IN **THE COURT OF COMMON PLEAS OF PHILADELPHIA**
FIRST JUDICIAL **DISTRICT OF** PENNSYLVANIA
CIVIL TRIAL DIVISION

2673 EDA 2007

MERLE SIMON, and
STEVEN A. SIMON,

Plaintiffs/Appellants.

vs.

WYETH PHARMACEUTICALS,
INC., *et aL, Defendants/Appellees*
JUNE TERM, 2004

No. 4229

James A.. Morris, Jr., Esquire
Brian Ketterer, Esquire ’
Attorneys for Plaintiffs

David E. Dukes, Esquire
Attorney for Defendant Wyeth

Gregory G. Little, Esquire
Attorney for Defendant Upjohn

COPIESSENT ***PURSUIT***

TO **Pa.R.C.P, 236(b)**

DEC 2 6 ZOO7

SUPERIOR COURT DOCKET FIRST JUDICIAL DISTR ICTOFPA

2620 EDA 2007

QUI~ONES ALEJANDRO, J. **DATE: December 26, 2007**

OPINION

INTRODUCTION

Merle and Steven Simon (Plaintiffs) filed a negligent products liability action against, *inter alia,* Wyeth Pharmaceuticals, Inc., ..(Defendant Wyeth), and Pharmacia & Upjohn, Inc., (Defendant Upjohn), (collectively Defendants) essentially alleging that Merle Simon (Plaintiff-wife) developed invasive lobular breast, cancer as a result of her long-term use of an estrogen and progestin hormone replacement therapy (I-IRT) drug combination ~vhose components were

manufactured by Defendants. This action was subsequently tried before a jury which returned, a verdict in favor of Plaintiff-wifet *only* and against Defendant Upjohn *only in the* amount of one million five hundred thousand dollars ($1,500,000.00).

Thereafter, Defendant Upjohn timely filed' a post-trial motion requesting either the entry of a judgment notwithstanding the verdict (judgment n.o.v.) or, in the alternative, a new trial. Plaintiff-wife filed a petition for delay damages. After hearing oral argument on these motions, this trial judge granted Defendant Upjolm's post-trial motion and entered a judgment n.o.v., in its favor, deemed the request for new trial moot, and denied the petition for delay damages.

Plaintiff-wife timely filed this appeal challenging this trial judge's ruling which granted Defendant Upjohn's post-trial motion. Defendant Upjohn filed a cross-appeal and requested that this trial judge enumerate the reason(s) for granting a new trial in the event that the appellate court vacates and/or roverses the entry ofjudgrnent in its favor. This opinion addresses *only the* appeal filed by Plaintiff-wife.2

RELEVANT FACTUAL AND PROCEDURAL HISTORY

From the trial testimony, elicited, it is reasonable to infer that the jury considered the following evidence:

> Plaintiffs ~ residents of New Jersey. Defendant Wyeth is a pharmaceutical company headquartered in Pennsylvania. Defendant Upjolan is a pharmaceutical company headquartered in New Jersey.
>
> Sometime in 1992, Plaintiff-wife was first prescribed a combination of estrogen and progestin HRT by h~r gynecologist, Kenneth Dollinger, M.D., to combat symptoms of menopause. Specifically, Dr. Dollinger prescribed to Plaintiff-wife the drugs

Premarin, an estrogen manufactured bay Defendant Wyeth *and Provera,* a progestin manufactured by Defendant Upjohn. *The Provera was*

The jury found against Steven Simon in his claim for loss of consortium. In the event the appellate court overrules this trial judge and an opinion is needed addressing the motion for a new trial, a supplemental opinion will b¢ submitted. 4/24/2007 P.M. Tr. at 47: I 0- 49:2. *id.* at 48:25 -49:2; 4/25/2007 AaM. Tr. at 38:5-15.

prescribed for protection against endometrial cancer since Plaintiff-wife had a uterus,

When Dr. Dollinger retired in 1994, Joarm Somers, M.D., and later Catherine Sladowksi, M.D., became Plaintiff-wife's treating physicians.~ In I996, Plaintiff-wife's medications were switched to *Prempro, a drug* manufactured by Defendant Wyeth which combines the two components of HRT (estrogen and progestin) into one pill.6 Plaintiff remained on *Prempro* until she was diagnosed with breast cancer on May 21, 2002.7

Numerous experts called by Plaintiffs and Defendants explained the relationship, and/or function of estrogen and progesterone/progestin in the female body. Ttiese experts essentially testified to the following:

The female body produces estrogen, the primary female sex hormone, in the -initial stages of the monthly menstrual cycle. This production acts to form a new layer of tissue on the endometfial lining of the ~terus.s After ovulation oh, curs, the female body then produces progesterone in conjunction with estrogen. The progesterone converts the newly formed endometrial lining into a s.uffa~e capable of supporting a fertilized egg.9 If fertilization has not. occurred, the progesterone levels fall, which causes menstrual shedding; . otherwise known as menstruation, and the cycle repeats itself.~°When. a .woman reaches a stage in life when she is no longer fertile, she may develop common menopausal and/or post-menopause, symptoms such as, hot .flashes and flushes, insomnia,- fatigue, irritability, and/or osteoporosis. These menopausal symptoms.are attributed to the female body's reduced production of estrogen,t~ To

relieve these symptoms, physicians have preseribecl~ for. decades, a HRT which has estrogen as its primary componem?" Medical studies haveshown, ... however, "~'~,,,,, unless a woman's-uterus has been removed (such as .by a hysterectomy) taking estrogen alone *(i.e.,* estrogen replacement therapy, or "ERT"), without opposing progesterone, can increase the risk of

4/24/2007 P.M. Tr. at 52:9-1), 54:16 - 56:14; 4/25/2007 A_M. Tr. at 37:23-4; Kenneth Dollinger, M.D., Video Tr. at 10:16 - 12:8;.Catherine Sladowski, M.D., Video Tr. at 45:25 - 46:14. 4/24/2007 P.M. Tr. at 52:14-16; 4/25/2007 A.M. Tr. at 38:9-19. 4/23/2007 P.M. Tr. at 7:18 -9:3; 4/24/2007, P.M. Tr. at 51:16 - 52:8, 54:11-15, 56:20- 57:6. 5/8/2007 A.M. Tr. at 27:6-13.- 4I 16/2007, t~.M. Tr. at 46:21-25; 5/8/2007 A.M. Tr. at 27:13 - 28:17. t0 4/16/2007, P.M. Tr. at 47:2-7; 5!8/2007 A,M. Tr. at 28:17-20.

t~ 4/16/2007, P.IVL Tr. at 57:21 -~-55:20; 5/1/2007, A~I. Tr. at 64:3 - 66:12; 5/8/2007, A.M. Tr. at 3320 - *35:9.* t2 5/1/2007 A.M. Tr. at 66:22 - 68:5; 5/8/2007, A.M. Tr. at 35:15 - 38:11.

endometrial bleeding and cancer.~3 This is because unopposed estrogen in a woman with a uterus causes endometrial hyperplasia, or extreme cell proliferation on the endometrial lining of the uterus which, in turn, is responsible for endometrial bleeding and an elevated risk of endometrial cancer.~4

In a combined HRT regimen, progestin is used to regulate and keep in check the cell growth caused by estrogen, much the same way that progesterone naturally does in the menstrual cycle.~5 Since the potency of ordinary p~,gesterone supplements is inconsistent from woman to woman,~°doctors instead prescribe progestin, a synthetically produced progesterone.17 Unlike ordinary progesterone supplements, the enhanced progestin when metabolized, delivers a predictable dose of progesterone in all women using the drug. ~s

All experts agreed that a number of independent medical studies were commissioned to e~aluate the effects of eonibined estrogen and progestin HRT. The ultimate findings of these published studies sl~owed a correlation between the long-term use of combined HRT and an increased risk of breast cancer.~9 Plaintiffs' expert, Graham Colditz, M.D., referenced the Harvard Nurses Health (HNH) Study, a study funded primarily by the National CancerInstitute, and one with which he was actively

involved.2° Dr. Colditz testified that in 1976, the HNH Study commenced collecting data to determine if a connection between the use of Oral contraceptives and increased breast cancer risk existed.2~ In the 1980s, the study began to focus on the possible relation between HRT and breast cancer,z~ Based On the data collected, Dr. Colditz and several colleagues published in 1998 a paper in the-Annals *of Internal Medicine* entitled *Plasma Sex Hormone Concentrations and Subsequent Risk of Breast Cancer Among IVomen Using Postmenopausal Hormones.* These writers found that the evidence supported a causal relationship between the use of estrogen and progestin and an increased risk. of breast cancer.23

4/19/2007 P.M. Tr. at 67:3 -69:6, 96:15-17; 5/1/2007, A.M. Tr. at 67:9 - 68:5; 5/3/2007, A.M. Tr. at 155:9-17; 5/8/2007, A.M. Tr. at 36:19-44:4. 4/19/2007 P.M. Tr. at 67:3-7, 95:22 - 96:14; 5/I/2007,A.M. Tr. at 67.'9 - 68:5; 5/8/2007, AaM. Tr. at 29:5-21. 4/19/2007 P.M. Tr. at 51:5-1], 66:7 - 67:14; 4/24/2007, A.M. Tr. at 40:6-10; 5/1/2007, A.M. Tr. at 68:6-11;

