IN THE COURT OF COMMON PLEAS OF PHILADELPHIA

FIRST JUDICIAL DISTRICT OF PENNSYLVANIA

CIVIL TRIAL DIVISION

JENNIE NELSON and LAWRENCE NELSON, Appellants,	:	January Term 2004, No. 1670
v.	:	Superior Court No. 1520 EDA 2007
WYETH, et. al. Appellees,	:	

OPINION OF THE COURT

Ricardo C. Jackson, J.

On January 14th, 2004, the Appellants, wife and husband, Jennie and Lawrence Nelson filed a complaint alleging that Jennie Nelson developed breast cancer as a result of ingesting PREMPRO, a prescription drug manufactured by Appellee Wyeth. On February 20th, 2007, the jury awarded the Appellants $3 million. The jury found the Appellee negligent for failing to adequately warn prescribing physicians of the breast cancer risk associated with the ingestion of PREMPRO. The jury also found that an inadequate warning led the prescribing physician to prescribe the drug which was the factual cause of Jennie Nelson developing breast cancer. On March 2nd, 2007, a Motion for Post-Trial Relief was filed by the Appellee. On May 30th, 2007, after oral argument, this Court granted Appellee's Motion for Judgment Notwithstanding the Verdict ("JNOV"). On June 12th, 2007, the Appellants filed this appeal.

In response to this Court's order, the Appellants filed a Concise Statement of Matters, pursuant to Pa.R.A.P. §1925(b), raising the following four issues:

1. *Trial Court erred in Granting Wyeth's Motion to Apply Pennsylvania Law.*

2. *Trial Court erred in granting Wyeth's Motion for JNOV on causation.*

3. *Although Appellants presented sufficient evidence at trial to withstand a judgment notwithstanding the verdict on causation, if the trial Court granted JNOV on the basis of insufficient evidence, it did so because the Court erred in excluding admissible evidence of causation.*

4. *The trial Court erred in granting Wyeth's motion for compulsory nonsuit on punitive damages and denying Appellant's post trial motion for a new trial solely on the issue of punitive damages.*

I. Court's Application of Pennsylvania Law

The Appellants argue that according to Pennsylvania's choice of law principles, the law of the Appellants' home state, Ohio, should have been applied. Pursuant to the Pennsylvania choice of law analysis, before a Pennsylvania court can apply the law of another state, the Pennsylvania court must first find that the laws of the alternate state actually differ. *Ratti v. Wheeling Pittsburgh Steel Corp.*, 2000 Pa. Super. 239, 758 A.2d 695, 702 (Pa. Super. 2000). If the laws do not differ, then a true conflict is not present and no further analysis is necessary. However, if a true legal conflict is present, the governmental interests underlying the issue must be analyzed and a determination must be made as to which state has the greater interest in the application of its law. *Id.*

As in Pennsylvania, Ohio state law imposes a duty to adequately warn on pharmaceutical drug manufacturers. The manufacturer of prescription drugs satisfies this duty by providing adequate warnings to the medical profession and not to the ultimate user. *White v. Wyeth Labs.* (1988), 40 Ohio St. 3d 390, 398, 533 N.E. 2d 748, 754. Ohio courts have also adopted the learned intermediary doctrine. *Seley v. G.D. Searle & Co.* (1981), 67 Ohio St. 2d 192, 21 O.O. 3d 121, 423 N.E. 2d 831. The learned intermediary doctrine as applied in Ohio recognizes that a pharmaceutical drug manufacturer may reasonably assume that when the physician, who is the learned intermediary, is appropriately warned of the risks involved with a particular drug, that physician will exercise his or her informed judgment in the patient's best interest. *Tracy v. Merrell Dow Pharmaceuticals, Inc.*, 58 Ohio St. 3d 147, 149-150, 569 N.E. 2d 875, 878 (1991). As in Pennsylvania, Ohio courts have held that the duty to warn is not extended to the patient, even if the pharmaceutical drug manufacturer creates brochures intended to be read by patients. A direct relationship between the manufacturer and the patient does not arise merely because the manufacturer has created brochures for the patient's use. *See Seley*, 67 Ohio St. 2d 203. Ohio courts also require that a causal connection between the alleged negligence and the resulting harm be established by evidence that the lack of adequate warnings contributed to the patient being prescribed the drug. *Id.*

The duty imposed on pharmaceutical drug manufacturers and the causal connection required between the negligence and resulting harm are alike in both Ohio and Pennsylvania. As in both states, where there is an allegation by the plaintiff of a failure to adequately warn, the plaintiff is required to establish that the defendant's negligence in

failing to adequately warn resulted in the learned intermediary prescribing the drug for the plaintiff. Further, had a more accurate label been made available, the learned intermediary would not have prescribed the drug. As such the laws of the Commonwealth of Pennsylvania and the State of Ohio on failure to adequately warn claims are not in conflict and did not require that this court apply Ohio law.

