In the Supreme Court of Pennsylvania

No. 17 EAP 2011

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

Appellee,

v.

WYETH, formerly known as
American Home Products Corporation,

Appellant.

REPLY BRIEF FOR CROSS–APPELLANT

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

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I. INTRODUCTION

Wyeth's Reply Brief for Appellant/Brief for Cross–Appellee, filed a little more than three weeks before oral argument, contains citations to 129 cases. In at least two instances, a large number of those citations appear in "string cites," contrary to the well–established admonition that "[s]tring cites are rarely useful or impressive." *See* Harry Pregerson, "The Seven Sins of Appellate Brief Writing and Other Transgressions," 34 UCLA L. Rev. 431, 435–36 (1986) (describing "String Cites and Other Poor Use of Authority" as one of the seven sins of appellate brief writing).[1]

In this case, plaintiff is asking this Court to hold, in accordance with its earlier precedent, that although a plaintiff injured as the result of consuming a dangerous prescription drug cannot assert claims sounding in strict liability against the prescription drug's manufacturer, claims sounding in negligence can be maintained under Pennsylvania law. This clear line of demarcation — that claims sounding in strict liability are prohibited while claims sounding in negligence are permitted — shines like a beacon from this Court's earlier rulings in this area.

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[1] Given Wyeth's lack of constraint in citing cases, it is noteworthy that when it came to identify the two cases from other states that supposedly prohibit plaintiffs from pursuing claims for negligent design defect against the manufacturer of a prescription drug, Wyeth fails to include the names or citations to those cases. *See* Wyeth's step–three brief at 9. Perhaps this is because neither case in fact so holds, and one is merely an unpublished, non–precedential federal trial court ruling from Massachusetts. *See Grundberg* v. *Upjohn Co.*, 813 P.2d 89 (Utah 1991) (deciding, on certified question from a federal district court, only whether Utah law would recognize a strict liability design defect claim); *Sprague* v. *Upjohn Co.*, 1995 WL 376934, at *1–*2 (D. Mass. 1994) (entering summary judgment against negligent design defect claim on the merits, because plaintiff could not show that the drug in question could have been more safely designed, while recognizing that negligent design defect claims could be maintained against other medications) (citing *Brochu* v. *Ortho Pharmaceutical Corp.*, 642 F.2d 652 (1st Cir. 1981)).

If plaintiff's arguments actually lacked merit, surely Wyeth would not have felt the need to present such a complex and elaborate argument in opposition. As is explained in more detail below, to the extent that Wyeth's step–three brief scores any points whatsoever, it is in the course of attacking "straw man" arguments that mischaracterize what is actually at issue in this case. For example, Wyeth's step–three brief repeatedly denounces plaintiff's supposed effort to impose "absolute liability" on the manufacturer of a prescription drug. The key fact that Wyeth's "absolute liability" argument overlooks, however, is that plaintiff is merely seeking to pursue claims expressly based in negligence, and negligence is the antithesis of absolute liability. *See Bugosh* v. *I.U. North America, Inc.*, 601 Pa. 277, 296, 971 A.2d 1228, 1239 (2009) (Saylor, J., dissenting from the dismissal of appeal as improvidently granted) (recognizing that negligence and absolute liability are distinct standards); *see also Smithbower* v. *Southwest Cent. Rural Elec. Co–op., Inc.*, 542 A.2d 140, 141 (Pa. Super. Ct. 1988) (recognizing that absolute liability, strict liability, and negligence are three distinct standards). The fact that plaintiff is decidedly not seeking to impose absolute liability on Wyeth renders much of Wyeth's step–three brief irrelevant.

Because this Reply Brief for Cross–Appellant is being filed just one week before the date of oral argument, and because this Court's earlier decisions rejecting strict liability claims against prescription drug manufacturers while allowing claims against those very same defendants sounding in negligence suffice to resolve this case in plaintiff's favor, plaintiff has elected to forgo presenting lengthy string

citations and arguing irrelevant points to focus directly on why this Court should overturn the Superior Court's refusal to allow plaintiff to pursue her claims for negligent failure to test, negligent marketing, and negligent failure to withdraw from the market.

