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 CORP.,

Defendant-Appellant/Cross-Appellee.

BRIEF OF *AMICI CURIAE* THE AMERICAN ASSOCIATION FOR JUSTICE AND PENNSYLVANIA ASSOCIATION FOR JUSTICE IN SUPPORT OF APPELLEE

Appeal from the Judgment of the Superior Court of Pennsylvania at No. 2905 EDA 2008, filed August 2, 2010, Affirming in Part and Reversing in Part the Judgment of the Court of Common Pleas of Philadelphia County, Pennsylvania, Civil Trial Division, November Term 2006, No. 926, entered September 19, 2008

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INTRODUCTION

Redux (dexfenfluramine) is a drug that should never have been marketed. The risks it posed to users of the drug—of valvular heart disease (VHD) and primary pulmonary hypertension (PPH)—far outweighed its limited benefits as a diet drug. The federal Food and Drug Administration (FDA) eventually came to realize this fact, and prohibited drug companies from manufacturing dexfenfluramine and its close chemical relative, fenfluramine. This action came too late for Catherine Lance, who died as a result of PPH she developed as a result of using Redux in 1997. Wyeth, the manufacturer of Redux, had information well before that time of Redux's dangers, yet negligently continued to market the drug until late 1997, resulting in serious injuries and death for numerous users, including Catherine Lance. The issue before this Court concerns the causes of action available pursuant to Pennsylvania law for those persons injured by Redux to hold Wyeth liable for these injuries.

The Superior Court ruled that Plaintiff could proceed on a cause of action for negligent design. Plaintiff has, alternatively, suggested that Wyeth could be held liable for its negligent failure to test Redux or for its unreasonable decision to market the drug and its failure to remove Redux from the market. This Court should uphold each of these claims as a valid means to hold Wyeth responsible for the injuries caused by its unreasonably dangerous product.

STATEMENT OF *AMICI* INTEREST

The American Association for Justice ("AAJ") and the Pennsylvania Association for Justice ("PAJ") submit this brief as *amici curiae* in support of Plaintiff-Appellee/Cross-Appellant Patsy Lance, Administratrix for the Estate of Catherine Ruth Lance, Deceased. AAJ is a voluntary national bar association whose trial lawyer members primarily represent individual plaintiffs in civil suits, including personal injury actions, consumer lawsuits, and employment-related cases. PAJ is AAJ's state affiliate organization in Pennsylvania. Many AAJ and PAJ

member attorneys represent consumers who have been harmed by dangerous prescription drugs, including consumers who live in Pennsylvania. AAJ and PAJ believe that holding drug makers accountable justly compensates those they have harmed and provides drug companies with a strong incentive to use the due care needed to minimize the risks to consumers in the future.

SUMMARY OF ARGUMENT

Pennsylvania law has long recognized a cause of action for injury caused by the negligent design of a product. Moreover, consistent with this Court's treatment of negligence and strict liability as distinct legal theories and claims, the cause of action for negligent design has been treated as distinct from strict liability design defect. Pennsylvania law is consistent with black letter tort principles as reflected in the Restatement (Second) of Torts, which recognizes negligent design of a product as a separate and independent tort from strict liability. *Compare* Restatement (2d) of Torts, §§ 395, 398 and 402A.

None of this Court's precedents limit the application of the tort of negligent design to negligently designed prescription drugs. In a series of failure-to-warn cases against drug manufacturers, this Court has held that such companies may not be held strictly liable for injuries caused by their products—adopting comment k to Section 402A of the Restatement—but may be liable for negligent failure to warn. *See Incollingo v. Ewing*, 444 Pa. 263, 282 A.2d 206 (1971); *Baldino v. Castagna*, 505 Pa. 239, 478 A.2d 807 (1984); and *Hahn v. Richter*, 543 Pa. 558, 673 A.2d 888 (1996). These holdings thus support imposing liability on drug companies for their negligence and reaffirm the basic principle that drug manufacturers must be vigilant with respect to the risks posed by their products. *Henderson v. Nat'l Drug Co.*, 343 Pa. 601, 23 A.2d 743 (1942).

