

2010 PA Super 131

NANCY COCHRAN,	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
Appellant	:	
	:	
v.	:	
	:	
WYETH, INC.,	:	
	:	
Appellee	:	No. 2838 EDA 2008

Appeal from the Order entered September 4, 2008,  
Court of Common Pleas, Philadelphia County,  
Civil, at No. 000275, August Term 2004

BEFORE: STEVENS, GANTMAN and ALLEN, JJ.

OPINION BY ALLEN, J.:

Filed: July 27, 2010

¶ 1 In this failure to warn case, we are asked to decide whether a plaintiff can prove proximate causation where a drug manufacturer’s warning disclosed a risk of injury, the plaintiff sustained that very injury, but the manufacturer failed to disclose another risk of injury which the plaintiff did not sustain. We hold that in these circumstances, a plaintiff cannot prove proximate causation because the non-disclosed risk did not materialize in physical injury.

¶ 2 Nancy Cochran (“Appellant”) appeals from the trial court’s order granting summary judgment in favor of Wyeth, Inc. (“Wyeth”). We affirm.

¶ 3 The facts relevant to our disposition are not in dispute and are as follows. From November 1996 to August 1997, Appellant ingested the

prescription weight-loss drug dexfenfluramine, which was manufactured by Wyeth and sold under the brand name Redux. Dr. Stephen Anthay, M.D., was the physician who prescribed Redux to Appellant. Wyeth informed Dr. Anthay that Redux may cause primary pulmonary hypertension ("PPH"). Dr. Anthay warned Appellant of the risk of PPH prior to prescribing her Redux. At the time of his decision, however, Dr. Anthay was unaware of the risk that Redux may cause valvular heart disease ("VHD"). In April 2004, Appellant was diagnosed with PPH.

¶ 4 On August 3, 2004, Appellant filed a complaint against Wyeth, asserting that the warnings accompanying Redux were inadequate. Following discovery, on July 28, 2008, Wyeth filed a motion for summary judgment. In this motion, Wyeth claimed that its warnings were sufficient because they informed Dr. Anthay that PPH was a risk of ingesting Redux and Appellant was diagnosed with PPH.

¶ 5 In opposition, Appellant argued that Redux's warnings were faulty because they failed to warn of the danger of VHD. Appellant contended that as early as 1994, Wyeth had reason to suspect that Redux could cause VHD. According to Appellant, Wyeth misrepresented the amount of reports of VHD incidents to the FDA, and failed to alert the medical community of the risk of VHD. Appellant submitted that Dr. Anthay would not have prescribed Redux to her had he been warned that Redux could cause VHD.

¶ 6 In July 2007, the FDA requested Wyeth to issue “black box” warnings detailing the risk of VHD. In September 2007, Wyeth voluntarily withdrew Redux from the market.

¶ 7 On September 4, 2009, the trial court granted summary judgment in favor of Wyeth. The trial court concluded that Wyeth’s warnings with regard to PPH were adequate on the basis that Wyeth informed Dr. Anthay that Redux may cause PPH. The trial court further concluded that because Appellant suffered from PPH and not VHD, she could not establish that Wyeth’s failure to warn of the risk of VHD was the proximate cause of her particular injury. This appeal ensued.

¶ 8 Appellant raises the following issue for review:

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 [Appellant] would not have sustained serious injuries as a result of ingesting Wyeth’s medication had Wyeth provided adequate warnings to [Appellant’s] prescribing physician of the actual risks inherent in ingesting that product?

Brief for Appellant at 3.

¶ 9 We review a grant of summary judgment under the following well-settled standards:

Pennsylvania law provides that summary judgment may be granted only in those cases in which the record clearly shows that no genuine issues of material fact exist and that the moving party is entitled to judgment as a matter of law. The moving party has the burden of proving that no genuine issues of material fact exist. In determining whether to grant summary judgment, the trial court must view the record in the light most favorable to the non-moving party and must resolve all doubts

as to the existence of a genuine issue of material fact against the moving party. Thus, summary judgment is proper only when the uncontraverted allegations in the pleadings, depositions, answers to interrogatories, admissions of record, and submitted affidavits demonstrate that no genuine issue of material fact exists, and that the moving party is entitled to judgment as a matter of law. In sum, only when the facts are so clear that reasonable minds cannot differ, may a trial court properly enter summary judgment.

***Wright v. Allied Signal, Inc.***, 963 A.2d 511, 514 (Pa. Super. 2008)  
(citation omitted).

¶ 10 In support of her sole issue, Appellant maintains that had Dr. Anthay been informed of the risk of VHD, he would not have prescribed her Redux. Appellant reasons that if Dr. Anthay had not prescribed her Redux, she would not have ingested the drug and never would have been diagnosed with PPH. Based on this logic, Appellant proposes that Wyeth's failure to warn of the risk of VHD was the proximate cause of her injury.

