove the old models and replace them with the newer design. The court rejected any such "broad duty" that would hold "the manufacturer negligent if it does not retrofit its already sold products." *Id.* at 440, 548 A.2d at 1281. The Third Circuit, applying Pennsylvania law, agreed. *Habecker v. Copperloy Corp.*, 893 F.2d 49, 54 (3d Cir. 1990) ("no Pennsylvania case has recognized a duty to retrofit, and . . . such a duty would be inappropriate under established principles of Pennsylvania law").

Moreover, as the Superior Court acknowledged, courts nationwide have rejected similar claims that would impose liability for failure to remove a product from the market. *Lance*, 4 A.3d at 167 (citing *Ramirez v. Plough, Inc.*, 863 P.2d 167, 177-78 (Cal. 1993); *Ford Motor Co. v. Reese*, 684 S.E.2d 279, 283-85 (Ga. App. 2009); *Stanger v. Smith & Nephew, Inc.*, 401 F. Supp. 2d 974, 982 (E.D. Mo. 2005)). In *Ramirez*, the plaintiff asserted liability for failure to recall aspirin because, allegedly, "the risks of Reye's syndrome clearly outweighed any benefit to be derived from the product." *Id.* at 177. The California Supreme Court held that, unless and until the FDA reached that conclusion and ordered a recall, there was no basis for product liability based merely on the continued sale of the product:

> We conclude, however, as a matter of law, that defendant may not be held liable for failing to withdraw its product from the market. . . . A few scientific studies had shown an association between [the product] and [the condition] but the methodology of those studies had been questioned and the FDA had determined that further studies were needed to confirm or disprove the association. Pending completion of those studies, 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.***

863 P.2d at 177-78 (emphasis added).

Ramirez thus gave the same sort of "deference" to FDA decisions about whether approved products should remain available to the public as the Superior Court did here. In this case, undisputed facts demonstrate that: (1) FDA found Redux "safe and effective," despite its PPH risk, provided the drug carried a conspicuous PPH warning (which it did); (2) even after the use of Redux in this case had ended, FDA denied a citizen's petition seeking to remove Redux from the market; and (3) FDA never believed that the PPH risk warranted a recall, but a different risk, VHD, not at issue in this litigation, prompted Wyeth's voluntary withdrawal of Redux from the market. (R. 91a-92a, 94a-95a, 97a, 100a-101a). Plaintiff's claim is thus more extreme than the "failure to withdraw" claim dismissed in *Ramirez*, since the eventual removal of Redux from the market had nothing to do with the claimed injuries in this case.

In *Stanger* the court reached the same result where, as here, the defendant ultimately removed the product in question – an FDA-approved medical device – from the market voluntarily. The court held that without prior action by FDA, it would be improper to impose a common-law tort obligation to remove a product from the market:

> [T]here is no cause of action for negligent recall. "There is no indication, by case law, statute, or otherwise, that ... create[s] a common law duty to recall. Moreover, in light of the fact that there is no recognized duty to recall, we hold such a duty cannot arise as a result of defendant's voluntary undertaking to recall certain of its products.... [I]n order for [plaintiffs] to pursue a negligent recall claim, the defect in the product would have had to exist at the time the product left defendant's control and entered the stream of commerce." Absent a mandated recall by a governmental agency, defendants had no duty to recall.

401 F. Supp. 2d at 982 (quoting *Horstmyer v. Black & Decker (US) Inc.*, 151 F.3d 765, 773-74 (8th Cir. 1998)); *see also Yarbrough v. Actavis Totowa, LLC*, 2010 WL 3604674, at *4 (S.D. Ga. Sept. 13, 2010) ("product sellers are not required to issue recalls for defective products"); *Nat'l Women's Health Network, Inc. v. A. H. Robins Co.*, 545 F. Supp. 1177, 1180 (D. Mass. 1982) ("[n]o court has ever ordered a notification and recall campaign on the basis of state law"). No court, anywhere in the country, has imposed liability for failure to recall a product that was being marketed with FDA approval at the time of the alleged product use.

Overall, courts in 24 states – and the highest courts of California, New York, Michigan, Kentucky, Iowa, Kansas, and Hawaii – have considered whether to permit product liability claims alleging that defendants were obligated under common law to remove products from the market prior to any formal recall decision. Such purported "duties" have been rejected each and every time:

- ***Alaska***: *Nelson v. Original Smith & Wesson Business Entities*, 2010 WL 7125186, at *3-4 (D. Alaska May 18, 2010), *reconsideration denied*, 2010 WL 7125187 (D. Alaska June 14, 2010).
- ***California***: *Ramirez*, 863 P.2d at 177-78.
- ***Delaware***: *Smith v. Daimlerchrysler Corp.*, 2002 WL 31814534, at *6 (Del.

Super. Nov. 20, 2002).

- ***Florida***: *Thomas v. Bombardier Recreational Products, Inc.*, 682 F. Supp. 2d 1297, 1302 (M.D. Fla. 2010).

