# In the Superior Court of Pennsylvania

No. 2838 EDA 2008

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NANCY COCHRAN,
Appellant,

v.

WYETH, INC.

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BRIEF FOR APPELLANT

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On Appeal from the Judgment of the
Court of Common Pleas of Philadelphia County, Pennsylvania,
Civil Trial Division, August Term 2004, No. 275

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## I. STATEMENT OF JURISDICTION

On September 4, 2008, Judge Allan Tereshko of the Court of Common Pleas of Philadelphia County entered an order granting summary judgment against plaintiff Nancy Cochran and in favor of defendant Wyeth, Inc., holding as a matter of law that Wyeth's failure to warn of the risks of its prescription diet drug Redux (a so–called Fen–phen weight loss medication) was not the proximate cause of the serious injuries that Ms. Cochran sustained as a result of having consumed that drug. R.23a; *see also* Exhibit B attached hereto.

Ms. Cochran filed a timely notice of appeal on October 1, 2008. R.24a, 698a. 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 the unanimous Supreme Court of Pennsylvania recently 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). That decision 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 September 4, 2008, the trial court issued the following order:

> AND NOW, this 4th day of September, 2008, upon consideration of the Wyeth Defendants' Motion for Summary Judgment and any responses thereto, it is hereby **ORDERED**, **ADJUDGED**, and **DECREED** that Summary Judgment is hereby **GRANTED** in favor of the Wyeth Defendants and against Plaintiff Nancy Cochran.
>
> **IT IS FURTHER ORDERED** that Plaintiff Nancy Cochran's case is **DISMISSED WITH PREJUDICE**.

Exhibit B attached hereto.

## IV. STATEMENT OF THE QUESTION PRESENTED

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

## V. STATEMENT OF THE CASE

### A. Relevant Factual History

Nancy Cochran ingested the prescription weight loss drug dexfenfluramine, manufactured by Wyeth and sold under the brand name Redux, from November of 1996 through August of 1997. R.28a The physician who prescribed Redux to Ms. Cochran was Stephen Athay, M.D. R.28a. In April 2004, Ms. Cochran was diagnosed as having Primary Pulmonary Hypertension (PPH), a frequently fatal illness that is a signature injury of having consumed Redux. R.28a, 246a. For purposes of its summary judgment motion, Wyeth did not dispute that Ms. Cochran suffers from PPH, nor did Wyeth dispute that having consumed Redux was the cause of Ms. Cochran's PPH. R.81a–95a. In any event, when this case goes to trial, plaintiff's treating pulmonologist, Dr. Edelman, and Dr. Palevsky, a PPH expert at the University of Pennsylvania, will testify that Nancy Cochran's use of Redux caused her PPH. R.209a. Ms. Cochran is now in her early 70's and resides in Corvallis, Oregon. R.28a.

The medication Redux was a so–called Fen–phen medication sold to promote weight loss. This case is one of many PPH Fen–phen cases filed in the Court of Common Pleas of Philadelphia County, and this case presents a recurring question of law that is of great importance to the resolution of many of those cases.

"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.207a, 218a–19a.

Fenfluramine (Pondimin) is 50% dexfenfluramine, which is the active ingredient of Pondimin. The recommended daily dose of Pondimin was exactly twice that of Redux so the consumer received the same amount of the active ingredient, dexfenfluramine, with both Pondimin and Redux.

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.207a, 223a–25a, 246a–49a, 253a–58a. 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.207a, 276a–424a. 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.207a, 425a–58a. 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.208a, 459a–517a.

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.518a–21a.

As early as 1994 and 1995, Wyeth knew of far more reports of heart valve disease cases than it reported to the FDA. R.208a, 523a–47a. 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.548a–51a. 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 both Pondimin and

Redux off the market before late 1996, when Ms. Cochran was first prescribed Redux.