Public policy also strongly favors preservation of a cause of action for negligent design against drug manufacturers. As the United States Supreme Court recently observed in *Wyeth v.*

Levine, 555 U.S. 555, 129 S. Ct. 1187 (2009), state tort liability complements the federal regulatory scheme governing prescription drugs and creates appropriate incentives for drug companies to remain vigilant about the dangers posed by the products they sell. Contrary to the assertions of Wyeth and its *amicus*, deference to the conclusions of the FDA, weighs in favor of liability here, since the FDA—once it learned of the severe risks to human health posed by Redux—banned the product from the market.

If this Court nevertheless concludes that Pennsylvania law does not recognize a claim for negligent design, it should uphold the viability of the alternative negligence claims proffered by plaintiff: negligent failure to test and negligent marketing. While the Superior Court was undoubtedly correct that a manufacturer's breach of its duty to test can only result in injury if the product "is defective in design, manufacture, or warning," *Lance v. Wyeth*, 4 A.3d 160, 169 (Pa. Super. 2010) (quoting *Kociemba v. G.D. Searle & Co.*, 707 F. Supp. 1517, 1527 (D. Minn. 1989), a manufacturer's negligent conduct can occur at any stage of the marketing process: in the initial design of the drug, in the failure to investigate information about the risks the drug poses, and in its decision to continue to sell the drug despite those unreasonable risks. The defendant's unreasonable behavior at any point in this process should be sufficient to give rise to negligence liability when that conduct results in injury.

ARGUMENT

I. PLAINTIFF HAS ASSERTED A VALID CLAIM UNDER PENNSYLVANIA LAW FOR NEGLIGENT DESIGN OF A PRESCRIPTION DRUG.

The Superior Court ruled that Lance's negligent design claim was actionable under Pennsylvania law. That decision was consistent with longstanding tort doctrine in this State and should be affirmed.

A. Longstanding Pennsylvania Precedent Recognizes a Cause of Action for Negligent Product Design, Distinct from Strict Liability.

Long before this Court first recognized the doctrine of strict liability in tort, *Webb v. Zern*, 422 Pa. 424, 220 A.2d 853 (1966), a manufacturer could be held liable for its negligent conduct regarding the products it sold. Pennsylvania law has a history of recognizing a cause of action for negligent product design.

For example, as long ago as 1949, this Court reinstated a jury verdict based upon negligent design in *Foley v. Pittsburgh-Des Moines Co.*, 363 Pa. 1, 68 A.2d 517 (1949). The case grew out of the collapse of a tank containing liquefied natural gas, which ignited and killed more than one hundred employees of the natural gas company. Plaintiff's estate sued the company that had built the tank for negligent design, contending that, *inter alia*, the cylindrical shape of the tank—as opposed to a more traditional spherical design—led to the tank's collapse. *Id.* at 10-12, 68 A.2d at 522-23. Citing the Restatement (Second) of Torts § 395—the same provision of the Restatement on which the Superior Court relied in this case—this Court reversed a judgment n.o.v. for the defendant and reinstated a jury verdict in plaintiff's favor for negligent design. *Id.* at 39, 68 A.2d at 535;[1] *see also Bisson v. John B. Kelly, Inc.*, 314 Pa. 99, 102, 170 A. 139, 140

[1] *Foley* also upheld a claim growing out of the defendant's failure to adequately test the steel used in the construction of the tanks, 363 Pa. at 15-16, 68 A.2d at 524, and it thus also supports plaintiff's alternative cause of action on that ground. *See* Part II below. The substantive law at

(1934) (affirming negligence judgment against tiling subcontractor for injury caused by falling tiles; although tile wall had been built "according to plans and specifications," the design itself was negligent in lacking necessary safety features).

Pennsylvania law regarding negligent design parallels black letter common law doctrine. Two separate sections of the Restatement (Second) of Torts support liability for negligent design. Section 395 of the Restatement, the provision cited by the Superior Court, *Lance*, 4 A. 3d at 166, provides:

> **Negligent Manufacture of Chattel Dangerous Unless Carefully Made**
>
> 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 to those who use it for a purpose for which the manufacturer should expect it to be used and to those whom he should expect to be endangered by its probable use, is subject to liability for physical harm caused to them by its lawful use in a manner and for a purpose for which it is supplied.[2]

The comments to section 395 make plain that it applies not just to negligent manufacture, but also to negligent design: "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 . . . ." Restatement (Second) of Torts § 395, comm. f.

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issue in *Foley* was the law of Ohio, but this Court made clear that it was applying ordinary principles of negligence that would be equally applicable under Pennsylvania law.

