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.

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

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Trial court's Rule 1925(a) opinion ..... Exhibit A

Trial court's order granting Wyeth's summary judgment motion ..... Exhibit B

Plaintiffs' Rule 1925(b) statement ..... Exhibit C

I. STATEMENT OF JURISDICTION

On December 17, 2008, Judge Allan Tereshko of the Court of Common Pleas of Philadelphia County entered an order granting summary judgment against plaintiffs Marie and Fred Owens and in favor of defendant Wyeth, holding as a matter of law that Wyeth's failure to warn of the risks of its prescription diet drug Pondimin (a so–called Fen–phen weight loss medication) was not a proximate cause of the serious injuries that Mrs. Owens sustained as a result of having consumed that drug. R.9a; *see also* Exhibit B attached hereto.

Plaintiffs filed a timely notice of appeal on January 6, 2009. R.10a, 684a. This Court possesses appellate jurisdiction pursuant to Pennsylvania Rule of Appellate Procedure 341(a).

II. STATEMENT OF THE SCOPE AND STANDARD OF REVIEW

This Court exercises *de novo*, entirely non–deferential review of a trial court's order granting summary judgment. As this Court has explained:

> Since the issue as to whether there are no genuine issues as to any material fact presents a question of law, our standard of review is *de novo*; thus, we need not defer to the determinations made by the lower tribunals. Our scope of review, to the extent necessary to resolve the legal question before us, is plenary.

Chanceford Aviation Properties, L.L.P. v. *Chanceford Tp. Bd. of Supervisors*, 592 Pa. 100, 107, 923 A.2d 1099, 1103 (2007). *Chanceford* recognizes that an appellate court "must view the record in the light most favorable to the non–moving party, and all

doubts as to the existence of a genuine issue of material fact must be resolved against the moving party." *Id.*

Both this Court and the Pennsylvania Supreme Court have held that "[s]ummary judgment is to be entered only in the clearest of cases where there is not the slightest doubt as to the absence of a triable issue of fact." *See Wells Fargo Bank, N.A.* v. *Long*, 934 A.2d 76, 77 (Pa. Super. Ct. 2007); *see also Trowbridge* v. *Scranton Artificial Limb Co.*, 560 Pa. 640, 644, 747 A.2d 862, 864 (2000) ("Because this is an appeal from the grant of a motion for summary judgment, our standard of review is well settled. Summary judgment may be granted only in the clearest of cases where the record shows that there are no genuine issues of material fact and also demonstrates that the moving party is entitled to judgment as a matter of law.").

III. TEXT OF THE ORDER IN QUESTION

On December 15, 2009, the trial court issued the following order:

> **AND NOW**, this 15th day of December, 2008, upon consideration of the Wyeth's Motion for Summary Judgment Based on Failure to Prove Proximate Cause and Plaintiffs' Response thereto, it is hereby **ORDERED** that Wyeth's Motion is **GRANTED**.

Exhibit B attached hereto.

IV. STATEMENT OF THE QUESTIONS PRESENTED

1. Did the trial court err as a matter of law in entering summary judgment in Wyeth's favor on the issue of proximate causation, where a reasonable jury could find based on the evidence of record that Mrs. Owens would not have sustained serious injuries as a result of ingesting Wyeth's medication had Wyeth provided adequate warnings to Mrs. Owens's prescribing physician of the actual risks inherent in ingesting that product?

2. Did the trial court err as a matter of law in entering summary judgment in Wyeth's favor on plaintiffs' claims that Wyeth was negligent in marketing Pondimin and in failing to withdraw Pondimin from the market before the drug was prescribed to Mrs. Owens, given that (a) Wyeth did not move for summary judgment on these claims and (b) such claims are cognizable under Pennsylvania law?

V. STATEMENT OF THE CASE

A. Relevant Factual History

Marie Owens is a restaurant owner and cook now in her early 60's who lives in East Carbon, Utah. R.19a, 190a. Her primary physician, Glen Etzel, M.D., prescribed Pondimin to Mrs. Owens from November 1995 to April 1996, and again from January to June 1997. *Id.* She has been diagnosed with exercise–induced Primary Pulmonary Hypertension (PPH), a frequently fatal illness that is a signature injury of having consumed Pondimin. R.19a, 233a. For purposes of its summary judgment motion, Wyeth did not dispute that Mrs. Owens suffers from PPH, nor did Wyeth dispute that having consumed Pondimin was the cause of Mrs. Owens's PPH. R.105a–17a.

The medication Pondimin was a so–called Fen–phen medication sold to promote weight loss. "Fen–phen" refers to the use of fenfluramine in combination with phentermine. Wyeth was the sole supplier of fenfluramine in the United States, and Wyeth's trade name for fenfluramine was Pondimin. R.205a. Fenfluramine (Pondimin) is 50% dexfenfluramine, which is the active ingredient of Pondimin.

Wyeth knew fenfluramine and dexfenfluramine caused PPH as early as 1993, and possessed additional evidence of that fact in March 1995, but Wyeth took no steps to investigate these disturbing findings. R.210a –12a, 224a–25a, 228a–29a, 233a–36a, 240a–45a. By mid–1995, Wyeth had also received numerous reports of valvular heart disease (VHD) in fenfluramine users, but deliberately chose not to

investigate those cases, and did not follow up at all on those reports until the Mayo Clinic forced Wyeth's hand in April 1997. R.266a–411a. Even then, Wyeth intentionally deleted 17 of the 24 Mayo Clinic heart valve disease cases from its database and re–used the report numbers for other products, so that they would be untraceable by the FDA. R.421a–47a. Moreover, Wyeth failed to perform any studies of the potential harmful effects of fenfluramine and Fen–phen and failed to conform to FDA–mandated industry post–marketing surveillance standards.