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.550a. 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.209a, 552a–80a. Faced with these mounting pressures, on September 15, 1997, Wyeth withdrew both Redux and Pondimin from the market. R.581a–84a.

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; (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 what it described as the issues of "proximate cause" and "factual cause," Wyeth asserted that it had accurately and fully disclosed to physicians such as Dr. Athay the PPH risks to patients from ingesting Redux before Dr. Athay decided to prescribe Redux to Ms. Cochran in November 1996. R.83a–85a. Wyeth thus argued that Ms. Cochran could not establish that Wyeth's PPH–related warning was inaccurate or incomplete or that Dr. Athay would not have prescribed Redux to Ms. Cochran 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 Redux for Ms. Cochran to use. R.91a–92a.

Ms. Cochran filed a response in opposition to Wyeth's summary judgment motion in which she argued that summary judgment should be denied because Wyeth's Redux warning, as it existed between November 1996 and August 1997, 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.204a–13a. VHD is another signature injury caused by ingesting Redux and other Fen–phen medications. For purposes of its summary judgment motion, Wyeth did not dispute that its VHD warning for Redux between November 1996 and August 1997 (when Dr. Athay was prescribing the drug for Ms. Cochran's use) failed to fully and accurately disclose the serious VHD risk that Redux posed to patients who

ingested the drug. In fact, the medication's label during that period contained no warning about or mention of contracting VHD as a result of ingesting Redux, even though Wyeth was aware of that risk at that time.

Around the time that Ms. Cochran stopped using Redux in August 1997, the federal government's Food and Drug Administration (FDA) required Wyeth to strengthen Redux'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 Redux in a prominent "black box," which is the most emphatic and serious type of warning that a drug's label can contain. R.550a. Soon thereafter, Wyeth decided to pull its Fen–phen drugs, including Redux, from the market (R.583a–84a), and ultimately the FDA decided that Redux 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 the deposition testimony that he gave under oath in this very case, Dr. Athay testified that had he known of the actual valvular heart disease (VHD) risk that Redux presented when he was deciding whether to prescribe Redux to Ms. Cochran in November 1996, he would not have prescribed Redux to Ms. Cochran. R.588a–93a. Thus, on the record in this case, it is undisputed that had Wyeth fully and accurately disclosed to Dr. Athay and other prescribing physicians the true risk of *both* VHD *and* PPH that Redux presented to patients as of November 1996, Dr. Athay would have decided not to prescribe Redux to Ms. Cochran, and Ms. Cochran

would not have sustained the often fatal medical condition known as PPH as a result of having ingested Redux.

In its reply brief in further support of its summary judgment motion, Wyeth argued that because the only injury Ms. Cochran sustained was PPH, and because Ms. Cochran did not sustain any VHD injury, she could not establish proximate cause because she had failed to dispute that Wyeth's PPH warning for Redux was accurate as of November 1996. According to Wyeth, because Ms. Cochran did not sustain VHD, she could not establish proximate cause by proving that Wyeth's VHD warning for Redux was woefully inadequate as of November 1996 or that a complete and accurate VHD warning for Redux in November 1996 would have caused Dr. Athay not to have prescribed Redux to her. R.594a–600a.

In ruling on the summary judgment motion, the trial court agreed with Wyeth. In an opinion explaining the basis for the trial court's ruling, the trial court wrote that, under Pennsylvania law, Ms. Cochran 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 Redux, the physician would not have prescribed Redux to her, and thus her injury would have been averted. *See* Exhibit A attached hereto at 7–9. Rather, according to the trial court, Ms. Cochran 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 Ms. Cochran's claim against Wyeth, the trial court has ruled here. *Id.*

This case presents a question of first impression of great importance to the many PPH cases now pending in the Fen–phen program of the Philadelphia Court of Common Pleas — whether a pharmaceutical manufacturer's duty in a prescription drug failure–to–warn case is to provide the prescribing physicians with a fair and accurate disclosure of all of the drug's relevant harmful side–effects, so that the physician can make an informed decision whether to prescribe the medication to any of his patients, or whether the pharmaceutical manufacturer's duty to warn the prescribing physician depends in each individual case on what particular injury or ailment the plaintiff has sustained as a result of ingesting the medication.