II. ARGUMENT IN REPLY

A. If Accepted, The Limited, Incremental Approach To Appellate Decisionmaking That Wyeth Favors In Its Waiver Argument Would Necessitate The Reinstatement Of All Of Plaintiff's Negligence Claims

Although plaintiff believes, for the reasons set forth in plaintiff's previously filed Brief for Appellee/Cross–Appellant, that Wyeth's waiver arguments lack merit, for present purposes it is sufficient to note that if this Court were to nevertheless accept the limited, incremental approach to appellate decisionmaking that Wyeth favors in its waiver argument, the proper relief would be the reinstatement of all of plaintiff's negligence claims against Wyeth.

Wyeth's motion for summary judgment, which despite its name was essentially in the nature of a demurrer or motion to dismiss for failure to state a claim on which relief may be granted, was constructed around the central contention that "[h]aving disavowed any claim that Wyeth provided inadequate warnings, Plaintiff does not have a cognizable claim for negligence." R.75a. Beyond that main contention, Wyeth's summary judgment motion did not even address plaintiff's specific claims for negligent design defect or negligent failure to test and barely alluded to plaintiff's claims for negligent marketing or negligent failure to

withdraw from the market. The trial court, in granting Wyeth's motion for summary judgment, agreed with Wyeth that because plaintiff was not asserting a claim for negligent failure to warn, plaintiff's lawsuit had to be dismissed.

On appeal to the Superior Court, plaintiff argued that the trial court had erred as a matter of law in holding that the only negligence claim that a plaintiff injured as the result of ingesting a dangerous prescription drug can maintain against the manufacturer of that prescription drug is a claim for negligent failure to warn. In the context of this case, a negligent failure to warn claim would be nonsensical, because the only warning adequate to guard against the ingestion of a medication that the FDA had ultimately decided was too dangerous for any potential class of patients is a warning that the medication should not be ingested by anyone for any purpose.

In its step–three brief, Wyeth asserts that plaintiff concedes the adequacy of Redux's PPH warning. Wyeth's is absolutely incorrect in that regard. R.126a. Moreover, Wyeth suggests that Redux's VHD risk led the FDA to prohibit any further use of the medication, when in fact it is clear that the medication's overall risk profile, consisting of both PPH and VHD risks, led to the FDA's decision to prohibit entirely the use of Redux's active ingredients by anyone. R.129a. Because this case does not involve a claim for negligent failure to warn, Wyeth's arguments on these points are not just incorrect but entirely irrelevant.

If Wyeth's waiver argument were correct, and the Superior Court in this case should not have proceeded any farther than to decide whether the only negligence

claim available to a plaintiff injured as the result of ingesting a dangerous prescription drug is a claim for negligent failure to warn, then the Superior Court's holding would simply have consisted of a rejection of Wyeth's argument that the only negligence claim that a plaintiff may maintain is a claim for negligent failure to warn. The consequence of that holding would have been the reinstatement of *all* of plaintiff's negligence claims against Wyeth. Wyeth perhaps then would have been able to challenge plaintiff's negligence claims on a claim–by–claim basis in the trial court by arguing that Pennsylvania law does not or should not recognize each distinct claim, likely resulting in a second round of appellate proceedings.

What the Superior Court did instead, of course, actually inured to Wyeth's benefit by examining on a claim–by–claim basis whether Pennsylvania law would recognize the specific negligence claims that plaintiff had asserted in her complaint. Wyeth now proposes an improper double–standard, whereby the Superior Court acted properly in rejecting certain of plaintiff's specific claims as unavailable under Pennsylvania law but supposedly abused its discretion in recognizing the existence of a claim for negligent design defect. Thus, if Wyeth's waiver argument were to be accepted, this Court should order the reinstatement of plaintiff's claims for negligent failure to test and negligent marketing/failure to withdraw from the market in addition to affirming the Superior Court's reinstatement of plaintiff's negligent design defect claim.

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

Wyeth's argument in opposition to reinstatement of plaintiff's claim for negligent failure to test consists, in essence, of the argument that ordinarily courts have refrained from recognizing a freestanding claim for negligent failure to test where instead the plaintiff can pursue a claim for negligent failure to warn or negligent design defect. In the context of this case, however, Wyeth's argument proves too much.