II. Judgment Notwithstanding the Verdict

Judgment Notwithstanding the Verdict (JNOV) is appropriate when "the evidence was such that no two reasonable minds could disagree that the outcome should have been rendered in favor of the movant." *Moure v. Raeuchle,* 529 Pa. 394, 604 A.2d 1003, 1007 (Pa. 1992). JNOV as a matter of law is appropriate when the court concludes that even if all factual inferences are decided in favor of the non-moving party, the law requires a verdict in favor of the movant because "the evidence was such that a verdict for the movant was beyond peradventure." *Id.* However, "a judge's appraisement of evidence is not to be based on how he would have voted had he been a member of the jury, but on the facts as they come through the sieve of the jury's deliberations." *See also Brown v. Shirks Motor Express*, 393 Pa. 367, 143 A.2d 374, 379 (Pa. 1958).

When this Court granted Appellee's motion for JNOV, it concluded that the Appellants failed to prove that Appellee's negligence was the factual cause of Jennie Nelson developing breast cancer. This Court found that Appellee's alleged failure to adequately warn could not have been the factual cause of Jennie Nelson developing breast cancer since the prescribing physician did not read nor rely upon any of Appellee's

warnings as contained in the label accompanying the prescription drug, Prempro. This Court concluded that even if the Appellee had provided a more accurate label, such a label would not have altered the prescribing habits of the prescribing physician since as will be shown later in our analysis, the prescribing physician did not read nor rely upon Wyeth's warnings when deciding whether or not to prescribe Prempro to Jennie Nelson between the years of 1996 to 2001.

A manufacturer of prescription drugs is not strictly liable for harm resulting from use of the drug but rather is only liable "if he fails to exercise reasonable care to inform those for whose use the article (prescription drug) is supplied of the facts which make it likely to be dangerous." *Incollingo v. Ewing,* 444 Pa. 263 at 288, 282 A.2d at 220 (1971). The holding in *Incollingo* is premised upon this Commonwealth's adoption of the Second Restatement of Torts §402A[1] in 1971. Since a drug manufacturer is not an insurer against all possible consequences associated with use of the drug, the Superior Court has held that a pharmaceutical drug manufacturer is not strictly liable for injury later proven to be caused by the prescription drug. *Leibowitz v. Ortho Pharmaceutical Corp.,* 224 Pa. Super

[1] Comment K. Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk. *Restat 2d of Torts, § 402A.*

418, 433, 307 A.2d 449, 458 (1973). Hence, liability is only imposed if a drug manufacturer fails to adequately warn the prescribing physician, also known as the learned intermediary, of those dangers that are known at the time warnings are issued. Under the learned intermediary doctrine, as applied in Pennsylvania, a manufacturer will be held liable only where it fails to exercise reasonable care to inform the prescribing physician of the facts which make the product likely to be dangerous. *Lineberger v. Wyeth,* 2006 Pa. Super. 35, 894 A.2d 141, 149 (2006).

Since prescription drugs require a presentation of a doctor's prescription at a pharmacy, the duty to warn of any risks associated with the drug is owed to the prescribing physician and not the general public. *Incollingo,* 444 Pa. at 288, 282 A.2d at 220. The prescribing physician acts as the learned intermediary since it is the duty of the prescribing physician to be fully aware of the characteristics of the drug he is prescribing, the amount of the drug which can be safely administered, and the different medications the patient is taking. *Leibowitz,* 224 Pa. Super. at 431. 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. This is why the warnings accompanying such drugs are directed to the physician rather than to the patient-consumer. "[I]t is for the prescribing physician to use his independent judgment, taking into account the data supplied to him from the manufacturer, other medical literature, and any other sources available to him, and weighing that knowledge against the personal medical history of his patient, whether to prescribe a given drug." *Mazur v. Merck & Co.,* 964 F.2d 1348, 1356 (3d Cir. 1992).