In late 1995 and early 1996, Wyeth was in the process of seeking FDA approval for its new diet pill, Redux, which contained only dexfenfluramine, the potent half of fenfluramine. Wyeth did not want a "black box" warning about PPH or VHD to be attached to the Redux package label, and Wyeth was determined not to make public any bad information about Pondimin and Fen–phen during the approval process, since Pondimin and Redux were the same drug. R.451a–53a, 457a–58a, 463a–64a, 467a–96a, 498a–506a.

Wyeth was successful in getting Redux approved and marketed without the black box warning. The FDA advisory committee approved Redux by only one vote. One of the members who voted to approve, Dr. Illingworth, later testified that he would have voted against approval if he had been fully informed of the risks of the drug. R.510a.

As early as 1994 and 1995, Wyeth knew of far more reports of heart valve disease cases than it reported to the FDA. R.515a, 521a–26a. Wyeth also did not alert the medical community to these potential heart valve disease outcomes in

long–term users. As a result, independent investigators made their discovery without the benefit of knowing about these other cases known only to Wyeth. Wyeth delayed public disclosure of the risk of heart valve disease caused by its fenfluramine until July 1997, less than two months before these drugs were taken off the market. R.539a–40a. Most tragically, Wyeth did nothing to investigate the possible association of fenfluramine and heart valve disease for two years after it knew about these reports in 1995.

Wyeth should have conducted an investigation in early 1995, and if it had, it would have found then what was discovered in August 1997: that a significant portion of long–term Pondimin users developed serious heart valve disease. Had that happened — had Wyeth acted as a reasonably prudent pharmaceutical company — Wyeth would never have completed its application for FDA approval of Redux, or at least Wyeth would have taken Pondimin off the market before November 1995, when the medication was first prescribed to Mrs. Owens.

Eventually, Wyeth could no longer cover up the PPH/VHD epidemic. The truth percolated to the surface as outside researchers began publishing reports of VHD cases cropping up throughout the United States. Immediately thereafter, the FDA pressured Wyeth to issue a new black box warning for both PPH and VHD. R.539a. The FDA also demanded to see the sizable database of PPH/VHD cases that Wyeth had managed to keep hidden from the agency for several years. R.542a–69a. Faced with these mounting pressures, on September 15, 1997, Wyeth withdrew both Redux and Pondimin from the market. R.572a–73a.

Since then, the FDA added fenfluramine and dexfenfluramine to the list of unsafe products ineligible for compounding exemptions. In other words, the FDA determined that fenfluramine and dexfenfluramine are unsafe and unfit for their intended use regardless of warnings, and the FDA has made it illegal to compound these drugs, effectively preventing their use for any purpose whatsoever.

In order for a plaintiff who sustained injuries as the result of ingesting a prescription drug to prevail under Pennsylvania law in a negligent failure–to–warn action, the plaintiff must establish several things: (1) the manufacturer of the prescription drug negligently failed to warn prescribing physicians of the medication's actual harmful risks so that the physicians could make a truly informed decision concerning whether to prescribe the medication; (2) had the physician known of the prescription drug's actual harmful risks, the physician would not have prescribed the drug to the plaintiff; and (3) ingesting the drug caused the plaintiff to suffer injury and resulting damages. *See Demmler* v. *SmithKline Beecham Corp.*, 671 A.2d 1151, 1155 (Pa. Super. Ct. 1996).

In moving for summary judgment in this case on the issue of "proximate cause," Wyeth asserted that it had accurately and fully disclosed to physicians the PPH risks to patients from ingesting Pondimin before Mrs. Owens's physician decided to prescribe Pondimin to her in November 1995. R.106a–07a. Wyeth thus argued that Mrs. Owens could not establish that Wyeth's PPH–related warning was inaccurate or incomplete or that her doctor would not have prescribed Pondimin for her had he known of the medication's actual PPH risk, because he did know of the

medication's actual PPH risk when he decided to prescribe Pondimin for Mrs. Owens to use. R.107a.

Mrs. Owens filed a response in opposition to Wyeth's summary judgment motion in which she argued that summary judgment should be denied because Wyeth's Pondimin warning, as it existed when her doctor prescribed that drug for her to use, materially underrepresented the medication's actual risk of causing patients to suffer valvular heart disease (VHD) as a result of having consumed the medication. R.185a–96a. VHD is another signature injury caused by ingesting Pondimin and other Fen–phen medications. For purposes of its summary judgment motion, Wyeth did not dispute that its VHD warning for Pondimin when Mrs. Owens's physician was prescribing the drug for her use failed to fully and accurately disclose the serious VHD risk that Pondimin posed to patients who ingested the drug. R.105a–17a. In fact, the medication's label during that period contained no warning about or mention of contracting VHD as a result of ingesting Pondimin, even though Wyeth was aware of that risk at that time.