- ***Georgia***: *Ford Motor Co. v. Reese*, 684 S.E.2d 279, 283-85 (Ga. App. 2009), *cert. denied* (Ga. Feb. 8, 2010); *Yarbrough*, 2010 WL 3604674, at *4.

- ***Hawaii***: *Tabieros v. Clark Equipment Co.*, 944 P.2d 1279, 1301 (Haw. 1997) ("it is unnecessary and unwise to impose or introduce an additional duty to retrofit or recall a product separate and apart from those duties to which manufacturers are already subject").

- ***Illinois***: *Rogers v. Clark Equipment Co.*, 744 N.E.2d 364, 370 (Ill. App. 2001), *appeal denied*, 754 N.E.2d 1292 (Ill. 2001); *Modelski v. Navistar International Transportation Corp.*, 707 N.E.2d 239, 247-48 (Ill. App. 1999); *Smith v. BOC Group PLC*, 2001 WL 477237, at *5 (N.D. Ill. May 4, 2001); *Moorehead v. Clark Equipment Co.*, 1987 WL 26158, at *2-3 (N.D. Ill. Dec. 2, 1987).

- ***Iowa***: *Lovick v. Wil-Rich*, 588 N.W.2d 688, 696 (Iowa 1999) (affirming jury instruction that defendant "had no duty to recall or retrofit"); *Burke v. Deere & Co.*, 6 F.3d 497, 508 n.16 (8th Cir. 1993) (applying Iowa law).

- ***Kansas***: *Patton v. Hutchinson Wil-Rich Manufacturing Co.*, 861 P.2d 1299, 1315 (Kan. 1993) ("product recalls are properly the business of administrative agencies as suggested by the federal statutes"); *Kinser v. Gehl Co.*, 184 F.3d 1259, 1270 (10th Cir. 1999) (applying Kansas law).

- ***Kentucky***: *Ostendorf v. Clark Equipment Co.*, 122 S.W.3d 530, 534 (Ky. 2003) ("[p]roduct recalls, however, are properly the province of administrative agencies").

- ***Massachusetts***: *Nat'l Women's Health Network*, 545 F. Supp. at 1181.

- ***Michigan***: *Gregory v. Cincinnati Inc.*, 538 N.W.2d 325, 333-34 (Mich. 1995) ("we are persuaded that it is unnecessary and unwise to impose or introduce an additional duty to retrofit or recall a product"); *Eschenburg v. Navistar Int'l Transp. Corp.*, 829 F. Supp. 210, 214-15 (E.D. Mich. 1993).

- ***Minnesota***: *Kladivo v. Sportsstuff, Inc.*, 2008 WL 4933951, at *5 (D. Minn. Sept. 2, 2008); *Hammes v. Yamaha Motor Corp.*, 2006 WL 1195907, at *11 (D. Minn. May 4, 2006); *Berczyk v. Emerson Tool Co.*, 291 F. Supp. 2d 1004, 1016 (D. Minn. 2003); *McDaniel v. Bieffe USA, Inc.*, 35 F. Supp. 2d 735, 743 (D. Minn. 1999).

- ***Mississippi***: *Murray v. General Motors*, 2011 WL 52559, at *2 (S.D. Miss. Jan. 7, 2011).

- ***Missouri***: *Horstmyer v. Black & Decker (U.S.), Inc.*, 151 F.3d 765, 773-74 (8th

Cir. 1998) (applying Missouri law); *Smith v. Firestone Tire & Rubber Co.*, 755 F.2d 129, 135 (8th Cir. 1985) (applying Missouri law); *Stanger*, 410 F. Supp. 2d at 982; *Efting v. Tokai Corp.*, 75 F. Supp. 2d 1006, 1011 (W.D. Mo. 1999); *Davidson v. Besser Co.*, 70 F. Supp. 2d 1020, 1027 (E.D. Mo. 1999).

- ***New Jersey***: *Leslie v. United States*, 986 F. Supp. 900, 913 (D.N.J. 1997), *aff'd mem.*, 178 F.3d 1279 (3d Cir. 1999).

- ***New Mexico***: *Morales v. E.D. Etnyre & Co.*, 382 F. Supp. 2d 1285, 1287 (D.N.M. 2005).

- ***New York***: *Adams v. Genie Industries, Inc.*, 929 N.E.2d 380, 385 (N.Y. 2010) ("[w]e have never imposed a post-sale duty to recall or retrofit a product").

- ***North Dakota***: *Eberts v. Kawasaki Motors Corp., U.S.A.*, 2004 WL 224683, at *2-3 (D.N.D. Feb. 2, 2004).

- ***South Carolina***: *Bragg v. Hi-Ranger, Inc.*, 462 S.E.2d 321, 331 (S.C. App. 1995), *cert. denied* (S.C. Nov. 20, 1996).

- ***South Dakota***: *Robinson v. Brandtjen & Kluge, Inc.*, 2006 WL 2796252, at *8 (D.S.D. Sept. 27, 2006), *aff'd* 500 F.3d 691 (8th Cir. 2007).