Once the Appellant has proven that the Appellee failed to adequately warn Dr. Schubert-Moell of the risks associated with use of Prempro, the Appellant had to further prove a causal connection between the failure to adequately warn and the resulting harm. "[T]here must be some reasonable connection between the act or omission of the Appellee and the injury suffered by the Appellant." *Burnside v. Abbott Laboratories,* 351 Pa. Super. 264, 274, 505 A.2d 973, 978 (1985). "In the duty to warn context, assuming that plaintiffs have established both duty and a failure to warn, plaintiffs 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." Mazur, *supra* at 262. Even if the warning is proven to be inadequate, proximate cause is not presumed. *Id.* "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 Appellant from receiving the drug." *Demmler v. Smithkline Beecham Corp.,* 448 Pa. Super. 425, 434, 671 A.2d 1151, 1155 (1996).

Where the prescribing physician bases her decision to prescribe a drug based on clinical experience and medical literature rather than any information supplied by the drug manufacturer, a reasonable jury could not find that the alleged failure to warn was the proximate cause of plaintiff's injuries. *Demmler* at 435. The court in *Demmler* granted summary judgment finding that without evidence that a more explicit warning would have prevented the plaintiff from being prescribed prescription drug Parnate, the plaintiff was unable to prove that the defendant's failure to adequately warn was the factual cause of the plaintiff's injuries. The Superior Court reasoned that there was no reason to conclude that

had a more explicit warning been available, the prescribing physician would not have prescribed Parnate to the plaintiff. *Id.*

Similarly, in the case *sub judice,* Dr. Schubert-Moell never testified that she read or relied upon the Prempro label when deciding whether or not to prescribe Prempro to Jennie Nelson. In fact, when Dr. Schubert-Moell was directly asked "Do you use the Physicians' Desk Reference to determine what the potential risks and benefits are of a given medication?" her response was "Not normally, no." Tr. Depo. Dr. Schubert-Moell 136:8 to 136:11 (Oct. 19, 2005). Dr. Schubert-Moell then testified that when determining the risks and benefits of prescription medication generally, she relies upon literature, textbooks, conferences and journal articles. Tr. Depo. Dr. Schubert-Moell 107:15-107:17. Dr. Schubert-Moell was not asked nor did she testify that she relied upon or read the warnings issued by the Appellee when deciding whether or not to prescribe PREMPRO to Jennie Nelson. If Dr. Schubert-Moell did not take into consideration Appellee's PREMPRO warnings, a reasonable mind could not conclude that a different label would have resulted in Dr. Schubert-Moell altering her prescribing habits in such a way as to have prevented Jennie Nelson from developing breast cancer, by not prescribing PREMPRO.

II. Exclusion of Admissible Evidence

Appellants argue that the Court erred in excluding four categories of evidence: International Marketing Solutions ("IMS") Data, evidence of sales trends, evidence of Dr. Schubert-Moell's prescription habits and evidence concerning Appellee's sales

representatives who visited Dr. Schubert-Moell. Collectively, this evidence was excluded for not having been properly introduced and for being irrelevant. Appellants sought to have most of this evidence introduced through John Ryan, Wyeth's Director of Sales Training for the Women's Health Care Division. Appellants attempted to have Mr. Ryan, testify to the quantity of Prempro prescriptions issued by Dr. Schubert-Moell, both before and after the Women's Health Initiative ("WHI Study"). The Appellants sought to introduce into evidence spreadsheets of prescription records also known as IMS Data. This data was not compiled by Wyeth but rather made available to Wyeth by contracting with the provider of the data. Trial Tr. vol. 2 page 17 (January 23rd, 2007). Pursuant to Pennsylvania Rules of Evidence §803[6], the IMS Data was excluded since John Ryan, a Wyeth employee, could not properly authenticate the data. He was not a custodian of the data compilation nor was he a person with knowledge of how the data was compiled[2].

The IMS data was also irrelevant since it represented Dr. Schubert-Moell's cumulative prescription habits and not the specific risk-benefit analysis that was done when deciding whether or not to prescribe Prempro to Jennie Nelson. As discussed earlier, the Appellants needed to prove that had Dr. Schubert-Moell been provided with a more explicit Prempro warning, she would have changed her prescription habits in such a way as to have prevented Jennie Nelson from developing breast cancer. Statistical data on the

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[2] **(6) Records of regularly conducted activity.** A memorandum, report, record, or data compilation, in any form, of acts, events, or conditions, made at or near the time by, or from information transmitted by, a person with knowledge, if kept in the course of a regularly conducted business activity, and if it was the regular practice of that business activity to make the memorandum, report, record, or data compilation, all as shown by the testimony of the custodian or other qualified witness, or by certification that complies with Rule 902(11), Rule 902(12), or a statute permitting certification, unless the sources of information or other circumstances indicate lack of trustworthiness. The term "business" as used in this paragraph includes business, institution, association, profession, occupation, and calling of every kind, whether or not conducted for profit. *Pa.R.E. §803.*

quantity of Prempro prescriptions issued by Dr. Schubert-Moell is irrelevant since it does not make it any more or less likely that she would not have prescribed Prempro in Jennie Nelson's particular case[3]. A drop in Prempro prescriptions being issued by Dr. Schubert-Moell can be attributed to a variety of factors considering that patients have different medical conditions and family histories. Doctors create individual treatment plans for their patients therefore, it would have been erroneous to conclude that because Dr. Schubert-Moell did not prescribe Prempro for certain patients that she also would not have prescribed the drug for Jennie Nelson.