Just several months after Mrs. Owens stopped using Pondimin in June 1997, the federal government's Food and Drug Administration (FDA) required Wyeth to strengthen Pondimin's VHD warnings after the FDA had learned of the true severity and extent of VHD among users of the medication. Most significantly, the FDA required Wyeth to place the VHD and PPH warnings for Pondimin in a prominent "black box," which is the most emphatic and serious type of warning that a drug's label can contain. R.539a. Soon thereafter, Wyeth decided to pull its Fen–

phen drugs, including Pondimin, from the market (R.572a–73a), and ultimately the FDA decided that Pondimin and other Fen–phen weight loss drugs are so unsafe that they can no longer be sold, nor can their ingredients even be compounded by pharmacists authorized to formulate their own medications.

In opposing Wyeth's motion for summary judgment, Mrs. Owens advanced three arguments. First, she argued that the physician who prescribed Pondimin for her use, Dr. Glenn T. Etzel, M.D., would not have prescribed Pondimin to her had Wyeth accurately warned him about the actual risks — including the substantial VHD risk — and only miniscule benefits that Pondimin presented for patients such as Mrs. Owens. R.185a–96a. Second, Mrs. Owens argued that Wyeth had not moved for summary judgment on her separate, additional claims for negligently marketing Pondimin and negligently failing to withdraw Pondimin from the market before Mrs. Owens took the drug. R.197a. And third, Mrs. Owens argued that her claims for negligently marketing Pondimin and negligently failing to withdraw Pondimin from the market were valid claims under Pennsylvania law in a prescription drug injury case. R.197a–98a.

In its reply brief in further support of its summary judgment motion, Wyeth argued that because the only injury Mrs. Owens sustained was PPH, and because Mrs. Owens did not sustain any VHD injury, she could not establish proximate cause because she had failed to dispute that Wyeth's PPH warning for Pondimin was accurate when the medication was prescribed for her use. R.587a–90a. According to Wyeth, because Mrs. Owens did not sustain VHD, she could not

establish proximate cause by proving that Wyeth's VHD warning for Pondimin was woefully inadequate when the medication was prescribed for her use or that a complete and accurate VHD warning for Pondimin would have caused her treating physician to have not prescribed Pondimin to her. *Id.*

Wyeth's reply brief also disputed whether Mrs. Owens had actually asserted claims for negligently marketing Pondimin and negligently failing to withdraw Pondimin from the market. R.587a. Lastly, Wyeth's reply brief argued that such claims, even if Mrs. Owens had asserted them in this action, are not valid claims under Pennsylvania law in a prescription drug injury case. *Id.*

In ruling on the summary judgment motion, the trial court only explicitly addressed Mrs. Owens's negligent failure–to–warn claim and held that Wyeth was entitled to summary judgment on that claim. *See* Exhibit A hereto (trial court's Rule 1925(a) opinion). Nonetheless, the trial court's order dismissed Mrs. Owens' action in its entirety, thereby entering summary judgment in Wyeth's favor without discussion on Mrs. Owens's claims for negligently marketing Pondimin and negligently failing to withdraw Pondimin from the market. *See* Exhibit B hereto (trial court's summary judgment order).

In an opinion explaining the basis for its ruling, the trial court wrote that, under Pennsylvania law, Mrs. Owens could not establish proximate cause by proving that, had Wyeth provided physicians with an accurate and complete warning of all of the significant, harmful side–effects of Pondimin, the physician would not have prescribed Pondimin to her, and thus her injury would have been

averted. *See* Exhibit A attached hereto at 11–12. Rather, according to the trial court, Mrs. Owens to prevail must establish that the warning pertaining to the particular harmful side–effect that she actually suffered from was inadequate and incomplete. *Id.* Whether Wyeth had provided accurate and complete warnings of the drug's other harmful side–effects, which were necessary to enable the physician to make an adequately informed decision about whether to prescribe the medication to any of his patients, was irrelevant to Mrs. Owens's claim against Wyeth, the trial court has ruled here. *Id.*

As an additional basis for its ruling, the trial court proceeded to hold that even if Mrs. Owens could rely on Wyeth's failure to provide her physician with an adequate VHD warning as a basis for recovery, the deposition testimony from Mrs. Owens's prescribing physician failed to establish that he would not have prescribed Pondimin to Mrs. Owens had Wyeth fully and adequately warned him of all of that medication's potentially harmful side–effects. *Id.* at 12–13.

Lastly, the trial court's Rule 1925(a) opinion failed to address Mrs. Owens's argument that summary judgment should not be entered on her claims against Wyeth for negligently marketing Pondimin and negligently failing to withdraw Pondimin from the market.

B. Relevant Procedural History

Marie and Fred Owens, husband and wife, filed this lawsuit on August 13, 2004. R.3a. After relevant discovery had concluded, Wyeth filed its motion for summary judgment on the issue of proximate cause on October 31, 2008. R.8a. Plaintiffs filed a timely response in opposition, and then Wyeth filed a reply brief. On December 17, 2008, the trial court entered an order granting Wyeth's motion for summary judgment. R.9a; Exhibit B attached hereto.

Thereafter, on January 6, 2009, plaintiffs filed a timely notice of appeal. R.10a, 684a. After the trial court ordered plaintiffs to file a "Statement of Errors Complained of on Appeal" pursuant to Pennsylvania Rule of Appellate Procedure 1925(b) (R.687a), and after plaintiffs a timely Rule 1925(b) statement in response to that order (Exhibit C attached hereto), the trial court issued its opinion explaining the basis for its summary judgment order on August 17, 2009 (Exhibit A attached hereto).