### B. Relevant Procedural History

Nancy Cochran filed this lawsuit on August 3, 2004. R.5a. After relevant discovery had concluded, Wyeth filed its motion for summary judgment on the issue of proximate cause on July 28, 2008. R.23a. Ms. Cochran filed a timely response in opposition, and then Wyeth filed a reply brief. On September 4, 2008, the trial court entered an order granting Wyeth's motion for summary judgment. R.23a; Exhibit B attached hereto.

Thereafter, on October 1, 2008, Ms. Cochran filed a timely notice of appeal. R.24a, 698a. After the trial court ordered Ms. Cochran to file a "Statement of Errors Complained of on Appeal" pursuant to Pennsylvania Rule of Appellate Procedure 1925(b) (R.700a), and after Ms. Cochran filed 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 July 15, 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 plaintiff Nancy Cochran could not establish proximate cause, because Ms. Cochran's evidence to prove proximate cause in this prescription drug failure–to–warn case is clearly sufficient to establish that element of her claim. Indeed, the evidence of proximate cause in this case is a paradigm of what Pennsylvania law requires: (1) it is undisputed, for purposes of summary judgment, 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 Redux to patients such as Ms. Cochran; and (2) had Wyeth warned adequately and completely of those risks, Dr. Athay (Ms. Cochran's prescribing physician) would not have prescribed Redux to Ms. Cochran, as Dr. Athay's testimony under oath at his deposition makes unmistakably clear. R.588a–93a.

The trial court in this case improperly disemboweled Pennsylvania 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. Athay's patients sustained valvular heart disease (VHD) as the result of ingesting Redux, that patient would have a valid claim against Wyeth for failing to warn Dr. Athay in an accurate and complete manner of all of Redux's harmful side–effects. But where a patient of Dr. Athay sustained PPH as a result of having ingested Redux, 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 Redux and from suffering their Redux–induced 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, the doctor testifies 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.

Accordingly, the trial court's entry of summary judgment in Wyeth's favor on the issue of proximate cause 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 Redux Was Not A Proximate Cause Of Ms. Cochran's Injuries

Pennsylvania law recognizes that because prescription medications such as Redux 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).

Thus, for example, where a prescribing physician has testified that he or she never relies on warnings that the prescription drug's manufacturer provides, this Court has held that the plaintiff failed establish the element of proximate cause because a different warning would not have come to the physician's attention. *See Demmler*, 671 A.2d at 1155–56. Similarly, if the prescribing physician testifies that he or she would still have prescribed the drug in question to the plaintiff even if the manufacturer had provided an adequate warning, the element of proximate cause is not satisfied. *See Lineberger*, 894 A.2d at 150–51.

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 Redux was accurate during the period between November 1996 and August 1997 when Dr. Athay was prescribing Redux to Nancy Cochran. However, it is also undisputed, for purposes of this summary judgment motion, that the warnings Wyeth gave to physicians about the valvular heart disease (VHD) risk to patients from ingesting Redux was inaccurate and significantly downplayed and underrepresented the medication's actual VHD risk between November 1996 and August 1997, when Dr. Athay was prescribing Redux to Nancy Cochran.

When the federal government's Food and Drug Administration (FDA) ultimately learned of the true VHD risk to patients from Redux, 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.