- ***Tennessee***: *Spence v. Miles Laboratories, Inc.*, 810 F. Supp 952, 959 (E.D. Tenn. 1992).

- ***Texas***: *Syrie v. Knoll Int'l*, 748 F.2d 304, 311-12 (5th Cir. 1984) (applying Texas law); *Guizhi v. Bell Helicopter Textron, Inc.*, 1997 WL 786494, at *3 n.4 (N.D. Tex. Dec. 16, 1997); *Hernandez v. Ford Motor Co.*, 2005 WL 1574474, at *1 (S.D. Tex. June 28, 2005); *Flock v. Scripto-Tokai Corp.*, 2001 WL 34111725, at *8-9 (S.D. Tex. Sept. 11, 2001).

- ***Washington***: *Bear v. Ford Motor Co.*, 2007 WL 870344, at *3 (E.D. Wash. March 20, 2007).

Plaintiff offers no legal basis for imposing absolute liability through a novel cause of action for "negligent failure to withdraw." Her only argument is that, when a drug (or, presumably, any product) is later withdrawn or recalled, it is appropriate to impose absolute liability for every injury ever caused by that product – even when the injury (here, PPH) is not the reason that the product was withdrawn (here, VHD). As Wyeth has already noted, *supra*, at 11, such *ex post facto* reasoning – in addition to allowing absolute liability – violates two other established tenets of Pennsylvania product liability: (1) the state of the art defense applicable to

negligence actions generally, and to prescription drug litigation in particular; and (2) the prohibition against liability resulting from subsequent remedial measures. The law should encourage manufacturers to withdraw products voluntarily even before evidence of risk has become conclusive. Imposing retroactive absolute liability on the manufacturer of any product voluntarily withdrawn for any reason would be the most severe deterrent possible to engaging in such socially responsible conduct.[20]

Pennsylvania law simply does not, and should not, recognize Plaintiff's claims for "negligent marketing" or "negligent failure to withdraw." Thus, Wyeth was entitled to summary judgment and the Superior Court's ruling on this issue should be affirmed.

3. The Court Should Disapprove The Superior Court's *Dictum* Concerning The Moot Issue Of Post-Sale Duty To Warn.

Finally, in its discussion rejecting Plaintiff's claim based upon failure to remove Redux from the market, the Superior Court addressed yet another issue that was neither briefed nor argued – whether a post-sale duty to warn exists in prescription drug cases. *Lance*, 167-68 & n.4. This was error, as all warning-related issues are plainly moot by reason of Plaintiff's tactical decision to "disclaim" any warning-based claims. *See, e.g.*, Pl. Br. at 7; *see also* (R. 592a) (same disclaimer in Plaintiff's Superior Court brief). The Superior Court thus ignored this Court's admonition in *Stecher v. Ford Motor Co.*, 571 Pa. 312, 812 A.2d 553 (2002), not to decide moot questions. In *Stecher* this Court held that the Superior Court had erred in reaching out for and deciding a moot issue:

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[20] Both Plaintiff and her *amici* refer to federal preemption while discussing Plaintiff's "negligent failure to withdraw" claim. Pl. Br. at 44, Pl. *Amicus* Br. at 14. While this appeal does not involve any preemption issue, the potential for direct conflict between FDA prescription drug approvals and a common-law claim that an FDA-approved drug should nonetheless never have been marketed is obvious. Avoidance of such conflict is the motivating force behind the FDA deference principle recognized by the Superior Court. *Lance*, 4 A.3d at 167. *See supra* at 14-16.

> We hold that this issue need not be reached, as it was rendered moot by the jury's finding.... Due to this disposition, we pass no judgment on the merits of the Superior Court's decision ... but merely hold that the Superior Court erred in addressing the issue.

Id. at 313-14, 812 A.2d at 554. The Court should make a similar mootness finding here. The Superior Court's decision to address issues not properly before it violates the "well settled" rule that Pennsylvania courts "will not decide moot questions,"[21] and like *Stecher* calls for an exercise of the Court's supervisory powers. *See* 42 Pa. C.S.A. §502.

VI. CONCLUSION

Tragically, Ms. Lance died from PPH. Redux, however, bore such an explicit and conspicuous PPH warning that Plaintiff did not even try to contest its adequacy. The risk of PPH was an unavoidably unsafe attribute of the drug. Thus, under established Pennsylvania law, there is no liability. Plaintiff's radical alternative theories, no matter how styled, would impose liability for the mere sale of an adequately-labeled, FDA-approved drug. The Superior Court, applying over forty years of this Court's consistent precedent, correctly rejected such novel claims. Therefore, for all the reasons in this brief, the court should affirm in Appeal 18 EAP 2011.

[21] *Rogers v. Lewis*, 540 Pa. 299, 302, 656 A.2d 1368, 1369 (1995); *accord, e.g., In re Adoption of L.J.B.*, 18 A.3d 1098, 1109 (Pa. 2011) (plurality opinion); *In re Gross*, 476 Pa. 203, 209, 382 A.2d 116, 119 (1978).

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