VI. SUMMARY OF THE ARGUMENT

The trial court erred as a matter of law in holding on summary judgment that plaintiffs could not establish proximate cause, because plaintiffs' evidence to prove proximate cause in this prescription drug failure–to–warn case, when viewed in the light most favorable to plaintiffs as non–movants, is sufficient to establish that element of their claim. The evidence of proximate cause in this case would allow a reasonable jury to find: (1) that Wyeth failed to warn accurately and completely of all the material risks that prescribing physicians should have been made aware of when deciding whether to prescribe Pondimin to patients such as Mrs. Owens; and (2) had Wyeth warned adequately and completely of those risks, Dr. Etzel (Mrs. Owens's prescribing physician) would not have prescribed Pondimin to Mrs. Owens.

The trial court in this case erred as a matter of law when the trial court allowed a drug company's duty to warn a prescribing physician of a prescription drug's risks to fluctuate depending on what injury or injuries a patient ultimately sustained as a result of having consumed the medication. In other words, if one of Dr. Etzel's patients sustained valvular heart disease (VHD) as the result of ingesting Pondimin, that patient would have a valid claim against Wyeth for failing to warn Dr. Etzel in an accurate and complete manner about the medication's VHD risk. But where a patient of Dr. Etzel sustained PPH as a result of having ingested Pondimin, the same faulty and incomplete warning of the medication's harmful side–effects that would suffice to establish proximate cause in the first case would

no longer suffice to establish proximate cause in the second case, even though in both cases the accurate and complete warning (had Wyeth given it) would have prevented both patients from receiving Pondimin and from suffering their Pondimin–related injuries.

Pennsylvania law requires a prescription drug's manufacturer to fully and fairly warn prescribing physicians of all material harmful risks that the prescription drug presents, so that the physician can decide, in a well–informed manner, whether to prescribe the drug to his or her patients. Whether the drug manufacturer has breached that duty, and whether the breach was the proximate and factual cause of a given patient's injury, does not depend on what injury the patient suffered in cases where, as here, a jury could reasonably find from the doctor's testimony that he would not have prescribed the drug to the plaintiff had the doctor received from the drug's manufacturer an accurate and complete warning of all of the drug's harmful side–effects.

In addition, the trial court also erred in dismissing plaintiffs' claims against Wyeth for negligently marketing Pondimin and negligently failing to withdraw Pondimin from the market. Wyeth did not move for summary judgment as to these claims, plaintiffs have adequately pleaded these claims, and these claims are cognizable under Pennsylvania law.

For all of these reasons, the trial court's entry of summary judgment in Wyeth's favor should be reversed, and this case should be remanded for trial.

VII. ARGUMENT

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 Mrs. Owens's Injuries

Pennsylvania law recognizes that because prescription medications such as Pondimin are only available to patients at the direction of a licensed physician, the duty to warn of risks inherent in prescription medications runs from the manufacturer to the physician. *See Incollingo* v. *Ewing*, 444 Pa. 263, 288, 282 A.2d 206, 220 (1971); *Makripodis ex rel. Makripodis* v. *Merrell–Dow Pharmaceuticals, Inc.*, 523 A.2d 374, 378 (Pa. Super. Ct. 1987).

In order for a plaintiff in a failure–to–warn lawsuit to establish the element of proximate cause, the plaintiff must therefore establish that if the prescription drug's manufacturer had provided adequate warnings to the prescribing physician, the physician would not have prescribed the medication to the plaintiff. *See Lineberger* v. *Wyeth*, 894 A.2d 141, 149–50 (Pa. Super. Ct. 2006); *Demmler* v. *SmithKline Beecham Corp.*, 671 A.2d 1151, 1155 (Pa. Super. Ct. 1996).

In this case, Wyeth argued, and the trial court agreed, that the warnings Wyeth gave to physicians about the PPH risk to patients from ingesting Pondimin were accurate during the period when Dr. Etzel was prescribing Pondimin to Marie Owens. However, in opposing Wyeth's summary judgment motion, plaintiffs maintained that the warnings Wyeth gave to physicians about the valvular heart disease (VHD) risk to patients from ingesting Pondimin were inaccurate and

significantly downplayed and underrepresented the medication's actual VHD risk when Dr. Etzel was prescribing Pondimin to Mrs. Owens.

Once the federal government's Food and Drug Administration (FDA) ultimately learned of the true VHD risk to patients from Pondimin, the FDA first required Wyeth to supply new warnings that accurately reported the drug's actual, heightened VDH risk and to place the medication's VHD and PPH warnings into a "black box" on the medication's labeling. R.550a. Such "black box" warnings of a prescription drug's side–effects and risks are reserved by the FDA for the most critically important warnings that prescribing physicians should keep at the forefront of their minds when deciding whether or not to prescribe the medication.

Although Dr. Etzel's deposition testimony in this case is certainly open to multiple interpretations, because it is defendant Wyeth that is seeking summary judgment, it is necessary for the Court to view that testimony in the light most favorable to the plaintiffs as non–movants. *See Chanceford Aviation Properties*, 592 Pa. at 107, 923 A.2d at 1103.

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. Dr. Etzel ultimately concluded that the diet pills such as Pondimin do not work, that their risks exceed their benefits, that most patients regained lost weight and could not stay on the

pills to maintain weight loss, and what bothered him the most and caused him to stop prescribing Pondimin was that Pondimin caused heart valve disease.

