In the Superior Court of Pennsylvania

No. 185 EDA 2009

MARIE OWENS and FRED OWENS, JR.,
Appellants,

v.

WYETH, f/k/a
AMERICAN HOME PRODUCTS CORP; et al.

REPLY BRIEF FOR APPELLANTS

On Appeal from the Judgment of the
Court of Common Pleas of Philadelphia County, Pennsylvania,
Civil Trial Division, August Term 2004, No. 1756

Howard J. Bashman
2300 Computer Avenue
Suite G–22
Willow Grove, PA 19090
(215) 830–1458

Linda C. Love
Michael L. Williams
Williams Love O'Leary & Powers, P.C.
9755 S.W. Barnes Road
Suite 450
Portland, OR 97225–6681
(503) 946–5412

Counsel for Plaintiffs/Appellants

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I. INTRODUCTION

This case presents the same unresolved question of Pennsylvania law that is presented in *Cochran* v. *Wyeth, Inc.*, a case that will be argued in tandem with this appeal — namely, where the plaintiff in a prescription drug failure–to–warn case demonstrates that she was injured as the result of ingesting the defendant's medication and that her physician would not have prescribed the medication had the defendant adequately warned the physician of all of the medication's significant actual risks, may a reasonable jury find that the defendant's failure to warn was a proximate cause of the plaintiff's injury if the inadequate warning pertained to a harm different from the harm that the plaintiff suffered?

This case also presents two other, related questions that are not presented in the *Cochran* case — namely, does Pennsylvania law recognize claims against a prescription drug manufacturer alleging that the manufacturer was negligent in allowing the drug to be offered for sale to the public and that the manufacturer was negligent in not withdrawing the drug from the market sooner given the medication's actual risks.

In this case, on the first question presented, the trial judge ruled as a matter of law on summary judgment that unless the defendant specifically failed to warn fully and adequately about the particular harm from which the plaintiff suffered, the plaintiff cannot establish that the defendant's failure to warn proximately caused the plaintiff's injuries, even though had the defendant provided adequate warnings the plaintiff would never have been prescribed the medication.

The first issue involved in this appeal thus presents a question of law concerning the limits of proximate cause. Sometimes a defendant's act or omission may be a cause–in–fact of harm that befalls a plaintiff, but due to the large number of intervening steps in the causative process, or the presence of one or more superseding causes, a court may properly conclude that the defendant's act or omission was not the proximate cause of the plaintiff's injuries.

Here, by contrast, it is undisputed that a prescription drug manufacturer has the duty to provide physicians with adequate warnings about all of a prescription drug's materially harmful side–effects so that the doctor can decide whether to prescribe the medication to his or her patients. *See Demmler* v. *SmithKline Beecham Corp.*, 671 A.2d 1151, 1154 (Pa. Super. Ct. 1996) (noting that a physician's task involves "weighing the benefits of any medication against its potential dangers"). The very purpose of that requirement, of course, is to safeguard the health and well–being of patients such as plaintiff Marie Owens. In this case, the inadequate warnings pertained to the very medication that Ms. Owens's doctor prescribed for her. And that doctor provided testimony under oath from which a reasonable jury could infer that had Wyeth's warnings disclosed the actual risks of ingesting that medication, he would not have prescribed the medication for Ms. Owens to use.

Accordingly, this is not a case where some lengthy and tenuous causative chain exists, or where superseding causes have intervened, to excuse the defendant's act or omission from being the proximate cause of the plaintiff's

injuries. Rather, this is a case where the defendant had a duty to warn about the risks of a particular drug. The duty to warn was for the direct benefit of a class of patients who might be prescribed the medication, and the plaintiff was a member of that class of patients. Here, (1) the defendant breached its duty to warn, (2) as a result of which the plaintiff was prescribed the defendant's medication, and (3) as a result of ingesting that medication the plaintiff was injured. Those three steps are the exact three elements a plaintiff must prove to prevail in a prescription drug negligent failure–to–warn lawsuit against a drug manufacturer. *See Demmler*, 671 A.2d at 1155 (quoting *Mazur* v. *Merck & Co.*, 742 F. Supp. 239, 262 (E.D. Pa. 1990)). There are no extraneous or unnecessary steps in the causative chain that would allow a court to say that proof of proximate cause in this case is too tenuous or remote. *See also Simon* v. *Wyeth Pharmaceuticals, Inc.*, 2009 PA Super 263, at ¶30, 2009 WL 5154031, at *9 (Pa. Super. Ct. Dec. 31, 2009) (describing a plaintiff's proximate cause burden in a prescription drug failure–to–warn suit).