Wyeth can cite to no failure to warn case where it is the plaintiff's argument that the medication or other product in question should not have been on the market, and thus the only proper warning was a direction to the user that the product should not be used under any circumstances. Because this is not and under plaintiff's theory cannot be a failure to warn case, the hypothetical availability of a failure to warn claim in other, distinguishable cases does not compensate for the unavailability of a negligent failure to test claim in this case.

Similarly, Wyeth is arguing that plaintiff cannot maintain a negligent design defect claim here. Although, for the reasons set forth in plaintiff's Brief for Appellee/ Cross–Appellant, this Court should hold that the Superior Court properly recognized a claim for negligent design defect involving Redux, if this Court were to

categorically hold that such a claim is not available under Pennsylvania law, then no viable alternative exists to recognizing a claim for negligent failure to test.[2]

Wyeth, of course, does not deny that it has a duty to test for the harmful side–effects of a brand name prescription drug such as Redux before deciding whether to offer the medication for sale. Wyeth further does not deny that this duty must be performed in a non–negligent manner. Thus, recognizing a claim for negligent failure to test would impose on Wyeth no duties beyond those that Wyeth already acknowledges it must satisfy.

Plaintiff does not quarrel with the outcome of cases holding that a claim for negligent failure to test cannot be maintained where the plaintiff can maintain another claim, such as a claim for negligent failure to warn or negligent design defect, in which the claim for negligent failure to test is subsumed.[3] Nor does

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[2] As plaintiff demonstrated in her Brief for Appellee/Cross–Appellant, Wyeth's other arguments for upholding the trial court's entry of summary judgment against plaintiff's negligent design defect claim — consisting of deference to the FDA and a supposed need to show a feasible alternate design — are waived because Wyeth never raised those arguments until after the Superior Court's three–judge panel issued its ruling in this case. Regardless of what issue preservation obligations an appellee ordinarily has, a defendant cannot obtain summary judgment on one ground and then, after that ground is rejected on appeal, raise for the very first time an entirely different ground — neither raised in the trial court nor argued and briefed before the intermediate appellate court — as a new, alternate basis for affirming the trial court's entry of summary judgment on appeal to this Court.

[3] Plaintiff, however, does disagree that the cases from Pennsylvania federal and state trial courts that Wyeth has cited for this proposition constitute "on–point precedent," *see* Wyeth's step–three brief at 25, given that trial court rulings do not constitute precedent because they do not bind appellate courts or other trial courts. *See*, *e.g.*, *Harzewski* v. *Guidant Corp.*, 489 F.3d 799, 806 (7th Cir. 2007) (Posner. J.) ("Forty–five of the cases that the parties cite are district court cases, which, as we tirelessly but futilely remind the bar, are not precedents.").

plaintiff contend that a negligent failure to test claim can succeed in the absence of any contention that proper testing would have altered the defendant's conduct and avoided plaintiff's injuries. *Cf. Oxford* v. *Foster Wheeler LLC*, 99 Cal. Rptr. 3d 418, 435 (Cal. Ct. App. 2009) (cited by Wyeth at page 27 of its step–three brief).

Here, by contrast, it is plaintiff's contention that had Wyeth tested to ascertain the harmful side–effects of Redux in a non–negligent manner, Wyeth would have concluded, as the FDA later determined, that Redux was too unsafe to be offered for sale to any class of patients for any purpose whatsoever. Plaintiff's negligent failure to test claim thus represents an ordinary, garden–variety type of negligence claim that this Court should have no reluctance to recognize in the context of this case.

Accordingly, this Court should reverse the Superior Court's ruling to the extent that it affirmed the trial court's entry of summary judgment against plaintiff's negligent failure to test claim against Wyeth.