Dr. Etzel testified under oath at his deposition:

> Q. Was it your experience that most people regained the weight that they lost when they had taken these diet pills?
>
> A. The answer is yes, and it's to every fad diet, every fad pill, everything. The answer is absolutely yes. The way you lose the weight is the way you have to continue to live your life. And if that's on pills, you need pills the rest of your life. If it's on diet drinks or whatever, you need that the rest of your life. And if you don't, with rare, rare exception, the weight comes back. And it's — the actual studies that have been done do not confirm the impression that the weight comes back plus some, but they certainly do confirm that the weight comes back at least to that level. So yes, don't believe them —

R.576a–77a.

Dr. Etzel further testified:

> Q. Well, I guess I really need to know whether you agree that if the patients were going to gain the weight back after they quit taking the pill, that that pill wasn't been beneficial enough to make it worth the risks?
>
> A. I think I already stated that. Whatever the means of weight loss, that person needs to continue that program forever, and unless they continue that program forever, it is not going to be successful. If Pondimin and Fastin had not had side effects and if it could be used forever and ever — I know you don't want to hear this, but it's wonderful. Look at Marie Owens's chart. Look at how much she lost.
>
> But as it turns out, it is not wonderful. It's like every other get–rich–quick scheme. In retrospect every generation of physicians seem to have to learn this.

R.578a–79a.

Regarding the risk of heart valve disease, Dr. Etzel testified:

Q. I want to ask you something else, Doctor, about the risks associated with this drug. In August of 1997, right before the drug was taken off the market, the Mayo Clinic published a study on heart valve disease, Heidi Connolly was the doctor involved, and it describes heart valve disease found in patients who had taken fenfluramine and dexfenfluramine. Do you remember when that happened, when this study came out about heart valve disease in August of '97?

A. I absolutely remember that that was available. It was at that point no surprise to me because it reminded me very much of carcinoid syndrome, which is a serotonin syndrome, which causes valvular disease on the right side of the heart. Again, in retrospect, that was not surprising. But I do absolutely — yes, I do remember that. That probably — that probably played more of a part in my — well, I wouldn't say that.

That I know was there, and if there was any medical reason that I stopped the Pondimin, even in my grossly obese person that had horrible sleep apnea — quite frankly he's probably dead now — it was the study that you just mentioned. That was probably the thing that bothered me the most medically, but at that point it didn't matter much because it was not very long before it wasn't available anyway.

R.580a–81a.

Understood in context, what Dr. Etzel testified to under oath was that he would weigh the risks and benefits of prescribing prescription drugs for each individual patient. He described a grossly obese male patient — the patient mentioned in the final paragraph of deposition testimony quoted above — as the one patient among all of his patients (including Mrs. Owens) who faced the greatest health risks in the absence of weight loss medications such as Pondimin or Redux. Nevertheless, even as to that grossly obese patient, Dr. Etzel testified that it was learning about medical studies that confirmed the VHD risk of Pondimin and Redux that caused Dr. Etzel to stop prescribing Pondimin: "if there was any medical

reason that I stopped the Pondimin, even in my grossly obese person that had horrible sleep apnea — quite frankly he's probably dead now — it was the study that you just mentioned." R.580a–81a. The published study to which Dr. Etzel was referring was the first to publicly reveal the true, widespread risk of VHD from consuming Pondimin.

Viewing Dr. Etzel's deposition testimony in the light most favorable to plaintiffs as the non–moving parties, *see Chanceford Aviation Properties*, 592 Pa. at 107, 923 A.2d at 1103, a jury could reasonably conclude that if learning of Pondimin's true VHD risk would have caused Dr. Etzel to stop prescribing Pondimin to Dr. Etzel's grossly obese male patient who was most in need of that medication's weight loss benefits, then Dr. Etzel would *a fortiorari* have stopped prescribing Pondimin to Mrs. Owens, who was less in need of that medication's weight loss benefits, due to Dr. Etzel's concern about the medication's actual VHD risk.

Thus, if Dr. Etzel had known of Pondimin's true VHD risk when he was deciding whether to prescribe that medication to Mrs. Owens in November 1995, a reasonable jury could conclude that he would not have prescribed Pondimin to her. And, had Dr. Etzel not prescribed Pondimin to Mrs. Owens, she would not have ingested Pondimin, nor would she have consequently sustained the life–threatening injury known as PPH as a result of having ingested Pondimin.

Contrary to the trial court's erroneous ruling in this case, Pennsylvania law does not require the plaintiff in a pharmaceutical failure–to–warn case to establish

that the manufacturer of the medication failed to warn of the very same risk that ultimately caused the plaintiff's injury. Rather, the warnings that Pennsylvania law requires a pharmaceutical manufacturer to provide to prescribing physicians about the material potential risks of a medication remain the same regardless of what sort of patients the doctor may be treating or what injuries those patients may eventually develop from having ingested the medication.

In *Incollingo* v. *Ewing*, 444 Pa. 263, 282 A.2d 206 (1971), the Supreme Court of Pennsylvania recognized that the manufacturer of a prescription drug "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 (emphasis added). And this Court, in *Makripodis ex rel. Makripodis* v. *Merrell–Dow Pharmaceuticals, Inc.*, 523 A.2d 374 (Pa. Super. Ct. 1987), recognized "the requirement that *all warnings* as to potential dangers associated with prescription drugs be provided to prescribing physicians * * *." *Id.* at 378 (emphasis added).