¶ 11 Countering, Wyeth asserts that its warnings informed Dr. Anthay that Redux may result in PPH and that Appellant assumed the risk that she may develop PPH. Wyeth argues that even if its warnings with regard to VHD were inadequate, its failure to warn of VHD was not the proximate cause of Appellant's PPH. Wyeth submits that to establish proximate causation, Appellant must prove that its warnings failed to disclose the risk of her particular injury - PPH.

¶ 12 Upon review, we agree with Wyeth.

¶ 13 In cases involving the failure to warn of risks associated with prescription drugs, Pennsylvania applies the learned intermediary doctrine. ***Simon v. Wyeth Pharms., Inc.***, 989 A.2d 356, 368 (Pa. Super. 2009). Under the learned intermediary doctrine, a manufacturer will be held liable only where it fails to exercise reasonable care to inform a physician of the facts which make the drug likely to be dangerous. ***Taurino v. Ellen***, 579 A.2d 925, 927 (Pa. Super. 1990). The manufacturer has the duty to disclose risks to the physician, as opposed to the patient, “because it is the duty of the prescribing physician to be fully aware of (1) the characteristics of the drug he is prescribing, (2) the amount of the drug which can be safely administered, and (3) the different medications the patient is taking.” ***Id.*** “It is also the duty of the prescribing physician to advise the patient of any dangers or side effects associated with the use of the drug as well as how and when to take the drug.” ***Id.***

¶ 14 Proximate cause is an essential element in a failure to warn case. ***Simon***, 989 A.2d at 368. A proximate, or legal cause, is defined as a substantial contributing factor in bringing about the harm in question. ***Whitner v. Von Hintz***, 263 A.2d 889, 893-94 (Pa. 1970). Assuming that a plaintiff has established both duty and a failure to warn, a plaintiff “must further establish proximate causation by showing that had defendant issued a proper warning to the learned intermediary, he would have altered his behavior and the injury would have been avoided.” ***Demmler v.***

***SmithKline Beecham Corp.***, 671 A.2d 1151, 1155 (Pa.Super. 1996) (citation omitted). “To create a jury question, the evidence introduced must be of sufficient weight to establish . . . some reasonable likelihood that an adequate warning would have prevented the plaintiff from receiving the drug.” ***Id.***

¶ 15 Here, in his deposition testimony, Dr. Anthay stated that he would not have prescribed Redux to Appellant had he known of the risk of VHD that the FDA required Wyeth to disclose on a black box warning. R.R. at 589-93. Appellant submits that under ***Demmler***, Dr. Anthay’s testimony, standing alone, was sufficient to establish that Wyeth’s failure to disclose the risk of VHD proximately caused her PPH. To resolve this matter, we must decide whether the ***Demmler*** standard applies to Appellant, vis-à-vis a plaintiff’s burden of establishing proximate causation in a failure to warn case. We gauge the ***Demmler*** standard in light of the circumstances before us, namely where the manufacturer disclosed a risk of injury, the plaintiff sustained that very injury, but the manufacturer failed to disclose another risk which, if revealed, would have resulted in the physician deciding not to prescribe the drug. Since this issue is unique to Pennsylvania, we turn to the case law from foreign jurisdictions for guidance.

¶ 16 To support her position, Appellants cites ***Cipollone v. Liggett Group***, 1987 U.S. Dist. Lexis 9936 (D.N.J. 1987), *aff’d in part and rev’d in part on other grounds in* 893 F.3d 541 (3d. Cir. 1990), *later aff’d in part and rev’d in*

*part on other grounds in* 505 U.S. 504 (1992); ***Sanderson v. Upjohn Co.***, 578 F. Supp. 338 (D. Mass. 1984); and ***Dartez v. Fibreboard Corp.***, 765 F.2d 456, 468 (5th Cir. 1985). These cases, however, are distinguishable and/or unpersuasive.