Evidence of Prempro's sales trends would also have also led the jury to speculate. Evidence of sales trends is overly broad and does not take into account the possibility that even with the new, more accurate warnings, Jennie Nelson could have been among the millions of women who continue to take Prempro today, had she not been diagnosed with breast cancer. This Court notes that the best evidence of what Dr. Schubert-Moell would have done with the more accurate label would have been in the form of direct questioning of Dr. Schubert-Moell who was an actual witness in this trial. A trial deposition was taken of Dr. Schubert-Moell and this very question could have been directly posed to the witness. Furthermore, Pennsylvania jurisprudence does not permit the testimony of the learned intermediary to be substituted with evidence of what a "reasonable doctor" would have done. *Gronniger v. American Home Products Corp.,* 2005 Phila. Ct. Com. Pl. Lexis 505. Likewise, the argument that the Appellants are entitled to a rebuttable presumption that Dr. Schubert-Moell would not have prescribed Prempro for Jennie Nelson had an

[3] "Relevant evidence" means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence. *Pa.R.E. 401*

accurate warning been available also fails since testimony from the actual prescribing physician is required to prove what their prescribing habits would have been had they been provided a more accurate warning. *Id.*

III. Punitive Damages

The Appellants argue that this Court should not have granted the Appellee's Motion for Compulsory Nonsuit on Punitive Damages as the Appellants presented sufficient evidence for the issue to have been decided by a jury. Specifically, in the 1925(b) Statement, the Appellants contend that they established sufficient evidence to prove:

> a. Wyeth's gross negligence in its failure to adequately warn physicians that it had never adequately tested combination estrogen and progestin ...
>
> b. Wyeth's willful failure to adequately warn about the breast cancer risk of Prempro to Jennie Nelson and her doctor
>
> c. Wyeth's deliberate intent to induce women to ingest Wyeth's combination hormone therapy long term, without the requisite testing
>
> d. Wyeth's deliberate and reckless marketing campaign designed to induced all post-menopausal women, including Jennie Nelson, to use Wyeth's PREMPRO drug for the rest of their lives.

The Supreme Court has stated the standard for compulsory nonsuit under Pennsylvania Rules of Civil Procedure § 230.1 is as follows: In reviewing the nonsuit entered in favor of defendants, we must view "the evidence adduced on behalf of the plaintiffs as true; reading it in the light most favorable to [them]; giving [them] the benefit

of every reasonable inference that a jury might derive from the evidence and resolving all doubts, if any, in [their] favor." Brannan v. Lankenau Hospital, 490 Pa. 588, 595, 417 A.2d 196, 199 (1980). The Pennsylvania Supreme Court has also adopted the guidelines of Section 908(2) of the Restatement (Second) of Torts regarding the imposition of punitive damages: "Punitive damages may be awarded for conduct that is outrageous, because of the defendant's evil motive or his reckless indifference to the rights of others." See *Chambers v. Montgomery*, 411 Pa. 339, 192 A.2d 355 (1963). Punitive damages must be based on conduct which is "'malicious,' 'wanton,' 'reckless,' 'willful,' or 'oppressive' . . ." *Id.*, 411 Pa. at 344-45, 192 A.2d at 358. Further, one must look to "the act itself together with all the circumstances including the motive of the wrongdoers and the relations between the parties . . ." *Id.* The state of mind of the actor is vital. The act, or the failure to act, must be intentional, reckless or malicious. *Feld v. Merriam*, 506 Pa. 383, 395-396, 485 A.2d 742, 748 (Pa. 1984). A showing of mere negligence, or even gross negligence, is insufficient for the imposition of punitive damages. *SHV Coal, Inc. v. Continental Grain Co.*, 526 Pa. 489, 587 A.2d 702, 705 (Pa. 1991).