[2] "For more than half a century" before the enactment of the Second Restatement, the common law held manufacturers liable for negligence in the manufacture or sale of products that were inherently dangerous to human safety. Drugs were among the archetypal products in this category, along with food, firearms, and explosives. *Id.*, comm. A; *see also Catani v. Swift & Co.*, 251 Pa. 52, 95 A. 931 (Pa. 1915) (reversing j.n.o.v. for defendant in case involving negligent manufacture of tainted pork).

Any doubt about section 395's application to negligent product design is resolved by Restatement section 398, which expressly applies the principles of section 395 to negligent design:

> **Chattel Made Under Dangerous Plan or Design**
>
> A manufacturer of a chattel made under a plan or design which makes it dangerous for the uses for which it is manufactured is subject to liability to others whom he should expect to use the chattel or to be endangered by its probable use for physical harm caused by his failure to exercise reasonable care in the adoption of a safe plan or design.

Restatement (Second) of Torts § 398. The comments to section 398 state explicitly that this section "is a special application of the rule stated in § 395." *Id.* comm. a.

Lower courts in Pennsylvania, both state and federal, have repeatedly cited to and relied upon Restatement sections 395 and 398 to define the tort of negligent design. *See, e.g., Dyson v. Gen. Motors Corp.*, 298 F. Supp. 1064, 1069-70 (E.D. Pa. 1969) (citing both sections); *Dorsey v. The Yoder Co.*, 331 F. Supp. 753, 755 (E.D. Pa. 1971) (jury verdict for plaintiff on claim pursuant to section 398); *W.D. Rubright Co. v. Int'l Harvester Co.*, 358 F. Supp. 1388, 1396-97 (W.D. Pa. 1973) (jury verdict finding negligent design pursuant to § 398); *Bowman v. Gen. Motors Corp.*, 427 F. Supp. 234, 245 n.20 (E.D. Pa. 1977) (citing § 398); *see also Harford Mut. Ins. Co. v. Moorhead*, 396 Pa. Super. 234, 247-48, 578 A.2d 492, 499 (1990) (collecting cases citing these sections).

Pennsylvania courts repeatedly treat negligent design claims as distinct from claims for strict liability design defect under Section 402A of the Restatement. *Phillips v. Cricket Lighters*, 576 Pa. 644, 658, 841 A.2d 1000, 1008 (2003) (plurality) (affirming dismissal of strict liability design defect claim while permitting plaintiff to proceed with claim for negligent design). These courts recognize that, under this Court's precedents, such negligence claims are "conduct-

oriented," rather than "product-oriented" like strict liability claims. *Id.* at 658, 841 A.2d at 1008; *see also, e.g., Moorhead*, 396 Pa. Super. at 250, 578 A.2d at 501; *Bowman*, 427 F. Supp. at 245 (negligent design claim focuses on defendant's fault, whereas strict liability design defect focuses on the product). Plaintiffs are often permitted to proceed simultaneously on both causes of action because the claims differ. *See Dyson, Dorsey, Rubright, and Bowman.*

Thus, the tort of negligent design is both long-standing and well-recognized in Pennsylvania. Moreover, nothing in Pennsylvania's jurisprudence regarding negligent design suggests that the tort is limited only to certain products or excludes prescription drugs. To the contrary, Restatement § 395's origins in common law claims for negligent manufacture of foods and drugs strongly suggests that drug manufacturers may be held liable for negligent design pursuant to this provision. As this Court said almost seventy years ago in *Henderson v. National Drug Co.*, 343 Pa. 601, 605, 23 A.2d 743, 746 (Pa. 1942):

> It is settled that a druggist or a manufacturer of drugs or medicines who negligently delivers a deleterious drug when a harmless one is called for is responsible for the harmful consequences to the user of that drug or medicine as being guilty of a breach of duty imposed on him by law to avoid acts dangerous to the lives or health of others.

B. This Court's Precedents Reject Strict Liability for Prescription Drugs, Not Negligent Design Claims.

Wyeth and its *amicus* argue that this Court's precedents applying comment k to Restatement (Second) of Torts § 402A to prescription drugs—*Incollingo*, *Baldino*, and *Hahn*—somehow preclude negligent design liability. The Superior Court properly rejected these arguments.