This Court should also reverse the trial court's holding, on summary judgment, that Pennsylvania law does not recognize claims against a prescription drug manufacturer for negligently bringing to market an unsafe drug that serves no useful purpose and for negligently failing to withdraw such a prescription drug from sale sooner. Comment k to Restatement (Second) of Torts §402A — which the Supreme Court of Pennsylvania has acknowledged as furnishing the basis for negligence claims that may be brought under Pennsylvania law against prescription drug manufacturers — expressly recognizes a prescription drug manufacturer's

independent duty to refrain from negligence in marketing prescription drugs. Moreover, Ms. Owens's claims would even be valid under Restatement (Third) of Torts: Products Liability §6(c), which sets forth a standard for prescription drugmaker liability that most courts have rejected as too pro–manufacturer, not sufficiently protective of consumers, and thus inconsistent with existing case law.

For these reasons, explained in more detail herein, this Court should reverse the trial court's entry of summary judgment and remand for further proceedings.

II. ARGUMENT IN REPLY

A. The Trial Court Erred In Granting Summary Judgment In Wyeth's Favor On The Ground That Wyeth's Failure To Warn Fully And Accurately Of The Risks Of Pondimin Was Not A Proximate Cause Of Ms. Owens's Injuries

1. Wyeth's appellate brief only serves to illustrate even more starkly the error inherent in the trial court's proximate cause ruling

Before turning to the areas of disagreement that remain between the parties on the issue of proximate cause that is central to the resolution of the first question presented in this appeal, it is useful to review the many important areas of agreement between the parties.

Wyeth, in its Brief for Appellees, does not dispute that the proximate cause issue presented here is a question of first impression at the appellate level in Pennsylvania. Wyeth's Brief for Appellees also does not dispute that Wyeth had the duty to provide full and accurate warnings about all of the material risks of Pondimin to physicians who were considering whether to prescribe that drug to

patients. Wyeth does not dispute that the purpose of the duty to warn is for the protection of the health and well–being of the physician's patients, so that a physician can weigh the risks and benefits of a particular medication in deciding whether to prescribe it for his or her patients. And, last but not least, Wyeth does not dispute for purposes of the summary judgment inquiry that Ms. Owens sustained the usually fatal illness known as PPH as a result of having consumed Pondimin.

As this Court no doubt well understands, the medication Pondimin posed two risks that are material for purposes of this case. The medication presented a slight risk of the commonly fatal illness known as PPH, which is the illness from which Ms. Owens suffers. Wyeth is correct that, for purposes of this appeal, Ms. Owens is not disputing the adequacy of Pondimin's PPH warning at the time her physician prescribed the medication. Yet Pondimin also presented a much greater, and thus much more frequently sustained, risk of VHD, which while not a virtual death sentence such as PPH is nonetheless still a quite serious condition.

As we explained in our Brief for Appellants, the VHD warning that Wyeth provided to physicians when Pondimin was prescribed to Ms. Owens greatly understated that medication's actual VHD risk. *See* Brief for Appellants at 4–6. Only later did the federal Food and Drug Administration (FDA) require Wyeth to change the Pondimin warning label to disclose the medication's actual VHD risk. R.539a. A reasonable jury could conclude, based on the testimony of Ms. Owens's prescribing physician, that he would not have prescribed Pondimin for Ms. Owens

had he know of that medication's actual VHD risk. R.576a–81a. Finally, had Ms. Owens not received the Pondimin prescription from her doctor, she would not have sustained PPH as the result of having ingested Pondimin.

In its Brief for Appellees, Wyeth features a lengthy block–quote from the treatise Dan B. Dobbs, "The Law of Torts," in support of Wyeth's assertion that "it is hornbook law that proximate cause cannot be established when the alleged failure to warn relates to an injury the plaintiff does not have." Brief for Appellees at 16. The lengthy quote from that treatise set forth on pages 16–17 of Wyeth's Brief for Appellees states, in full:

> More centrally, the injury suffered must be within the class of injury that the warning requirement was meant to avoid. For example, the plaintiff, if properly warned that asbestos might cause cancer, might have ceased to work around asbestos. A failure to give such a warning could result in liability if the plaintiff did develop cancer as a result of asbestos exposure. But the failure to provide such a warning would not result in liability if the plaintiff, not being warned, kept her job and lost a hand in a job–related machine accident. In that example, failure to warn would be a cause in fact — the plaintiff would have been elsewhere, not working at the machine, if a proper warning had been given — but it is not a proximate legal cause. It is not, in other words, within the risk that a warning was designed to avoid.

Dan B. Dobbs, "The Law of Torts," 1018 (2001).