When Dr. Etzel was deciding whether or not to prescribe Pondimin to Mrs. Owens, he had no way of knowing whether she might sustain VHD, PPH, some other ailment, or no injury at all as a result of taking that medication. What is clear, however, is that Wyeth owed a duty to Dr. Etzel to provide him with a full and accurate disclosure of the medication's risks, so that Dr. Etzel could decide whether to prescribe the medication to Mrs. Owens. *See Incollingo*, 444 Pa. at 288 n.8, 282 A.2d at 220 n.8; *Makripodis*, 523 A.2d at 378. As the Supreme Court of the United States explained earlier this year in *Wyeth* v. *Levine*, 129 S. Ct. 1187 (2009):

> [The manufacturer of a prescription drug] 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").

129 S. Ct. at 1198.

Because Wyeth breached its well–established duty to provide an adequate warning of the risks of ingesting Pondimin when that medication was being prescribed to Mrs. Owens, Mrs. Owens now suffers from PPH. Had Wyeth not breached that duty, Dr. Etzel would not have prescribed the medication to Mrs. Owens, and she would not have begun and continue to suffer from the frequently fatal condition known as PPH.

Whether Mrs. Owens developed VHD or PPH or some other ailment from taking Pondimin is of no relevance to establishing that Wyeth's failure adequately to warn of the risks of Pondimin was both the proximate cause and the cause in fact of Mrs. Owens's injuries that resulted from her having ingested Pondimin.

Although this case may present a question of first impression under Pennsylvania law on this particular question of proximate cause, decisions from other jurisdictions are instructive and demonstrate that the trial court's ruling in this case was erroneous. For example, in *Cipollone* v. *Liggett Group, Inc.*, 1987 WL 14666 (D.N.J. Oct. 27, 1987), the cigarette manufacturer defendants filed a motion *in limine* to exclude plaintiff's evidence of non–cancerous diseases that she did not

suffer. The court denied the motion, holding that the evidence of other diseases was relevant. Specifically, to prevail on her failure to warn claim, plaintiff had to prove that an adequate warning of the non–cancer risks of smoking would have prevented her from taking up smoking at the outset or that she would have quit smoking at an earlier time. The court explained:

> The court finds that evidence of diseases other than those contracted by Rose Cipollone is relevant to the existence of Liggett's duty to warn as to these diseases. If there are numerous risks from cigarette smoking, the mere fact that plaintiff suffered from only one does not limit defendants' duty to warn to that risk alone. The adequacy of the warning depends upon all of the risks encountered by the average consumer. A plaintiff may well argue that had she or he been warned of all the risks, cigarettes would have been avoided. The fact that only one of the risks manifested itself does not, as a matter of law, relieve defendants of their duty to warn of the others. Whether Liggett breached such a duty, and whether such a breach caused Mrs. Cipollone's injuries, are factual questions to be resolved at trial.

Id. at *4.

Similarly, the U.S. Court of Appeals for the Fifth Circuit has held that the warnings used by asbestos companies were inadequate because they did not contain a full disclosure of the risks of various illnesses, including those not suffered by the plaintiff. *See Dartez* v. *Fibreboard Corp.*, 765 F.2d 456, 468 (5th Cir. 1985) ("Whether 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."). The Philadelphia–based U.S. Court of Appeals for the Third Circuit cited that holding from *Dartez* with approval

in *In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Products Liab. Litig.*, 369 F.3d 293, 313 (3d Cir. 2004).

Finally, the federal district court in *Sanderson* v. *Upjohn Co.*, 578 F. Supp. 338 (D. Mass. 1984), squarely addressed the very same issue presented in this case:

> Preliminarily we note that the adequacy of warnings accompanying a product usually is a question of fact for the jury. Upjohn attempts to avoid this general rule on the basis that a warning which describes precisely the condition suffered by the plaintiff is adequate as a matter of law. The flaw in this argument is that it conflates the negligence issue (adequacy of warning) with the damages issue. To illustrate the point, assume a pharmaceutical manufacturer markets a prescription drug that carries with it a significant risk of both temporary dizziness and permanent blindness, but that the manufacturer warns doctors only of the temporary dizziness. Quite clearly the warning is inadequate. Now further assume that a patient who ingests the drug after being warned by her doctor about the risk of temporary dizziness would not have ingested it if warned about the risk of blindness. Clearly there is a causal connection between the manufacturer's failure to warn adequately and the patient's decision to take the drug. Finally, assume that the patient experiences temporary dizziness as a result of her ingesting the drug. Under Upjohn's argument, the drug manufacturer would be entitled to summary judgment. But this is clearly wrong; in fact the patient rather than the manufacturer probably would be entitled to summary judgment on liability, having made out the essential elements of any tort claim: negligence (failure to warn adequately), causation and injury. The fact that the patient experienced temporary dizziness rather than permanent blindness reduces the extent of her damages, but it does not cure the inadequacy of the manufacturer's warning.

Id. at 339–40 (citations omitted).

Plaintiffs respectfully urge this Court to reject Wyeth's argument that its warnings regarding PPH shield it from a finding that its inadequate VHD warnings caused Dr. Etzel to prescribe Pondimin to Mrs. Owens. Wyeth knew these diet pills caused heart valve disease, it knowingly avoided investigating the problem, and it

intentionally hid the number of VHD cases from the FDA. The warnings attached to these drugs when Dr. Etzel decided to prescribe Pondimin to Mrs. Owens did not even mention VHD. Therefore, the warnings were clearly and obviously inadequate. And, a reasonable jury could conclude that Dr. Etzel would not have prescribed Pondimin to Mrs. Owens had he received an adequate warning, that is, had he known about the medication's inherent risk of causing heart valve disease. R.580a–81a. Plaintiffs have sufficient evidence to prove proximate cause, and therefore the trial court's entry of summary judgment in favor of Wyeth should be reversed.