5/8/2007 A.M. Tr. at 29:22 - 30:3. 5/1/2007 A.M. Tr. at 68:23 - 69:6; 5/8/2007, A.M. Tr. at 30:20 - 31:11, 32:11-19. 4/19/2007, P.M. Tr. at 44:17-20, 45:20- 46~; 5/8/2007, A.M. Tr, at 31:12-14. 5/8/2007, A.M. Tr. at 31:12-16, 32:20 - 33:8. This opinion does not consider any of the numerous medical studies suggesting that estrogen-~nly hormone therapy, without an added progestin, also increases a woman's breast cancer risk since these studies are **not** relevant to Plaintiff-wife. Graham Colditz, M.D., Video Tr. at 26:4 - 27:6. *ld* at 27:7 -28:18. *nld* at 28:19- 31:4.

Id at 65:24 - 70:16.

An earlier publication written by Leif Bergkvist, M.D., and colleagues in 1989, entitled The *Risk of Breast Cancer after Estrogen and Estrogen-Progestin Replacement,* and published in the *New England Journal of Medicine* concluded that women taking a combination of estrogen and progestin for six (6) years had four (4) times greater risk of developing breast cancer than women taking only estrogen therapy for nine (9) years.24 Likewise, in an article written by Catherine Schairer, Ph.D., and colleagues, entitled *Menopausal Estrogen and Estrogen- Progestin Replacement Therapy and Breast Cancer,* published in the *Journal of the American Medical Association (JAMA)* in 2000, these researchers concluded that there was a statistically significant relationship between combined HRT and an increased breasrcancer risk.2s

Plaintiffs' experts opined that Defendants were aware of these research findings. Specifically, Cheryl Blume, Ph.D., discussed several of Defendant Wyeth's internal memoranda which showed that the pharmaceutical company knew of much, if not all, of the early data and findings.26 Likewise, Rodney Carlson, M.D., testified that Defendant-Upjohn in 1990 commissioned its own independent-inv~tigation of a possible.link of cancer with the use of HRT, which was performed by the *Degge*

Group.27 Specifically, the focus of the review by the *Degge Group* was to summarize the clinical and epidemiological data available in the early 1990s in.order to understand the existing knowledge/studies which dealt with the relationship between combined HRT and breast cancer.28 The *Degge Repor~9* concentrated its review on seven (7) epidemiologieal studies which considered the use of estrogen and progestin in H_R.T,3° and concluded that the existing evidence Was inconclusive and that fttrther research was necessary to determine whether the use of combined HRT did *in fact* increase the risk of breast cancel..31Although Defendants were aware Of research which found a correlation or at least suggested a correlation between, the use of combined HRT and an increased breast cancer risk during the time period when Plaintiff-wife was using combined HRT, Defondants reacted to this-information differently when labeling their respective products:

Prempro (Defendant Wyeth's combination drug) carried a label warning to patients explaining that some stud.ies had found a link between estrogen and progestin.-HRT, and further encouraging its users to seek bi-yearly mammograms and to consult with their doctors immediately if a breast lump is susp~ted.32

Premarin (Defendant Wycth's estrogen) can, led a label warning of potential cancer risks associated only with ERT.33 (The drug labeling did not carry any warning regarding the use of Premarin in conjunction with a progestin.).

Provera (Defendant Upjohn's progestin) carried a label which explained that beagle dogs treated with progestin had developed breast malignancies,

24 5/1/2007, A.M. Tr. at 100:I0- 105:22; Exhibit P-101. 7~Exh~it P- **116.** 265/1/2007, A.M. Tr. at 100:11 - 101:9. See a/so 111:2-3 - 112:1 g; 5/1/2007, P.M. Tr. at 5:6 - 12 (showing that Defendant Wyeth was aware of the JAMA article). 27 Rodney Carlson, M.D., Video Tr. at 21:17 - 24:1, 27:19 - 28:10. ***2s Id*** **at** 30:21 - 31:5, 35"93 - 36:4; 5/8/2007, A.M. Tr. at 102:13-20; Exhibit P-7. 29 Exh~it **P-8.** 30 Rodney Carlson, M.D., Video Tr. at 36:19 -37:15; 5/8/2007, A.M. Tr. at 103:14 - 107:16. 3~ Rodney Carlson, M.D., Video Tr. at 37:16 -38:21; 5/8/2007, A.M. Tr. at 107:24- 108:6, 109:13 - 110:14.