In actuality, however, the above quotation supports Ms. Owens's position on appeal. The example that is discussed in the quotation, where a failure to warn of the risks of asbestos would not be the proximate cause of a hand lost due to a workplace machine, is a textbook example of the limits of proximate cause. The asbestos did not cause the hand injury; rather, the machine did. In Ms. Owens's case, by contrast, Wyeth failed to adequately warn of the risks of its medication,

Pondimin; that inadequate warning led Ms. Owens's physician to prescribe Pondimin to Ms. Owens; and Ms. Owens now suffers from PPH as the direct result of having consumed Pondimin. In this case, the inadequate warnings pertain to the very item that caused the injury at issue.

Moreover, Professor Dobbs's treatise only would require that "the injury suffered" be "within the *class of injury* that the warning requirement was meant to avoid." Here, the "class of injury" that the requirement to warn fully and accurately of a prescription drug's potential harmful risks most assuredly encompasses any and all injuries that flow from having ingested the medication as the result of a physician's prescription. In short, the example intended to demonstrate what falls outside the limits of proximate cause as set forth in the Dobbs treatise is not analogous to this case, and the facts and circumstances of Ms. Owens's case fit comfortably within the proximate cause rule announced at the outset and again at the conclusion of the above quotation from the treatise.

Wyeth's Brief for Appellees proceeds to note that in both *Demmler* v. *SmithKline Beecham Corp.*, 671 A.2d 1151 (Pa. Super. Ct. 1996), and *Lineberger* v. *Wyeth*, 894 A.2d 141 (Pa. Super. Ct. 2006), the plaintiffs' failure–to–warn claim involved warnings about the very same injuries that the plaintiffs claimed to have sustained as the result of ingesting the drugs at issue in those cases. Of course, that neither proves nor disproves whether the trial court's proximate cause ruling was correct in this case, because neither of those two cases involved circumstances similar to this case. Indeed, Wyeth's citation to *Demmler* on page 18 of its Brief for

Appellees is mistaken, because *Demmler* did not involve a plaintiff's claim that the drug's warning was inadequate because it failed to properly warn about a condition that she did not have. Rather, as the final paragraph of this Court's ruling in *Demmler* makes clear, in that case it was undisputed that the manufacturer's label adequately warned of the risk of the harm that she sustained, but the plaintiff nonetheless contended that the label was inadequate because it failed to advise of an effective *antidote* to the harmful side–effect. *See Demmler*, 671 A.2d at 1156. This Court's rejection in *Demmler* of the plaintiff's "failure to give notice of an antidote" claim does not and cannot control the outcome here.

In addition to *Demmler*, page 18 of Wyeth's Brief for Appellees cites six other cases from other jurisdictions. Two of those cases — *In re Norplant Contraceptive Prods. Liab. Litig.*, 1997 WL 81094 (E.D. Tex. 1997), and *Grenier* v. *Medical Engineering Corp.*, 99 F. Supp. 2d 759 (W.D. La. 2000) — contain no reasoned analysis of the legal issue presented here.

In two other of those cases — *Mills* v. *United States*, 764 F.2d 373 (5th Cir. 1985), and *Stahl* v. *Novartis Pharmaceuticals Corp.*, 2000 WL 33915848 (E.D. La. 2000) — the plaintiffs lacked any evidence that they would not have taken, or their physicians would not have prescribed, the medications had the warnings been adequate in all material respects. Moreover, when the Fifth Circuit squarely confronted the very issue presented here in *Dartez* v. *Fibreboard Corp.*, 765 F.2d 456, 468 (5th Cir. 1985), it issued a decision that favors Ms. Owens's position on appeal, holding that "[w]hether a specific disease has been diagnosed in an

individual plaintiff does not determine the scope of defendants' duty to warn. What is significant is whether the warning of the nondisclosed risks could have averted plaintiff's injury, or afforded him the opportunity to make a knowing choice."

And finally, the remaining two cases — *Coursen* v. *A.H. Robins Co.*, 764 F.2d 1329 (9th Cir. 1985), and *In re: Rezulin Prods. Liab Litig.*, 2004 WL 1802960 (S.D.N.Y. 2004) — in fact support Ms. Owens's position on appeal. In *Coursen*, the Ninth Circuit explained that the trial court properly exercised its discretion to exclude the evidence of other harms under the balancing text found in Federal Rule of Evidence 403. But, by definition, Rule 403 only applies to relevant evidence, *see* Fed. R. Evid. 403 (titled "Exclusion of relevant evidence on grounds of prejudice, confusion, or waste of time"), and the recognition that evidence of other harms or inadequate warnings was relevant is directly contrary to Judge Tereshko's summary judgment ruling here.