C. This Court Should Hold That Pennsylvania Law Recognizes Claims For Negligently Marketing And Negligently Failing To Withdraw From The Market A Dangerous Prescription Drug

Numerous mischaracterizations and "straw man" arguments pervade Wyeth's response to plaintiff's efforts to reinstate her claims for negligent marketing and negligent failure to withdraw from the market. In the very first paragraph of its response, on page 29 of Wyeth's step–three brief, Wyeth incorrectly asserts that plaintiff seeks to "impose absolute liability on Wyeth" even though a

claim sounding in negligence is the antithesis of a claim asserting absolute liability. *See Bugosh* v. *I.U. North America, Inc.*, 601 Pa. 277, 296, 971 A.2d 1228, 1239 (2009) (Saylor, J., dissenting from the dismissal of appeal as improvidently granted) (recognizing that negligence and absolute liability are distinct standards); *see also Smithbower* v. *Southwest Cent. Rural Elec. Co–op., Inc.*, 542 A.2d 140, 141 (Pa. Super. Ct. 1988) (recognizing that absolute liability, strict liability, and negligence are three distinct standards).

Wyeth's second mischaracterization appears in the second paragraph of Wyeth's argument in response, on page 29 of its step–three brief, where Wyeth asserts that plaintiff relies on the U.S. Supreme Court's decision in *Wyeth* v. *Levine*, 129 S. Ct. 1187 (2009), as the only authority in support of her argument that this Court should recognize claims for negligent marketing and negligent failure to withdraw from the market. In actuality, as any review of plaintiff's Brief for Appellee/Cross–Appellant readily discloses, plaintiff has cited three other judicial decisions (including two earlier rulings of this Court) and one Restatement section before citing to *Levine* in support of this argument. *See* Plaintiff's Brief for Appellee/ Cross–Appellant at 41–44. Moreover, plaintiff's purpose in citing to *Levine* was to illustrate that the Superior Court had improperly relied on supposed deference to the FDA as a reason for not recognizing these claims.

Wyeth next argues (*see* Wyeth's step–three brief at 30, citing *Baldino* v. *Castagna*, 505 Pa. 239, 244, 478 A.2d 807, 810 (1984)) that the only variety of negligent marketing claim that this Court has shown itself willing to recognize

involves a claim of "overpromotion." On the one hand, plaintiff welcomes Wyeth's concession that this Court has already recognized the existence under Pennsylvania law of a claim for negligent marketing. But nowhere in *Baldino* or in any of this Court's other cases has this Court held that *the only type* of negligent marketing claim that a plaintiff may make under Pennsylvania law is a negligent marketing claim in support of a claim for negligent failure to warn.

After another attempt at mischaracterizing plaintiff's negligent marketing claims as claims that seek to impose absolute liability (*see* step–three brief at 31–32), Wyeth next turns to refute the "straw man" argument — an argument that plaintiff is not making and never has made — that plaintiff's claims should be recharacterized as claims seeking the recall or retrofit of a product. Although Wyeth's attempt to misportray plaintiff's claims as a claim seeking the recall of a product provides the occasion for one final *tour de force* of string citations (*see* Wyeth's step–three brief at pages 34–36), plaintiff is not arguing that Wyeth had any duty to conduct a recall of Redux from the market. Rather, what Wyeth should have and could have done to satisfy the duty that plaintiff asks this Court to recognize was merely to issue a public statement, before Redux was prescribed to plaintiff, advising that Redux was unsafe for consumption by any class of patients for any purpose whatsoever. In the realm of prescription medications, such a statement suffices to withdraw a medication from the market.

At pages 36–37 of its step–three brief, Wyeth proceeds to argue that the "state of the art" defense and the evidentiary limitations on introducing subsequent

remedial measures should cause this Court to refrain from recognizing plaintiff's claims for negligent marketing and negligent failure to withdraw from the market.

Wyeth's invocation of the "state of the art" defense represents just the latest instance, *see supra* page 7 n.2, of an attempt by Wyeth to belatedly raise for the first time on appeal to this Court a factual defense without any support in the record that Wyeth was required to invoke earlier in order to have the defense available on appeal to this Court. As the Superior Court explained in *Carrecter* v. *Colson Equip. Co.*, 499 A.2d 326, 331 (Pa. Super. Ct. 1985), the "state of the art" defense "focus[es] on the knowledge of the defendant and/or the reasonableness of the defendant's conduct" at the time in question. In the context of this case, plaintiff asserts that Wyeth either knew or should have known of all of the harmful side–effects of Redux before the medication was first prescribed to plaintiff and, as a result, the medication should no longer have been available on the market as of that time.