¶ 17 For instance, in ***Sanderson***, the court addressed the adequacy of the drug manufacturer's warning, assessing the duty and breach elements of a failure to warn case. The ***Sanderson*** court concluded that although the plaintiff suffered from injuries of which the manufacturer expressly warned, the manufacturer's warnings could not be deemed adequate as a matter of law because they failed to disclose other risks. The only issue before the court in ***Sanderson*** was the adequacy of the warnings, and ***Sanderson*** never decided the issue of proximate causation presently before this Court. Although there is a passing reference in ***Sanderson*** related to causation and a plaintiff's burden of proof in a failure to warn case, this discussion is at best *dicta*. Moreover, it is apparent that ***Sanderson's*** statement regarding causation was limited to the element of causation-in-fact, and not the separate inquiry of proximate causation. ***See First v. Zem Zem Temple***, 686 A.2d 18, 21 n. 2 (Pa. Super. 1996) (discussing the differences between causation in fact and proximate causation); ***Frangis v. Duquesne Light Co.***, 335 A.2d 796 (Pa. Super. 1975) (same). Therefore, ***Sanderson*** offers little to no guidance in deciding the issue of proximate causation at hand and we find it unpersuasive.

¶ 18 In *Cipollone*, the plaintiff suffered from lung cancer and instituted a failure to warn suit against the drug manufacturer because the manufacturer failed to adequately warn of the risk of lung cancer. The court in *Cipollone* determined that evidence of risks, other than the risk of lung cancer, was relevant and admissible to prove that the manufacturer had a duty to warn of those risks. Here, unlike *Cipollone*, Appellant was adequately warned of PPH, the precise injury which she sustained, and Appellant is not seeking to introduce evidence of the risk of PPH to establish the existence of a duty on the part of Wyeth. Regardless of whether Wyeth had a duty to disclose the risk of VHD, the issue remains whether a breach of that duty was the proximate cause of Appellant's PPH. *Cipollone* did not resolve, let alone address, this issue. Thus, we find *Cipollone* inapposite.

¶ 19 Finally, in *Dartez*, the United States Court of Appeals for the Fifth Circuit upheld the admission of evidence that asbestos could cause cancer or mesothelioma when the plaintiff did not suffer from either medical condition. In that case, however, the plaintiff's legal injury was that she "feared" she would obtain cancer or mesothelioma in the future, and Texas law permitted damages for stand alone emotional distress proximately caused by asbestos exposure. Consequently, there was a direct causal correlation between the non-disclosed risks of cancer and mesothelioma and the plaintiff's fear of contracting cancer and/or mesothelioma. Here, by contrast, Appellant did not claim that Wyeth's failure to disclose the risk of VHD resulted in a fear



that she would later develop VHD.<sup>1</sup> Rather, Appellant argued that Wyeth's failure to disclose the risk of VHD proximately caused PPH, a condition wholly unrelated to the risk (or fear) of VHD. As such, **Dartez** is distinguishable on its facts.

¶ 20 Therefore, **Sanderson**, **Cipollone** and **Dartez** do not support Appellant's position.

¶ 21 Wyeth counters that Appellant is categorically barred from establishing proximate causation because it adequately warned Dr. Anthay of the risk of PPH and Appellant's injury was PPH. To substantiate its contention, Wyeth relies primarily on **Mills v. United States**, 764 F.2d 373, 379 (5th Cir. 1985); **Coursen v. A.H. Robbins Co.**, 764 F.2d 1329 (9th Cir. 1985); **In re Rezulin Prods. Liab. Litig.**, 331 F. Supp. 2d 196 (S.D.N.Y. 2004); **Bouchard v. American Home Prods.**, 213 F. Supp. 2d 802 (N.D. Ohio 2002); **Grenier v. Medical Eng'g Corp.**, 99 F. Supp. 2d 759, 766 (W.D. La. 2000); and **In re Norplant Contraceptive Prods. Liab. Litig.**, 1997 U.S. Dist. LEXIS 10382 (E.D. Tex. 1997).

¶ 22 We find that the case law cited by Wyeth does not lend credence to its argument because those cases involve factual patterns and issues distinct from the one before this Court. First, **Coursen**, **Bouchard**, and **In re Norplant Contraceptive Prods. Liab. Litig.** all addressed an issue of

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<sup>1</sup> Pennsylvania law does not permit claims for increased risk and fear of cancer where the plaintiff has not developed cancer. **Simmons v. Pacor, Inc.**, 674 A.2d 232 (Pa. 1996).

evidence, weighing the probative value of a non-disclosed risk of injury which the plaintiff did not sustain, against its prejudicial impact to the defendant and the likelihood of causing jury confusion. Second, in *In re Rezulin Prods. Liab. Litig.*, the court granted summary judgment in favor of the defendant because the plaintiff failed to establish that had the doctor known of the risk of liver toxicity, he never would have prescribed the drug to the plaintiffs. Third, in *Mills*, the court held that the specific wording of a warning was broad enough to inform the plaintiff of her particular injury. Although there is language in *Mills* that could be read to support Wyeth's position, this language was based on the court distinguishing other cases' textual analysis of a warning with respect to different medical conditions. In short, the only issue before the court in *Mills* was the scope and adequacy of the warning. Fourth, in *Grenier*, the court concluded, without any meaningful discussion or citation to authority, that "[a] claimant cannot seek to impose a duty to warn on a manufacturer of damage not sustained." 99 F. Supp. 2d at 766. This is simply incorrect; a manufacturer has a duty to disclose all risks irrespective of the plaintiff's injury. *See Makripodis v. Merrell-Dow Pharms.*, 523 A.2d 374, 378 (Pa. Super. 1987). For these reasons, we conclude that the authority cited by Wyeth does not support its position.