Moreover, in the *Rezulin* case, the federal district judge agreed that it would be relevant if physicians had testified that warnings about risks the patients did not suffer would have caused the physicians not to have prescribed the medication. *See* 2004 WL 1802960, at *3–4. However, the trial court went on to hold that the evidence of other inadequate warnings was not admissible in that case because no physicians had testified that they would not have prescribed the medication to their patients if they had received adequate warnings of those other risks. Here, by contrast, the evidence is relevant, because a reasonable jury could conclude that Ms.

Owens's physician would not have prescribed Pondimin to her had Wyeth warned him of that medication's actual VHD risk. R.576a–81a.

Wyeth's citation on pages 19–20 of its Brief for Appellees to seven decisions (six of which are unpublished and thus found in the Reproduced Record on appeal) discussing whether evidence of the PPH risk of diet drugs would be admissible in a case where the plaintiff claimed to suffer from VHD does nothing to advance Wyeth's argument, because those rulings either apply a Rule 403–style balancing test to decide whether the PPH evidence was admissible or contain no reasoned analysis of the question presented here. At the risk of repeating ourselves, any decision that applies a Rule 403 balancing test is contrary to Judge Tereshko's summary judgment ruling in this case, because such a decision acknowledges that the other risk is indeed relevant evidence. Judge Tereshko, by contrast, held that the evidence of the other risk is inadmissible as a matter of law due to his improperly narrow view of proximate cause, and not under a Rule 403 balancing test.

Finally, the one case that Wyeth cites on page 20 of its Brief for Appellees as holding that evidence of VHD would not be admitted in a PPH case consists of nothing more than a few unadorned pages of a Massachusetts trial court's transcript. And that decision itself applies a Rule 403–style balancing test (R.677a–79a), which is thus contrary to Judge Tereshko's proximate cause ruling from which Ms. Owens has appealed.

Although what we have already said above about the cases on which Wyeth relies in its Brief for Appellees provides a more than sufficient basis to reject Wyeth's argument that the trial judge's proximate cause ruling should be affirmed, it may be useful to discuss briefly why a trial court might decide under Rule 403 that evidence of PPH should be excluded in a case where the plaintiff claims to suffer from VHD, while remembering that that scenario is the *opposite* of the one presented in Ms. Owens's case (as she suffers from PPH but wishes to establish proximate cause using the inadequacy of Wyeth's VHD warnings for Pondimin).

In a case where the plaintiff suffers from VHD, the plaintiff should be able to establish the inadequacy of Wyeth's warnings without much difficulty, for the reasons explained in the statement of facts set forth in our Brief for Appellants at pages 4–6. Moreover, although VHD is certainly a serious condition, it is not the virtual death sentence that a diagnosis of PPH represents. *See In re Diet Drugs*, 2000 WL 1222042, at *8–*17 (E.D. Pa. 2000) (describing the health–related consequences of VHD and PPH). Thus, in a VHD case, the plaintiff does not require PPH–related evidence to establish inadequacy of warning, and the likely purpose of the PPH–related evidence is to inflame the jury about a different, extraordinarily serious risk of certain death that the diet drug medication carries — a risk that the plaintiff in that case did not manifest. It is thus readily apparent why, in a VHD case, the Rule 403 balancing test may tilt in favor of excluding PPH–related evidence, even though such evidence is nevertheless relevant.

By contrast, in Ms. Owens's case, she suffers from the virtual death sentence that a diagnosis of PPH represents. Yet, in order to establish that the warning her physician received about the risks of Pondimin was inadequate, she must rely on that medication's originally inadequate VHD warning. In other words, the probative value of the VHD evidence in her case is very, very high, because without it she cannot prevail on her failure to warn claim. At the same time, the fact that Pondimin is capable of causing somewhat less serious conditions such as VHD in addition to causing the fatal condition of PPH is unlikely to cause the jury to become more outraged, because Ms. Owens already suffers from the most life–threatening condition possible. For all of these reasons, in this case the Rule 403 balancing test, when the trial court eventually undertakes it, will favor Ms. Owens. It remains important to keep in mind, however, that Judge Tereshko has not undertaken any Rule 403 balancing test here. Moreover, because the application of that rule is initially entrusted to the broad discretion of the trial judge, *see Commonwealth* v. *Smith*, 808 A.2d 215, 225 (Pa. Super. Ct. 2002), it would not be appropriate for this Court to undertake that balancing test in the first instance on appeal.