If Wyeth wishes to advance the defense that no reasonable pharmaceutical manufacturer in Wyeth's position would have known all of Redux's harmful side–effects before the medication was prescribed for plaintiff's use, Wyeth certainly can advance that defense, but as the record now stands the applicability of the "state of the art" defense is assuredly a contested fact.

On the issue of subsequent remedial measure, plaintiff does not rely on Wyeth's later voluntary withdrawal of Redux from the market as evidence of Wyeth's negligence. Rather, plaintiff is instead relying on the FDA's decision, which occurred after Wyeth's withdrawal of the medication, that the active ingredient

contained in Redux was too unsafe to be prescribed to any class of patients for any purpose whatsoever. It is the FDA's ultimate conclusion about Redux's unsuitability for any patient that is the most critical evidence in this case. To the extent that Wyeth's voluntary withdrawal is relevant, it is for the purpose of establishing "feasibility of precautionary measures," which does not run afoul of the rule limiting the introduction into evidence of subsequent remedial measures. *See* Pa. R. Evid. 407 ("This rule does not require the exclusion of evidence of subsequent measures when offered for impeachment, or to prove other matters, if controverted, such as ownership, control, or feasibility of precautionary measures.").

In sum, as Wyeth's step–three brief has acknowledged, this Court has already recognized the existence of a claim for negligent marketing, although without mandating that such a claim can only be advanced in conjunction with a claim for negligent failure to warn. Moreover, this Court should recognize that where the FDA has ultimately concluded that a particular prescription drug was too dangerous to be offered for sale, Pennsylvania law will allow a plaintiff to maintain a claim that the manufacturer was negligent in failing to withdraw the medication from the market more promptly.

D. Wyeth's Argument That This Court Should Disapprove The Superior Court's Dicta Regarding A Prescription Drug Manufacturer's Post–Sale Duty To Warn Is Waived And Without Merit

The Superior Court's dicta regarding a prescription drug manufacturer's post–sale duty to warn is unquestionably a correct statement of the law. As the

Supreme Court of the United States recently explained in *Wyeth* v. *Levine*, 129 S. Ct. 1187 (2009):

> [T]hrough many amendments to the FDCA and to FDA regulations, it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market. *See*, *e.g.*, 21 CFR §201.80(e) (requiring a manufacturer to revise its label "to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug"); §314.80(b) (placing responsibility for postmarketing surveillance on the manufacturer); 73 Fed. Reg. 49605 ("Manufacturers continue to have a responsibility under Federal law . . . to maintain their labeling and update the labeling with new safety information").

Id. at 1197–98.

As the above–quoted passage from *Wyeth* v. *Levine* makes clear, prescription drug manufacturers have a continuing duty to warn under federal law, and thus the Superior Court's dicta on this issue is unquestionably correct.

In any event, Wyeth's has waived its ability to challenge this dicta. To begin with, this Court did not agree to review this issue, and, most importantly, Wyeth did not raise this issue among the questions presented in its petition for allowance of appeal. In another case now pending before this Court on petition for allowance of appeal, *see Daniel* v. *Wyeth*, Nos. 318 & 319 EAL 2011 (Pa.) (filed May 16, 2011), Wyeth in the third of its proposed questions presented asked this Court to grant review to consider dicta contained in the Superior Court's ruling in that case. Wyeth's express acknowledgement in *Daniel* of the necessity of raising a challenge to dicta as a question presented for review demonstrates that Wyeth's failure to do so in this case constitutes an irrevocable waiver of the relief that Wyeth now seeks.

Because this Court does not exist to review the dicta of lower courts, because the Superior Court's statement is in any event unquestionably correct, and because Wyeth has waived its ability to obtain review of this issue, this Court should reject the final argument contained in Wyeth's step–three brief.

III. CONCLUSION

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

Respectfully submitted,

Dated: September 6, 2011

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