B. The Trial Court Also Erred In Entering Summary Judgment In Favor Of Wyeth On Plaintiffs' Claims For Negligently Marketing Pondimin And Negligently Failing To Withdraw Pondimin From The Market

1. Wyeth did not seek summary judgment on these claims, which plaintiffs have properly pleaded in this case

In plaintiffs' response in opposition to Wyeth's motion for summary judgment on the issue of proximate cause, plaintiffs drew to the trial court's attention that plaintiffs were also asserting claims against Wyeth for negligently marketing Pondimin and negligently failing to withdraw Pondimin from the market. R.196a–97a. Because Wyeth had not expressly sought summary judgment as to those additional claims, plaintiffs argued that the trial court should not dismiss plaintiffs' lawsuit in its entirety. R.197a.

In its reply brief, Wyeth argued two points. First, Wyeth asserted that plaintiffs had failed to assert these additional claims in this case. R.587a. And,

second, Wyeth noted that Judge Tereshko had recently granted summary judgment in Wyeth's favor in a separate case, captioned *Lance* v. *Wyeth*, in which the plaintiff had only asserted claims against Wyeth for negligently marketing Redux and negligently failing to withdraw Redux from the market. Thus, Wyeth maintained, if plaintiffs have in fact asserted similar claims in this case, the trial court's summary judgment order in favor of Wyeth in the *Lance* case should lead to the entry of summary judgment in favor of Wyeth in this case on those claims. R.587a.

The trial court's Rule 1925(a) opinion issued in this case does not address plaintiffs' additional claims for negligently marketing Pondimin and negligently failing to withdraw Pondimin from the market. *See* Exhibit A hereto (trial court's Rule 1925(a) opinion). Nevertheless, the trial court's summary judgment order makes clear that plaintiffs' complaint in its entirety was being dismissed. *See* Exhibit B hereto (trial court's summary judgment order). Although the trial court granted summary judgment in favor of Wyeth in the *Lance* case on September 19, 2008, the trial court has yet to issue its Rule 1925(a) opinion in connection with plaintiff's appeal in the *Lance* case as of the date this Brief for Appellants is being filed. Thus, we cannot now address in this brief whatever reasons the trial court may later offer in connection with the *Lance* appeal for why the claims at issue both in *Lance* and here should have survived Wyeth's motions for summary judgment.

For present purposes, it suffices to show that: (1) plaintiffs here have adequately pleaded claims against Wyeth for negligently marketing Pondimin and negligently failing to withdraw Pondimin from the market; (2) Wyeth did not move

for summary judgment on those claims; and (3) those claims are cognizable under Pennsylvania law.

In these mass tort cases, each individual plaintiff is permitted to file a "Short Form Complaint" that adopts some or all of the claims asserted in the governing "Master Complaint" that was filed toward the outset of the litigation. Paragraph 4 of the "Short Form Complaint" that plaintiffs filed in this case states, "Plaintiffs hereby incorporate by reference the following Counts from the Master Long Form Complaint: __X__ Count I – Negligence . . . ." R.19a. Count I of the "Master Long–Form Complaint" asserts a claim for "Negligence" against Wyeth and consists of paragraphs 63 through 69. R.45a–48a. The "Negligence" claim asserted in the "Master Complaint" encompasses claims against Wyeth for negligently marketing Pondimin and negligently failing to withdraw Pondimin from the market.

Specifically, in paragraph 64 of the Master Complaint, plaintiffs allege that the pharmaceutical defendants had a duty to exercise reasonable care to properly design, research, develop, test, inspect, label, and prepare for use the drugs to ensure the product did not cause unreasonable, dangerous, or untoward adverse side effects. R.46a. In paragraph 65 of the Master Complaint, plaintiffs allege that the defendants failed to exercise ordinary care in their conduct described in paragraph 64. R.46a. Paragraph 67 of the Master Complaint expressly alleges that "Pharmaceutical defendants were negligent in the design, manufacture, testing, promotion, advertising, warning, labeling, marketing and sale" of Wyeth's Fen–Phen drugs. R.46a–48a. And paragraph 68 of the Master Complaint asserts that

Wyeth was negligent for failing to withdraw its Fen–Phen drugs from the market sooner. R.48a.

Thus, a review of the relevant paragraphs of the "Master Long–Form Complaint" that the plaintiffs in this case explicitly adopted establishes that plaintiffs have indeed alleged claims against Wyeth for negligently marketing Pondimin and negligently failing to withdraw Pondimin from the market. Moreover, the trial court in this case did not rule that these claims did not exist or were waived here.

Finally, a review of Wyeth's summary judgment motion establishes that Wyeth did not move for summary judgment on those claims. R.105a–17a. The trial court thus committed reversible error in *sua sponte* granting summary judgment in Wyeth's favor on those claims. *See Glover* v. *State Farm Mut. Auto. Ins. Co.*, 950 A.2d 335, 337 (Pa. Super. Ct. 2008) (recognizing that a trial court should not grant summary judgment on grounds not raised by the moving party).