In this series of cases involving claims of failure to warn against pharmaceutical companies, this Court has repeatedly held that the only basis of liability is negligence, such as, where the manufacturer fails to exercise reasonable care to warn of the dangers of its product. In

Incollingo v. Ewing, 444 Pa. 263, 282 A.2d 206 (Pa. 1971), this Court upheld a jury verdict for negligent failure to warn; the Court ruled that the standard of care required was that set forth in section 388 of the Restatement, under which the supplier "has a duty to exercise reasonable care to inform those for whose use the article is supplied of the facts which make it likely to be dangerous." *Id.* at 288 n.8; 282 A.2d at 220 n.8. In *Baldino v. Castagna*, 505 Pa. 239, 244, 478 A.2d 807, 810 (Pa. 1984), this Court reaffirmed the holding in *Incollingo*. Finally, in *Hahn v. Richter*, 543 Pa. 558, 673 A.2d 888 (Pa. 1996), this Court again announced that strict liability was not a proper basis for imposing failure-to-warn liability on a drug manufacturer (adopting comment k), and reaffirmed that the "manufacturer's negligence is the only recognized basis of liability." *Id.* at 563, 673 A.2d at 891.

In all three of these cases, this Court announced that negligence was an appropriate basis for imposing liability on drug companies. That is precisely the basis on which Plaintiff here seeks to hold Wyeth liable. Wyeth and its *amicus* fail to offer any plausible reason why these decisions upholding negligence liability should be construed to preclude liability for negligent design.

As the Superior Court recognized, *Incollingo*, *Baldino*, and *Hahn* provide support for a cause of action for negligent design. First, each upholds the principle of negligence liability for prescription drug manufacturers. Second, comment k to Restatement § 402A, on which those decisions rely, does not "act as a bar to negligence claims. By its own terms, the comment only bars . . . strict liability claims." *Lance*, 4 A.3d at 166 (quoting *Toner v. Lederle Labs.*, 732 P.2d 297, 309 (Idaho 1987)). The Restatement provisions applicable to negligent design claims, §§ 395 and 398, "contain[] no exemption or special protection for prescription drugs." *Id.* Indeed, Restatement § 402A itself "expressly limits its application to strict liability claims": "The rule [ ]

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." *Id.* (quoting Restatement (Second) of Torts § 402A, comm. a).

As both the Superior Court and the court in *Toner* recognized, barring strict liability for prescription drugs while retaining negligence liability strikes the appropriate public policy balance:

> 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. (quoting *Toner*, 732 P.2d at 310).

In *Henderson*, this Court emphasized the importance of the tort system in holding drug companies accountable for the safety of the products they sell: "the public interest requires the holding of companies which make and sell drugs and medicines for use in the human body to a high degree of responsibility under both the criminal and the civil law for any failure to exercise *vigilance* commensurate with the harm which would be likely to result from relaxing it." 343 Pa. at 610, 23 A.2d at 748. Nothing in this Court's failure-to-warn trilogy departs from this view that negligent design liability is essential to compel drug companies to maintain an appropriate level of vigilance about the safety of the products they sell.

C. Public Policy Considerations Favor Negligence Liability for Defective Drug Design.

Other public policy considerations also favor recognition of a claim for negligent drug design, especially concerning the relationship between state tort protections and the federal regulatory scheme governing prescription drugs. Just two years ago, in *Wyeth v. Levine*, 555 U.S.

555, 129 S. Ct. 1187 (2009), the Supreme Court opined at length about the many ways in which state-law remedies complement federal regulations. As the Court explained:

> The FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge. State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. . . . Thus, the FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation.

Id. at 1202. Most importantly, for present purposes, "state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs . . . ." *Id.* at 1200.

The tort of negligent design serves all of these purposes. It threatens to hold Wyeth liable for unreasonably marketing a drug with risks that far outweigh its benefits. It places responsibility squarely on the manufacturer to remain alert for serious drug hazards that emerge both during clinical trials and after the drug has entered the market and creates powerful incentives for the manufacturer to act upon that emerging risk information and to promptly disclose it to the FDA. Most importantly, the tort of negligent design provides a critical remedy for consumers who are injured when a drug manufacturer disregards these responsibilities.