but the significance of that data with respect to humans had not been established.34

The National Institutes of Health (N/H) commissioned the Women's Health Initiative (WHT) study to examine whether HRT had any effect in decreasing the risk of cardiovascular disease in post-menopausal women. This study was prematurely terminated when an unusually high number of women in the experimental group taking HRT developed breast cancer.3s On July 9, 2002, the WHI released a preliminary report which proclaimed that long-term use of estrogen and progestin HRT increased breast cancer risk.36 The WHI's findings received massive media attention and resulted in a significant decline in the use of HRT.37 As stated, in May 2002, approximately two (2) months before the WHI report was published, Plaintiff-wife was diagnosed with invasive lobular breast cancer. Plaintiff-wife testified that the first time she had any reason to suspect a causal connection between her usage of combined HRT and.her breast cancer was when a friend mentioned a newspaper article which reported the findings of the WHI study:s Plaintiff-wife did not say when precisely this conversation occurred.

Procedurally, on July I, 2004, Plaintiffs f'fled a complaint against Defendants averring counts of negligence, fraud, breach of express warranty, loss of consortium, and a violation of corporate responsibilities. Discovery ensued and trial commenced on April 16, 2007. Following

rz See Physicians Desk Reference (Exhibit P-43).

See Physicians Desk Reference (Exhibit D-29). See Physicians Desk Reference (Exhibit P-9-13), 4/24/2007, A.M. Tr. at 43:15 -44:3; 5/1/2007, A.M. Tr. at 86:11 - 87:14, 88:I2-23; 513/2007, P.M. Tr. at 13:20 - 14:21. 5/1/2007, A.M. Tr. at 83:19 - 85:9, 96:16 - 97:25; 5/I/2007, P.M. Tr. at *62:17-66:5;* 5/3/2007, P.M. Tr. at 16:3- 6. 4/24/2007, P.M. Tr. at 85:9 - 86:61 5/2/2007 P.M. Tr. at 64: I I - 65:9; 5/9/2007 A.M. Tr. at 25:8-23. 4/24/2007 P.M. Tr. at 85:9-20; 4/25/2007 A.M. Tr. at 44:19-45:6; Catherine Sladowski, M.D., Video Tr. at 77:2- 21.

a five (5) week trial with numerous experts, the jury rendered a verdict on May 15, 2007, in

favor of Plaintiff-wife *only* and against Defendant Upjohn *only,* and exonerated Defendant Wyeth from any liability. *As* previously stated, the verdict award to Plaintiff-wife was in the amount of one million five hundred thousand dollars ($1,500,000.00).

On May 23, 2007, Plaintiff-wife filed a petition for delay damages.

On May 25, 2007, Defendant Upjohn fded a timely post-tHai motion seeking judgment n.o.v., or, in the alternative, a new tHai. Specifically, Defendant Upjohn argued that in its motion for judgment n.o.v., that:

> (1) Plaintiffs failed to satisfy their burden of proving proximate causation, because, there is no evidence that a different warning by Upjohn would have resulted in Mrs. Simon not being presedbed *Provera;*
>
> (2) Plaintiffs' failure-to-warn claims are preempted by federal law;, and
>
> (3) Plaintiffs failed to satisfy their burden of proving an exception to the applicable two-year statute of limitations.

In the alternative, Defendant Upjohn argued it was entitled to a new tHai, because:

> (1) The jury's finding, regarding the adequacy of Defendant Wyeth's warning about the risk of breast cancer cannot be reeoneiled with its finding that the inadequacy of the *Provera* warning caused Mrs. Simon's breast caneer;
>
> (2) Failure to adequately instruct the jury on the law of proximate causation in the context of failtu-e-to-wam cases invo!v.;.ng prescription d_~gs w_a..s legal error;
>
> (3) Comb'matioa.of two distinct causation issues into one question on the verdict form was legal error;
>
> (4) Admission of advertisements not seen or relied upon by Mrs. Simon or her prescribing doctors, and FDA criticisms of those advertisements, was erroneous;
>
> (5) The jury's finding of negligence was against the weight of the evidence; and
>
> (6) Failure to submit Defendant Upjohn's product identification defense to the jury was legal error.

On September 5, 2007, oral argument was heard on Plaintiff-wife's petition for delay damages and Defendant Upjohn's post-trial motion. On September 7, 2007, this trial judge granted Defendant Upjohn's post-trial motion and entered a judgment n.o.v., in its favor. Consequently, Defendant Upjohn's request for a new trial was deemed moot, and Plaintiff-wife's petition for delay damages was denied.