¶ 23 This Court's independent research has similarly failed to locate any case law concerning proximate causation in failure to warn cases that could

be deemed directly on-point and persuasive. Due to the absence of authority on the issue, we find strong guidance in those cases that have addressed a plaintiff's burden of proving proximate causation in the informed consent context.

¶ 24 The tort of informed consent, like the tort of failure to warn, is grounded in a duty to disclose material risks.

To obtain a patient's informed consent, doctors must provide patients with material information necessary to determine whether to proceed with the surgical or operative procedure or to remain in the present condition. This information must give the patient a true understanding of the nature of the operation to be performed, the seriousness of it, the organs of the body involved, the disease or incapacity sought to be cured, and the possible results.

***Valles v. Albert Einstein Med. Ctr.***, 805 A.2d 1232, 1237 (Pa. 2002) (citations and internal quotation marks omitted).

¶ 25 In both informed consent and failure to warn cases, the duty to disclose risks is breached when the defendant fails to disclose a material risk. In informed consent cases, the patient must be warned of all material risks to decide whether to undergo an operation, while in failure to warn cases, the prescribing physician must be informed of all material risks to decide whether to prescribe a drug to a patient. Moreover, to succeed in a failure to warn claim, a plaintiff must establish that had the physician been aware of the non-disclosed risk, the physician never would have prescribed the drug. ***Demmler***, 671 A.2d at 1155. To prevail on an informed consent claim, the plaintiff must establish that the undisclosed risk substantially

affected his/her decision to undergo a procedure. 40 P.S. § 1303.504 (d)(1). As such, the torts of informed consent and failure to warn are very similar, given their elements of duty, breach of duty and causation.

¶ 26 Finding the torts of informed consent and failure to warn analogous, we are persuaded by the jurisdictions that have concluded a plaintiff cannot establish proximate causation where the non-disclosed risk never materialized into an injury. In a landmark informed consent case, ***Canterbury v. Spence***, 464 F.2d 773, 790 (D.C. Cir. 1972), the United States Court of Appeals for the District of Columbia first pronounced:

No more than breach of any other legal duty does nonfulfillment of the physician's obligation to disclose alone establish liability to the patient. An unrevealed risk that should have been made known must materialize, for otherwise the omission, however unpardonable, is legally without consequence. Occurrence of the risk must be harmful to the patient, for negligence unrelated to injury is nonactionable.

***Id.***

¶ 27 In ***Downer v. Veilleux***, 322 A.2d 82, 92 (Me. 1974), the Supreme Court of Maine formulated the proximate cause inquiry in informed consent cases as follows:

[A breach of] the physician's obligation to disclose the material risks incidental to a particular treatment . . . does not per se establish liability to the patient. As in the case of any breach of a legal duty, the plaintiff must . . . prove a proximate causal relationship between the physician's failure to adequately inform and injury to the patient.

Proof of proximate cause in such cases requires, initially, a showing that the unrevealed risk which should have been made known has materialized. Absent occurrence of the undisclosed risk, the doctor's omission is legally inconsequential.

*Id.*

¶ 28 The view espoused by the courts in *Canterbury* and *Downer* has been uniformly accepted by the high courts of numerous other jurisdictions. *See, e.g., Funke v. Fieldman*, 512 P.2d 539, 548 (Kan. 1973); *Scott v. Bradford*, 606 P.2d 554, 559 (Ok. 1979); *Hales v. Pittman*, 576 P.2d 493, 499 (Ariz. 1978); *Harnish v. Children's Hospital Medical Center*, 439 N.E. 2d 240, 244 (Mass. 1982); *Reinhardt v. Colton*, 337 N.W.2d 88, 95-96 (Minn. 1983); *LaCaze v. Collier*, 434 So.2d 1039, 1048 (La. 1983); *Nickell v. Gonzalez*, 477 N.E.2d 1145, 1148 (Ohio 1985); *Smith v. Cotter*, 810 P.2d 1204, 1209 (Nev. 1991); *Howard v. Univ. of Med. & Dentistry of N.J.*, 800 A.2d 73, 79-80 (N.J. 2002); *see also Doe v. Noe*, 690 N.E. 2d 1012, 1024 (Ill. App. Ct. 1st Dist. 1997); *Wachter v. U.S.*, 689 F. Supp. 1420, 1422 (D. Md. 1988) (applying Maryland law); *Hook v. Rothstein*, 316 S.E. 2d 690, 704 (S.C. Ct. App. 1984). Indeed, this Court is unable to locate any authority that has refused to adopt the proximate cause principle enunciated in *Canterbury* and *Downer*. In informed consent cases, it appears to be well-settled and without debate that the non-