The contention that Appellee intentionally failed to warn Dr. Schubert-Moell of the breast cancer risk by not adequately testing Prempro, requires a historical analysis of Appellee's conduct from the time it sought FDA approval of its drug to the time Jennie Nelson stopped taking Prempro. The record reflects that hormone replacement drugs have been sold in the United States since 1942. Initially, women only took estrogen for hormone replacement therapy, however, during the 1970's Appellee-Wyeth, formerly

known as Ayerst, became aware that gynecologists were prescribing both progestin and estrogen as a form of hormone replacement.

On March 9th, 1983, Ayerst formally requested that the FDA approve their plan to conduct clinical trials on the combined use of estrogen and progestin. *See Defense Exhibits 105 & 106.* Since the combined use of estrogen and progestin was not approved by the FDA, Ayerst needed to obtain authorization from the FDA to conduct clinical trials where both hormones would be combined. The clinical trial was eventually approved by the FDA and became known as the Prem-Pak Protocol. Subsequent clinical trials took place, in which Appellee investigated the appropriate dosages for combined hormone replacement therapy.

On December 30th, 1994, Appellee-Wyeth obtained FDA approval for the sale of Prempro which was a one pill combination of estrogen and progestin. The initial label accompanying Prempro which was FDA approved, disclosed a breast cancer relative risk of 1.3 to 2.0. The FDA required Appellee to include a statement regarding the effect of progestins on the breast cancer risk. Specifically, the FDA required Appelle to include the following language "...while the effects of added progestins on the risk of breast cancer are also unknown, available epidemiologic evidence suggests that progestins do not reduce and may enhance the moderately increased breast cancer risk that has been reported with prolonged estrogen replacement therapy." *See Appellee's Exhibit 101* Letter from the FDA dated December 28th, 1994.

The FDA's approval of Prempro was conditioned upon Appellee investigating if a lower dose Prempro would be safe and effective. The FDA also required that Appellee

continue the Women's Health, Osteoporosis, Progestin, and Estrogen Study. Already underway at the time Prempro was approved, the National Institute of Health, in 1993, launched the WHI Study. As with the Prem-Pak protocol, FDA approval for the WHI Study was required since the combined use of estrogen and progestin had not yet been approved. Appellee assisted the National Institute of Health in obtaining FDA approval for the WHI Study. Appellee also provided the combined estrogen and progestin pills that were used in the study. When the WHI study concluded in 2002, the breast cancer risk associated with Prempro was more clearly understood by the medical community and actually lower than previous estimates. Prempro labels after WHI actually disclosed a lower relative risk than was disclosed while Jennie Nelson took Prempro.

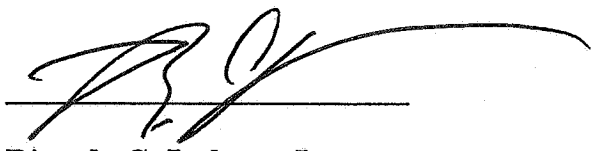
While the Appellant may argue that such testing was not as comprehensive as could have been, it cannot be said that Appellee was malicious. Appellee was aware of a breast cancer risk, disclosed it in its Prempro label and further aided the medical community in better understanding its drug. As such, Appellee's conduct could not rise to the requisite level necessary to justify an award of punitive damages which are intended to rectify a wrong doer's evil motive or oppressive behavior. Therefore, this Court concluded that Appellee's conduct was not outrageous and that the Appellants were not entitled to punitive damages.

As this Court has already held, the duty to adequately warn was not owed to Jennie Nelson, but rather to the learned intermediary, Dr. Schubert-Moell, who actually prescribed Prempro to Jennie Nelson. Therefore, Appellee could not have deliberately induced women, either through market campaigns or by other means, to ingest Prempro

since the drug was only available after the prescribing physician who made a medical decision to prescribe Prempro. This finding is further supported by the lack of any evidence indicating that the Appellant ever read, viewed or was persuaded by any information disseminated by the Appellee. Most compelling of all, is the testimony of Dr. Schubert-Moell in which she clearly indicates that her professional decision to prescribe Prempro was based upon her independent study of medical literature and her experience. At no point, did Dr. Schubert-Moell or the Jennie Nelson testify that they were influenced by any marketing material from Appellee, be it in the form of printed brochures or commercials. As for the Appellants allegation that the Appellee was grossly negligent in failing to adequately warn prescribing physicians that Prempro was never adequately tested, as stated previously, more than gross negligence, needs to be established to justify an award for punitive damages. *See SHV Coal.* Hence, an award for punitive damages on a gross negligence claim would be legally insufficient.

For the above reason, this Court respectfully requests that its order of May 30th, 2007, be affirmed.

BY THE COURT:



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