Wyeth and its *amicus* assert that recognition of the tort of negligent design would conflict with the public policy of deference to the judgments of the FDA. Wyeth Br. 33-36; PLAC Amicus Br. 15. At least in the factual context of this case, nothing could be further from the truth. When, following Wyeth's withdrawal of Redux from the market, the FDA took steps to prevent other drug makers from introducing their own generic versions of fenfluramine and dexfenfluramine, it did so based upon its determination that Redux was not safe and effective. *See* 64 Fed. Reg. 10944 (Mar. 8, 1999) (including fenfluramine and dexfenfluramine in list of

drugs that have been withdrawn or removed from the market for reasons of safety or effectiveness) (codified at 21 C.F.R. § 216.24). FDA's action thus reflects the agency's conclusion that the drug was defectively designed. Imposing state law liability on Wyeth for negligent design would therefore be entirely consistent with, and deferential to, this FDA judgment.[3]

For all of these reasons, this Court should affirm the judgment of the Superior Court permitting Plaintiff to proceed on her claim of negligent drug design.

II. PLAINTIFF HAS ASSERTED VALID CLAIMS UNDER PENNSYLVANIA LAW FOR NEGLIGENT FAILURE TO TEST AND NEGLIGENT MARKETING OF A PRESCRIPTION DRUG.

This Court should, however, reverse the Superior Court on the issues raised in Plaintiff's cross-appeal and reinstate her claims for negligent failure to test and negligent marketing of Redux. The duty to test and the duty not to sell an unsafe product are both part of the due care that a manufacturer owes to consumers of its product and breach of those duties can and should give rise to negligence liability under Pennsylvania law. The Superior Court's conclusion to the contrary rests on a confusion of the principles of strict liability with those of negligence, by focusing on the product and not on the defendant's conduct.

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[3] Wyeth is correct in observing that "[c]ompliance with governmental regulations is evidence of due care in negligence," Wyeth Br. at 33 (citations omitted), but such evidence is not conclusive under Pennsylvania law. *Berkebile v. Brantly Helicopter Co.*, 219 Pa. Super. 479, 484-85, 281 A.2d 707, 710 (1971) (quoting Restatement (Second) of Torts § 288C (1965)); *Maize v. Atl. Refining Co.*, 352 Pa. 51, 56-57, 41 A.2d 850, 853 (1945). At trial, Wyeth may certainly introduce evidence of FDA's approval of Redux to support its claim that the drug was not negligently designed. Likewise, Plaintiff should be permitted to introduce evidence of FDA's subsequent ban on the drug, as well as evidence of Wyeth's withholding of essential information about the risks of PPH and VHD associated with Redux use, to rebut Wyeth's claim that it was not negligent in its design of the drug.

The Superior Court denied Plaintiff's negligent failure to test claim on the theory that it was subsumed within her negligent design claim. That court was no doubt correct in its observation that a manufacturer's failure to test cannot be the cause of a plaintiff's injury unless the product has a defect—in design, manufacture, or warning—that testing could have uncovered. *Lance*, 4 A.3d at 169 (citing *Kociemba v. G.D. Searle & Co.*, 707 F. Supp. 1517, 1527 (D. Minn. 1989)). But, as this Court has frequently observed, negligence liability rests on the defendant's conduct, rather than on the product. *See, e.g., Phillips v. Cricket Lighters*, 576 Pa. at 658, 841 A.2d at 1008. Plaintiff should be permitted to introduce evidence of the defendant's negligent conduct at any point in the marketing process and to argue to the jury that Defendant's negligence in failing to conduct appropriate tests on Redux or in continuing to sell the drug after information about its serious risks emerged led to Catherine Lance's injuries.[4] And it may be easier for the jury to understand the Defendant's misconduct under these rubrics rather than as a case of negligent design.

The Restatement expressly contemplates that negligent failure to test is an actionable tort. Comment e to Restatement section 395 identifies "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" as one element of a non-negligent manufacturing process. Restatement (Second) of Torts § 395, comm. f. Likewise, Restatement section 392 states that a supplier of a product may be held liable for physical harm caused by the product "if he fails to exercise reasonable care to discover its dangerous condition or character." Restatement (Second) of Torts § 392(b). Pennsylvania courts have frequently

[4] It should noted that the pharmaceutical industry spends a reported $65 billion per year (reported as of 2004) in advertising to the public and in marketing to medical professionals. Marcia Angell, *The Truth About the Drug Companies* 12 (Random House 2004).

invoked both of these Restatement provisions. *Moorhead*, 396 Pa. Super. at 248, 578 A.2d at 499.