disclosed risk must manifest itself into actual injury in order for a plaintiff to establish proximate causation.<sup>2</sup>

¶ 29 Because the tort of informed consent corresponds with the tort of failure to warn, this Court applies the above law governing proximate causation for informed consent claims to Pennsylvania's jurisprudence in failure to warn claims. Here, Wyeth allegedly breached its duty in failing to disclose the risk of VHD, and Appellant's injury was PPH. The risk of VHD did not develop into the actual injury of VHD. Although Dr. Anthay testified in his deposition that he would not have prescribed Redux to Appellant had

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<sup>2</sup> We note that courts have imposed a similar requirement when discerning the proximate cause standard for claims sounding in fraudulent omissions/misrepresentations. These cases hold that in order to be compensable, the non-disclosed risk or misrepresented fact must materialize into an injury that is specifically related in scope to the peculiar nature of the omission or misrepresentation. *See, e.g., Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 173 (2d. Cir. 2005) (Rule 10-b5 securities fraud) ("[An] omission is the 'proximate cause' of an investment loss if the risk that caused the loss was within the zone of risk *concealed* by the [] omissions . . . [A] plaintiff must allege . . . that the loss [was] caused by the materialization of the concealed risk.") (emphasis in original); *accord Schaaf v. Residential Funding Corp.*, 517 F.3d 544, 552 (8th Cir. 2008) (Minnesota Consumer Fraud Act and state common-law fraud) ("To prevail, the plaintiffs must plead and prove that the loss was . . . caused by the materialization of the concealed risk."), *and also Criqui v. Pearl Music Co.*, 599 P.2d 1177, 1181 (Ore. App. 1979) (affirmative misrepresentation) ("It is only where the fact misstated was of a nature calculated to bring about such a result that damages for it can be recovered.") (citation omitted); *accord Giammanco v. Giammanco*, 625 N.E.2d 990, 1003 (Ill. Ct. App. 2d Dist. 1993) ("[A]lthough a transaction may have been induced by a misrepresentation, the requirement of proximate cause limits recovery to those damages that . . . follow from the character of the misrepresentation itself.").

he known of the risk of VHD, this does not alter the fact that Wyeth failed to disclose the risk of VHD and Appellant suffered from PPH. In these circumstances, the relationship between the legal wrong (the failure to disclose the risk of VHD) and the injury (PPH) is not directly correlative and is too remote for proximate causation. Therefore, as a matter of law, there is no proximate, causal connection between Wyeth's failure to disclose the risk of VHD and Appellant's specific injury. **See *Brown v. Philadelphia College of Osteopathic Medicine***, 760 A.2d 863, 868 (Pa. Super. 2000) (stating that as a matter of law, the court is required to make the determination of whether a defendant's alleged breach of duty could constitute the proximate cause of a plaintiff's injury before submitting the issue to the jury).

¶ 30 Although our decision in ***Demmler*** stated the general proximate cause standard for failure to warn cases, ***Demmler*** addressed only part of the proximate cause equation. Relying on the authority discussed above, we hold that before a plaintiff can prove that a non-disclosed risk would have altered the physician's decision to prescribe a drug, the plaintiff must first demonstrate that he/she suffered from the precise injury that the manufacturer allegedly failed to disclose. **See *Downer***, 322 A.2d at 92 ("Proof of proximate cause in such cases requires, initially, a showing that the unrevealed risk which should have been made known has materialized."). Only if the plaintiff carries this initial burden, can he/she

establish proximate causation with evidence that the physician would not have prescribed a drug had the physician known of the non-disclosed risk. Because Appellant did not make this threshold factual showing, *i.e.*, that her physical injury (PPH) was the result of the non-disclosed risk (VHD), she cannot establish proximate causation as a matter of law. The trial court, accordingly, did not err in granting summary judgment in favor of Wyeth on Appellant's failure to warn claim. Therefore, we affirm the trial court's order.

¶ 31 For the above-stated reasons, we affirm the trial court's order granting summary judgment.

¶ 32 Order affirmed.