In this case, Dr. Athay testified under oath at his deposition that had Wyeth disclosed to him the true VHD risk to patients from ingesting Redux, as the FDA later required Wyeth to do, Dr. Athay would not have prescribed Redux to Ms. Cochran in November 1996 nor would he have continued her on the drug until August 1997. R.588a–93a. At his deposition taken on October 27, 2005, Dr. Athay testified under oath as follows:

> Ms. Love: Q. Could you read that over and tell me whether you would have prescribed this medicine to Miss Cochran if you had seen this black box warning on the Redux label?
>
> A: No, I wouldn't have.
>
> * * *
>
> Ms. Love: Q. Doctor, had you known that the European Health Ministries had limited the use of Dexfenfluramine to no more than three months, would you have prescribed Redux for more than three months?
>
> The Witness: No.
>
> * * *
>
> Ms. Love: Q. Knowing what you know now would you have prescribed it to Miss Cochran, applying the risk/benefit analysis to her, not necessarily to a more obese patient with other health problems than she has, but to her, knowing what you know now would you have prescribed the drug to her for longer than three months?
>
> The Witness: No.
>
> * * *

> Mr. Moorman: Q. Doctor, preserving our objection to this line of questioning regarding valvular heart disease, let me ask you this: Isn't it true that you are unsure whether you would have prescribed Redux to Miss Cochran had you known of the association between valvular heart disease and taking Redux?
>
> A: I don't believe I would have prescribed it had I known that.

R.589a–93a (objections and other irrelevancies omitted).

Dr. Athay's deposition testimony, given under oath, thus makes this a paradigmatic case of what constitutes adequate evidence of proximate cause under Pennsylvania law to reach the jury in a prescription drug failure–to–warn case. The black box warnings disclosing Redux's VHD and PPH actual risks, which the FDA ultimately determined Wyeth must provide to physicians when marketing Redux and offering Redux for sale, would have caused Dr. Athay not to have prescribed Redux to Ms. Cochran had those adequate and complete warnings been given by Wyeth in or before November 1996, when Dr. Athay was considering whether to prescribe Redux to Ms. Cochran. R.588a–89a. And, of course, if Dr. Athay had not prescribed Redux to Ms. Cochran, she would not have ingested Redux nor would she have sustained the life–threatening injury known as PPH as a result of having ingested Redux.

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. Athay was deciding whether or not to prescribe Redux to Ms. Cochran, 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. Athay to provide him with a full and accurate disclosure of the medication's risks, so that Dr. Athay could decide whether to prescribe the medication to Ms. Cochran. *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 Redux when that medication was being prescribed to Ms. Cochran, Ms. Cochran now suffers from PPH. Had Wyeth not breached that duty, Dr. Athay would not have prescribed the medication to Ms. Cochran, and she would not have begun and continue to suffer from the frequently fatal condition known as PPH.

To be sure, had Dr. Athay instead testified at his deposition that he would not have cared about the actual VHD risk of Redux when deciding whether to prescribe that medication to Ms. Cochran in November 1996, then Wyeth would have a valid proximate cause argument. But, in actuality, Dr. Athay testified under oath at his deposition that had he known of the actual VHD risk of Redux in November 1996, he would not have prescribed the medication to Ms. Cochran. R.588a–89a. Whether Ms. Cochran developed VHD or PPH or some other ailment from taking Redux is of no relevance to establishing that Wyeth's failure adequately to warn of the risks of Redux was both the proximate cause and the cause in fact of Ms. Cochran's injuries that resulted from her having ingested Redux.

Although this case may present a question of first impression under Pennsylvania law, 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).

Plaintiff urges this Court to reject Wyeth's argument that its warnings regarding PPH shield it from a finding that its inadequate VHD warnings caused Dr. Athay to prescribe Redux to Ms. Cochran. 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. Athay decided to prescribe Redux to Ms. Cochran did not even mention VHD. Therefore, the warnings were clearly and obviously inadequate. Dr. Athay would not have prescribed Redux at all had he received an adequate warning, that is, had he known about the medication's inherent risk of causing heart valve disease. R.588a–89a. Plaintiff has sufficient evidence to prove proximate cause, and therefore the trial court's entry of summary judgment in favor of Wyeth must be reversed.

## 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: October 16, 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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