In *Foley*, this Court upheld a jury verdict based in part on a negligent failure to conduct adequate tests, citing Restatement § 395 and its comment. 363 Pa. at 16, 68 A.2d at 524. And both the Superior Court and the Third Circuit have recognized the viability of negligence claims for inadequate testing of prescription drugs. *Leibowitz v. Ortho Pharm. Corp.*, 224 Pa. Super. 418, 434, 446, 307 A.2d 449, 459, 464 (1973) (en banc);[5] *Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132, 140-41 (3d Cir. 1973).

While it is true that the Superior Court panel in *Viguers v. Philip Morris USA, Inc.*, 837 A.2d 534, 541 (Pa. Super. 2003), *summarily aff'd*, 584 Pa. 120, 881 A.2d 1262 (2005), ruled that "the claim for 'negligent failure to test' is not a viable cause of action recognized by our courts," that decision cannot be squared with this Court's decision in *Foley* and with its adoption of the Restatement comment regarding negligent testing. Both *Viguers* and the decision below make the improper leap from the fact that negligent testing will not cause injury unless a product is defective to the illogical conclusion that, even where a product is defective, the defendant's negligent failure to conduct adequate testing does not provide an independent basis for tort liability. This Court should correct that error. Although a defendant drug manufacturer can not be held liable *without fault* for its product, the law clearly permits an injured plaintiff to present

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[5] *Leibowitz* was an affirmance by an equally divided court of a defense verdict following a bench trial. While the six judges split on the sufficiency of plaintiff's evidence, all agreed that a drug company has a duty to test under Pennsylvania law. *See id.* at 434, 307 A.2d at 459 (opinion in support of affirmance) ("a drug manufacturer may not escape liability by merely ignoring existing reports of side-effects or dangers in the use of its product. Neither may a drug company fail to conduct tests and research to obtain such information."); *id.* at 446, 307 A.2d at 464 (opinion in support of reversal) (finding it relevant whether information uncovered subsequent to plaintiff's use of the drug "would have been and could have been revealed to the defendant in 1964 had it made proper testing and studies of the drug before marketing it").

proof that the manufacturer was at fault for her injuries, *i.e.*, it was negligent in its development of the drug by its inadequate testing.

As for the Superior Court's rejection of Plaintiff's negligent marketing and failure to withdraw claim, that ruling seems to rest on a fundamental misunderstanding of the claim. As *amici* understand it, Plaintiff does not assert that Wyeth was under a common law duty to recall Redux tablets that had already been distributed in the market. *See Lance*, 4 A.3d at 167 (interpreting claim that way). Rather, Plaintiff contends that, given what Wyeth knew or should have known about the dangers of Redux in early 1997, it was negligent of the company to continue to sell the product at that time. Had it stopped marketing Redux then, rather than in September 1997, Catherine Lance would not have taken the product and would not have been injured. As with the negligent testing claim, Plaintiff's negligent marketing claim assumes an underlying defect in the product, but it focuses on a separate negligent act, the decision to continue marketing the drug.

Properly understood, that claim does not conflict with FDA authority in any way. As the United States Supreme Court recognized in *Wyeth v. Levine*, primary responsibility for drug safety rests with the manufacturer, which has "superior access to information about [its] drugs, especially in the post-marketing phase as new risks emerge." 129 S. Ct. at 1202. FDA approval of a drug permits the manufacturer to market it, but it does not require the manufacturer to do so. If the manufacturer concludes that its product is unsafe, it can and must take it off the market. Indeed, that is precisely what Wyeth did when it withdrew Redux from the market in September 1997. Plaintiff's negligent marketing claim is simply that it was negligent of Wyeth not to take that action sooner, prior to the time that the drug caused injury to Ms. Lance. This Court should uphold the validity of such a negligence claim.

CONCLUSION

This Court should affirm the judgment of the Superior Court that Plaintiff has stated a viable claim for negligent design of a prescription drug, but should reverse the judgment of the lower courts regarding the claims in Plaintiff's cross-appeal and hold that Pennsylvania law also recognizes claims for negligent failure to test and negligent marketing of prescription drugs.

Date July 6, 2011

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Louis M. Bograd, hereby certify that on this 5th day of July 2011, two true and correct copies of the foregoing document were served upon the persons indicated below via UPS for overnight delivery which service satisfies the requirements of Pa. R. App. P. 2187:

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