To be sure, Wyeth's Brief for Appellees has cited many more diet drug cases than our Brief for Appellants, and Wyeth's Brief for Appellees has cited many more cases in its proximate cause discussion than did our Brief for Appellants. But what Wyeth's Brief for Appellees has failed to offer are any cases as directly on point, or even in the neighborhood of being on point, as are the cases discussed in detail at

pages 21–23 of our Brief for Appellants. What those cases cited in our Brief for Appellants establish are that — (1) where the manufacturer of a product or drug has the duty to provide full and adequate warnings of the product's or drug's risks; (2) where the failure to provide full and adequate warnings causes the product or the drug to be used or prescribed whereas the product or drug would not be prescribed or used had full and adequate warnings been given; and (3) where the product or drug directly causes injury to the user — a reasonable jury may properly find that the failure to warn was the proximate cause of the injury. Accordingly, this Court should reverse the trial court's entry of summary judgment against Ms. Owens and remand for further proceedings.

2. Wyeth's argument that Ms. Owens has failed to prove the inadequacy of Pondimin's VHD warning is waived and without merit

As this Court is well aware, a reply brief is not the appropriate place for a party to raise an entirely new argument that could have been raised in that party's opening brief. *See*, *e.g.*, *Commonwealth* v. *Basemore*, 560 Pa. 258, 275, 744 A.2d 717, 726–27 (2000) (noting that "[a] reply brief, however, is an inappropriate means for presenting a new and substantively different issue than that addressed in the original brief"). But that is precisely what Wyeth tried to do in its reply brief filed in the trial court in support of Wyeth's summary judgment motion. R.583a–91a. The trial court wisely did not rely on that argument first raised by Wyeth in its summary judgment reply brief as a basis for granting summary judgment in favor

of Wyeth, but on appeal Wyeth again seeks to assert that argument, now as an alternate basis for affirmance.

When Wyeth originally moved for summary judgment in this case, its motion asserted nothing more and nothing less than that the PPH warning that accompanied Pondimin when Ms. Owens's doctor decided to prescribe that drug to the plaintiff was adequate, and therefore the plaintiff could not establish proximate cause. R.105a–17a. In opposing Wyeth's summary judgment motion, Ms. Owens advanced the same argument that she is making on appeal — that the VHD warning accompanying Pondimin was inadequate. R.192a–96a. Wyeth should have known that this would be one of plaintiff's arguments in response to summary judgment given the questions plaintiff's counsel had asked Ms. Owens's prescribing physician at his deposition. R.580a–81a. Moreover, Wyeth could have served contention interrogatories on Ms. Owens to ascertain the basis for her claim that Wyeth's warnings for Pondimin were inadequate. *See* Pa. R. Civ. P. 4003.1 & 4005.

But, for whatever reason, Wyeth's original summary judgment motion did not seek summary judgment on plaintiff's claim that the Pondimin warnings were inadequate due to their failure to adequately warn of Pondimin's VHD risk, R.105a–17a, and therefore it would have been superfluous for Ms. Owens to have responded to Wyeth's actual summary judgment motion (which merely asserted that Pondimin's PPH warning was adequate) with expert testimony establishing that Pondimin's VHD warning was inadequate. Instead, what plaintiffs produced was the evidence showing that Wyeth had originally concealed Pondimin's true VHD

risk from the FDA and that, as a result, it was not until much later, long after Dr. Etzel began prescribing Pondimin to Ms. Owens, that the FDA required Wyeth to change its Pondimin label to reflect the medication's actual VHD risk. R.187a–96a.

Thus, although it takes great chutzpah for Wyeth to be arguing here that Ms. Owens has failed to show that Pondimin's original VHD warning was inadequate when it was the FDA's later appreciation of Pondimin's true VHD risk that led to the complete withdrawal of these diet drug medications from the marketplace (R.572a–73a), Ms. Owens does indeed plan to introduce at trial expert testimony establishing that Pondimin's original VHD warning was inadequate because it failed to warn of the medication's actual VHD risk. However, plaintiff had no obligation to come forward with such evidence in response to a summary judgment motion that was only asserting that Wyeth had properly warned of Pondimin's PPH risk. R.105a–17a (Wyeth's original summary judgment motion).

If Wyeth had wanted to put plaintiff to the test on this aspect of her claim, Wyeth could have made this aspect of plaintiff's claim the subject of its summary judgment motion. Or, Wyeth could have filed a separate summary judgment motion on this issue. Perhaps the trial court may even allow Wyeth, over the plaintiffs' objections, to file a summary judgment motion on this basis following reversal and remand here. But, because Wyeth's original summary judgment motion did not assert the adequacy of Pondimin's VHD warning, and because Wyeth did not argue that plaintiffs had failed to introduce expert testimony to prove the inadequacy of

Pondimin's VHD warning until Wyeth filed its reply brief (to which plaintiffs had no right to respond), Wyeth's argument in this regard is waived.