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

In moving for summary judgment as to these claims in the *Lance* case, Wyeth argued that claims for negligently marketing a prescription drug and negligently failing to withdraw a prescription drug from the market are not cognizable under Pennsylvania law. Although the trial court's reasons for dismissing those claims in

this case are not yet apparent from the record even in the *Lance* case, out of an abundance of caution plaintiffs will now turn to address those arguments.

In its summary judgment motion filed in the *Lance* case, Wyeth argued that *Leibowitz* v. *Ortho Pharmaceutical Corp.*, 307 A.2d 449 (Pa. Super. Ct. 1973), and other cases hold that the only claim available to a plaintiff injured by a product manufactured by a prescription drug manufacturer is a claim for negligent failure to warn. This is an incorrect reading of Pennsylvania case law. A careful analysis of *Leibowitz* and its progeny reveals that all of the statements to the effect that a drug manufacturer is liable only if it fails to adequately warn the prescribing physician were made in the context of plaintiffs' claims based on a manufacturer's failure to adequately warn.

To disprove Wyeth's assertion that a plaintiff can only prevail in a prescription drug injury case by proving failure–to–warn, this Court need look no further than the Supreme Court of Pennsylvania's critically significant ruling in *Incollingo* v. *Ewing*, 444 Pa. 263, 282 A.2d 206 (1971). There, the Supreme Court noted that plaintiff originally asserted claims for negligent manufacture, negligent failure to test, and negligent failure to warn. Since the plaintiff did not have evidence of negligent manufacture or negligent failure to test, the case proceeded solely on the negligent failure to warn claim. Nevertheless, the *Incollingo* decision recognized that plaintiff had a negligence claim against the manufacturer even if the warnings were adequate:

> The question, therefore, in this case is whether the warning that was given to the prescribing doctors was proper and adequate. A corollary

> question is whether, if the printed warning was proper and adequate, it was in effect nullified by the representations of the so–called 'detail men'.

444 Pa. at 288, 282 A.2d at 220.

Ultimately, the Pennsylvania Supreme Court removed all doubt on this question in *Baldino* v. *Castagna*, 505 Pa. 239, 478 A.2d 807 (1984), when the Court acknowledged the validity of plaintiff's negligent marketing theory of liability against a drug manufacturer. The Supreme Court stated:

> The theory of liability against CIBA–GEIGY was primarily based on this Court's decision in *Incollingo* v. *Ewing*, 444 Pa. 263, 282 A.2d 206 (1971), where we recognized a cause of action against drug manufacturers for the overpromotion of a drug that nullify otherwise adequate warnings.

505 Pa. at 244, 478 A.2d at 810.

And most recently, in *Taurino* v. *Ellen*, 579 A.2d 925 (Pa. Super. Ct. 1990), this Court observed:

> We recognize that under *Incollingo* and subsequent cases applying it a manufacturer of a prescription drug may be shown to be negligent despite the fact that adequate warnings were given to the prescribing physician. Negligence may be shown where, for example, the manufacturer employs "detail" men who instruct physicians on the use of the drug and who are proven to have promoted the product in such a way as to encourage the physicians to ignore the warnings or where the manufacturer knows its warnings are being widely ignored and does nothing about it. *See Incollingo*, *supra*, 444 Pa. at 292–94, 282 A.2d at 222; *Baldino* v. *Castagna*, 505 Pa. 239, 247–49, 478 A.2d 807, 812 (1984). Thus, it is clear that there are grounds on which a manufacturer of such a drug may be found liable in negligence despite the adequacy of its written warnings to physicians.

Id. at 929 n.3.

The above–quoted footnote from this Court's ruling in *Taurino* recognizes that negligence claims against a prescription drug manufacturer for injuries caused by consuming the medication are not limited to negligent failure–to–warn claims and that the "detail" men claim described in *Incollingo* is just one of the types of negligence claims against prescription drug manufacturers recognized under Pennsylvania law.

Moreover, the U.S. Court of Appeals for the Third Circuit has interpreted Pennsylvania law on the question of negligence claims against a drug manufacturer, and it recognized a claim for negligent inadequate testing of the drug, in addition to the negligent failure to warn claim. *See Hoffman* v. *Sterling Drug, Inc.*, 485 F.2d 132, 140–41 (3d Cir. 1973). The Third Circuit made no suggestion, and the manufacturer apparently made no argument, that the plaintiff was required to show inadequate warnings as a part of his negligent failure to test claim. Furthermore, the court recognized these claims as being completely separate and freestanding. *Id.*

Plaintiffs have extensively searched Pennsylvania case law and have found no case holding that the *only basis* for a negligence claim against a drug manufacturer is failure to warn, and any such holding would of course be contrary to the precedent established in *Incollingo, Baldino*, and *Taurino*. Indeed, the claim recognized in the first two of those three cases involved negligence arising from the manner in which the prescription drug manufacturer marketed its medications. Finally, plaintiff have found no case requiring them to prove inadequate warning as

an element of any other negligence claim, such as negligent marketing or negligent failure to withdraw from the market.

The Pennsylvania courts have never held that there must be a determination that the warnings were inadequate in all negligence cases against drug manufacturers. Accordingly, if the trial court in this case ruled that claims for negligently marketing Pondimin and negligently failing to withdraw Pondimin from the market are not cognizable under Pennsylvania law, the trial court committed reversible error.

VIII. CONCLUSION

For the reasons set forth above, 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,

Dated: December 28, 2009

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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:

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