To be clear, Wyeth could have and did properly argue in its reply brief filed in the trial court that the manner in which Ms. Owens seeks to prove proximate cause here is legally (as opposed to factually) insufficient. And that supposed legal insufficiency, of course, is the ground on which the trial court relied in ruling in Wyeth's favor. What was improper about Wyeth's reply brief filed in the trial court was that Wyeth's original summary judgment motion only challenged the evidentiary basis for a proximate cause argument that Ms. Owens was not making. After Ms. Owens pointed out in her response brief that Wyeth's evidentiary challenge pertained exclusively to a proximate cause argument that she was not making, Ms. Owens did not have the burden to do anything further than to identify what her actual proximate cause argument was. And this, of course, is precisely what she did. R.187a–96a.

Thereafter, when Wyeth, in its reply brief, sought to expand its summary judgment motion to encompass a challenge to the evidentiary basis for Ms. Owens's actual proximate cause argument, that challenge came too late, because Ms. Owens had no right to respond to Wyeth's reply brief. It is not Ms. Owens's argument on appeal that Wyeth *could not* have challenged on summary judgment the evidentiary basis of Ms. Owens's actual proximate cause argument; rather, it is Ms. Owens's argument on appeal that Wyeth *did not properly do so* by waiting until its reply brief filed in the trial court to assert such a challenge.

Wyeth's Brief for Appellees, in footnote 3 on page 14, takes issue with the assertion in our Brief for Appellants that Wyeth's summary judgment motion did not dispute that Pondimin's VHD warning was inadequate when Dr. Etzel decided to prescribe Pondimin to Ms. Owens. All that we had said in our Brief for Appellants was that Wyeth's original motion for summary judgment (R.105a–17a) did not assert that Pondimin's VHD warning was adequate when Dr. Etzel decided to prescribe Pondimin to Ms. Owens. Indeed, even Wyeth's reply brief filed in the trial court did not assert that the original Pondimin label adequately warned of the medication's VHD risk, but only that Ms. Owens had failed to present expert testimony showing that the warning was inadequate in that respect, notwithstanding that any such response would have been gratuitous given that Wyeth's original summary judgment motion did not even challenge the actual basis for Ms. Owens's failure–to–warn argument.

Perhaps recognizing that Wyeth had waived the argument by failing to raise it until Wyeth's reply brief filed in the trial court, the trial court did not rely on or even make note of this supposed evidentiary deficiency in Ms. Owens's response to Wyeth's summary judgment motion. And, due to waiver, this Court should likewise reject Wyeth's alternate basis for affirmance.

3. Wyeth's reliance on portions of Ms. Owens's prescribing physician's deposition testimony that appear to favor Wyeth instead of Ms. Owens is improper on summary judgment and should be disregarded

One of the cardinal rules at the summary judgment stage, and on appeal from a trial court's grant of summary judgment, is that the evidence in the record must be viewed in the light most favorable to the non–moving party (here, the plaintiffs) and all reasonable inferences must be drawn in favor of the non–moving party (the plaintiffs). *See Chanceford Aviation Properties, L.L.P.* v. *Chanceford Tp. Bd. of Supervisors*, 592 Pa. 100, 107, 923 A.2d 1099, 1103 (2007).

As we explained in our opening Brief for Appellants, at pages 16–19, viewing the deposition testimony of Dr. Etzel in the light most favorable to the plaintiffs, a reasonable jury could find that Dr. Etzel would have altered his prescribing behavior with regard to Marie Owens had he been warned of the actual greater risks and miniscule benefits related to using Pondimin. Those pages of our opening brief contain three lengthy direct quotations from Dr. Etzel's deposition testimony under oath in this case to establish this element of plaintiffs' failure–to–warn claim.

In its Brief for Appellees, Wyeth — relying on two other quotations from Dr. Etzel's deposition testimony — contends that Dr. Etzel would continue to prescribe Pondimin for Ms. Owens to use even at the present time, even though he now recognizes the medication's actual risks and notwithstanding the FDA's decision to completely withdraw Pondimin from the market. *See* Brief for Appellees at 12–13.

Unfortunately for Wyeth, even if this Court were to accept that Dr. Etzel's deposition testimony was open to two reasonable interpretations — which is the

most that Wyeth's argument for affirmance establishes — the entry of summary judgment in Wyeth's favor would nevertheless remain inappropriate, because it would be for the jury to decide which interpretation was correct and appropriate.

Accordingly, this Court should reject Wyeth's effort to rely on portions of Dr. Etzel's deposition testimony that favor Wyeth, rather than Ms. Owens, as improper. Rather, Wyeth's argument merely furnishes one more reason why a jury trial of this case is necessary.

B. Plaintiffs' claims against Wyeth for negligently marketing Pondimin and negligently failing to withdraw Pondimin from the market are cognizable under Pennsylvania law

Although, as Wyeth's Brief for Appellees correctly notes at page 22, the Supreme Court of Pennsylvania has rejected strict liability claims against prescription drug manufacturers, *see Hahn* v. *Richter*, 543 Pa. 558, 673 A.2d 888 (1996), the two additional claims that Ms. Owens seeks to assert against Wyeth are not strict liability claims. Rather, they are claims sounding in negligence.

In determining what type of negligence claims may be asserted against a prescription drug manufacturer for personal injuries resulting from prescription drugs, the Supreme Court of Pennsylvania, in the seminal case of *Incollingo* v. *Ewing*, 444 Pa. 263, 282 A.2d 206 (1971), obtained guidance from comment k of Restatement (Second) of Torts §402A. *See Incollingo*, 444 Pa. at 287–88, 282 A.2d at 219–20; *see also Hahn*, 543 Pa. at 560 & n.2, 673 A.2d at 889–90 & n.2 (relying on and favorably quoting comment k of Restatement (Second) of Torts §402A); Wyeth's

Brief for Appellees at 22–23 (citing to and relying on that very same Restatement comment).

Comment k to Restatement (Second) of Torts §402A concludes as follows:

> The seller of [prescription drugs], *again with the qualification that they are properly* prepared and *marketed*, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts §402A comment k (emphasis added).

As the above–quoted portion of comment k makes clear, the manufacturer of an unavoidably unsafe product such as a prescription drug has the duty not only to provide proper warnings, but also to properly market the medication. And comment k treats those two things as *separate* obligations and duties, for whose breach independent claims sounding in negligence may be brought.

The negligent marketing claim that Ms. Owens is asserting here is essentially identical to the negligent failure–to–test claim that the Third Circuit, applying Pennsylvania law, recognized in *Hoffman* v. *Sterling Drug, Inc.*, 485 F.2d 132, 140–41 (3d Cir. 1973). In its Brief for Appellees, Wyeth incorrectly argues that the only claim at issue in *Hoffman* was a negligent failure–to–warn claim. The Third Circuit's opinion itself, however, conclusively disproves Wyeth's assertion, as the Third Circuit in that opinion separately addresses both the plaintiff's failure–to–test claim (*id.* at 140–41) and the plaintiff's failure–to–warn claim (*id.* at 141–42).

This Court, in an en banc decision issued in 1973, unanimously recognized that Pennsylvania law imposes the duty on a prescription drug manufacturer to adequately test its products before bringing them to market. *See Leibowitz* v. *Ortho Pharmaceutical Corp.*, 307 A.2d 449 (Pa. Super. Ct. 1973) (en banc). Although that case failed to produce a majority opinion, all six judges who participated in that decision recognized the existence of such a duty to test under Pennsylvania law. *See id.* at 459 (opinion in support of affirmance) ("By this opinion, we wish to make it clear that 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 464 (opinion in support of reversal) ("The law required that defendant be bound to act in accordance with not only the knowledge it did actually possess but the knowledge it could have and should have possessed in 1964. The plaintiff's complaints in trespass and assumpsit expressly alleged that defendant did in 1964 market a drug without adequate testing. The body of knowledge subsequently obtained from testing conducted subsequent to 1964 by governmental agencies, other manufacturers, or by the defendant, was relevant . . . .") (internal citations omitted).

Ms. Owens's negligent marketing claim asserts that Wyeth was negligent in bringing Pondimin to market because, had Wyeth adequately tested the medication in advance of bringing it to market, Wyeth would have concluded (as the FDA later concluded) that Pondomin's risks outweighed its benefits as to all possible classes of users of that medication. That conclusion is why the FDA later required Wyeth to

remove both Pondimin and Redux from the market and is why, even today, pharmacists are prohibited from compounding or selling to patients the active ingredients in those medications for any purpose whatsoever.

Similarly, Ms. Owens's negligent failure to withdraw Pondimin from the market alleges that it was Wyeth's negligent failure to adequately evaluate the reports it was receiving of health problems being caused by Pondimin that resulted in Pondimin's remaining available on the market when Ms. Owens was prescribed that medication.

What makes this case and other cases involving these Fen–phen drugs different from the typical, run–of–the–mill prescription drug failure to warn cases is that these medications have been banned from the market entirely by the FDA. In other words, there is no risk–benefit balancing test that can be performed with respect to Pondimin or Redux that would allow anyone to conclude that those medications should be available to any class of patients, as demonstrated by the FDA's decision completely banning these drugs from the market.

Wyeth's argument that Pennsylvania law does not recognize the negligent marketing and negligent failure to withdraw from the market claims that Ms. Owens is asserting is further undermined by the fact that such claims are recognized as valid under Restatement (Third) of Torts: Products Liability §6(c). Section 6(c) states, in full:

> A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risk of harm posed by the drug or medical device are sufficiently great in relation to the foreseeable therapeutic benefits that reasonable health–care providers, knowing of

> such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.

Restatement (Third) of Torts: Prods. Liab. §6(c) (1998).

Courts and commentators have broadly criticized this provision as too pro–manufacturer and not sufficiently protective of consumers, in addition to thus being inconsistent with existing case law. *See, e.g.*, *Freeman* v. *Hoffman La–Roche, Inc.*, 618 N.W.2d 827, 839–40 (Neb. 2000) ("We conclude that §6(c) has no basis in the case law. We view §6(c) as too strict of a rule, under which recovery would be nearly impossible. Accordingly, we do not adopt §6(c) of the Third Restatement."). As a result, Section 6(c) has been rejected by the vast majority of courts that have considered it, and Section 6(c) does not accurately reflect existing Pennsylvania law, nor do plaintiffs urge its adoption in Pennsylvania.

That being said, however, it is noteworthy that even under the inappropriately restrictive standard for prescription drug manufacturer liability espoused in Section 6(c), Ms. Owens's claims for negligent marketing and negligent failure to withdraw from the market would remain viable. This is because the FDA's decision barring the sale of Pondimin for any purpose whatsoever conclusively establishes that "reasonable health–care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug * * * for any class of patients." Restatement (Third) of Torts: Prods. Liab. §6(c).

And lest Wyeth counter that the type of design defect claim recognized in Section 6(c) is the same sort of strict liability claim that the Supreme Court of Pennsylvania refused to recognize in *Hahn* v. *Richter*, 543 Pa. 558, 673 A.2d 888

(1996), this Court should note that here plaintiffs are asserting a prescription drug design defect claim sounding in negligence, not in strict liability. R.46a; *see*, *e.g.*, *Bruesewitz* v. *Wyeth Inc.*, 561 F.3d 233, 248 (3rd Cir. 2009) (recognizing that prescription drug design defect claims can sound in either strict liability or negligence), *cert. granted on other grounds*, 2010 WL 757696 (U.S. Mar. 08, 2010) (No. 09–152).

In sum, regardless of whether plaintiffs' claims against Wyeth, other than their negligent failure to warn claim, are characterized as claims alleging negligent marketing and negligent failure to withdraw from the market; claims alleging negligent failure to test; or claims alleging negligent design defect, such claims are recognized as valid under Pennsylvania law. This Court should therefore reverse the trial court's entry of summary judgment as to those additional claims.

III. CONCLUSION

For the reasons set forth above and in our opening brief, this Court should reverse the trial court's entry of summary judgment in Wyeth's favor and should remand this case for trial.

Respectfully submitted,

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Linda C. Love
Michael L. Williams
Williams Love O'Leary & Powers, P.C.
9755 S.W. Barnes Road
Suite 450
Portland, OR 97225–6681
(503) 946–5412

Howard J. Bashman
2300 Computer Avenue
Suite G–22
Willow Grove, PA 19090
(215) 830–1458

Counsel for Plaintiffs/Appellants

CERTIFICATE OF SERVICE

I hereby certify that I am this day serving two true and correct copies of the foregoing document upon the persons and in the manner indicated below which service satisfies the requirements of Pa. R. App. P. 121:

Service by First Class U.S. Mail addressed as follows:

Michael T. Scott, Esquire
Henry F. Reichner, Esquire
Barbara R. Binis, Esquire
Tracy G. Weiss, Esquire
Reed Smith, L.L.P.
2500 One Liberty Place
1650 Market Street
Philadelphia, PA 19103
(215) 851–8100
Counsel for Wyeth

Amy Rohe, Esquire
Arnold & Porter, LLP
555 Twelfth Street, NW
Washington, DC 20004
(202) 942–5535
Counsel for Wyeth

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

Tobias L. Millrood, Esquire
Pogust, Braslow & Millrood, L.L.C.
161 Washington Street
Suite 1520
Conshohocken, PA 19428
(610) 941–4204
Co–counsel for Appellants

Dated: March 15, 2010

Howard J. Bashman
2300 Computer Avenue
Suite G–22
Willow Grove, PA 19090
(215) 830–1458