On October 2, 2007, Plaintiff-wife appealed the entry of the judgment n.o.v.

Defendant Upjohn filed a cross-appeal on October 5, 2207, requesting that this trial judge enumerate, pursuant to Pa. R.C.P. 227.1(e),39 any reason for granting a new trial in the event the appellate court vacates or reverses this trial judge's decision to direct the entry of judgment for Defendant Upjohn.

ISSUESIn response to an order issued on October 4, 2007, in accordance with Pennsylvania Rule of Appellate Procedure (Pa. R.A.P.) 1925(b), Plaintiff-wife on October 23, 2007, filed of record and served onto this trial judge the following statement of errors complained of on appeal:

1. THE TRIAL COURT ERRED IN GRANTING UP JOHN'S MOTION FOR JUDGMENT N.O.V.

(1) The Trial Court erred by granting Defendant Upjohn's request for judgment n.o.v., as Plaintiffs presented sufficient evidence to carry their legal bttfden as to all issues at trial so as to render a jury verdict in their favor.

(2) The Trial court erred by granting Defendant Upjohn's request for judgment n.o.v., by failing to consider the evidence and any conflicts therein in the light most favorable to the Plaintiffs who are afforded the benefit of all reasonable inferences that arise from the evidence.

[39]Pa. R_C.P. 227.1(e) provides:

Ifa new trial and the entry ofjud~nent are sought in the alternative, the court shall dispose of both requests. If the eottrt directs the entry ofjudgraent, it shall also rule on the request for a new trial by

determining whether it should be granted if the judgment is thereafter vacated or reversed, and shall specify the grounds for granting or denying the request for a new trial.

(3) Defendant Upjohn in their post-trial motion requested judgment n.o.v., on statute of limitations grounds. To the extent that judgment n.o.v., was granted on the basis of this ground, Plaintiff submits that such a ruling constitutes reversible error.

2. ALTHOUGH PLAINTIFFS PRESENTED SUFFICIENT EVIDENCE AT TRIAL TO WITHSTAND A [JUDGlVIENT N.O.V.] ON CAUSATION, IF THE TRIAL COURT GRANTED [JUDGMENT N.O.V.] ON THE BASIS OF INSUFFICIENT EVIDENCE, IT DID SO BECAUSE THE COURT ERRED IN EXCLUDING ADMISSIBLE EVIDENCE OF CAUSATION.

(1) The Trial Court erred in excluding Plaintiffs from introducing evidence of IMS Data that showed Plaintiff's prescribing physicians substantially altered their prescription practices when faced with accurate information about Upjohn's drug and combination hormone therapy.

(2-) The Trial Court erred in excluding admissible evidence to post 2002 labels for both Prempro and Provera.

(3) The Trial Court erred in excluding evidence of sales trends because this is admissible evidence of a change in the prescribing habits of Plaintiff's prescribing physician.

(4) The Trial Court erred in excluding admissible evidence related to the sales representatives who "called on" Plaintiff's prescribing physician.

(5) The Trial Court erred in excluding evidence of total sales data figures..

(6) The Trial court erred in .Granting Motion to Exclude Evidence of Ghostwriting (Joined by Upjohn).

(7) The Trial Court erred in excluding the supplemental reports of Drs. Austin, Blume, Goldfarb, and Parisian.

(8) The Trial Court erred in excluding the correspondence between the FDA and Defendants' counsel in 2000.

LAW AND DISCUSSION

Succinctly, Plaintiffs contend that this trial judge erred in granting Defendant Upjohn's

motion for judgment n.o.v., and in ruling on certain evidentiary matters. This trial judge disagrees, and states that the reasons/grounds for granting Defendant Upjohn's motion for judgmem n.o.v., are that: (1) Plaintiffs" lawsuit is time barred, and (2) Plaintiffs did not establish proximate causation as a matter of law. This trial judge opines that Plaintiffs' contention, "that had this trial }udge not improperly precluded certain admissible evidence Plaintiffs would have met their burden of establishing causation", is erroneous and without merit.

Undisputedly, a judgment n.o.v., may be entered only where: (1) the moving party is entitled to judgment as a matter of law and/or (2) the evidence is such that no two reasonable minds could disagree that the verdict should have been rendered for the moving party. *Carrozza v. Greenbaum,* 866 A.2d 369, 379 (Pa. Super. 2004), *affirmed,* 916 A.2d 553 (Pa. 2007); *Campisi v. Acme Markets,* 915 A.2d 117, 119 (Pa. Super. 2006); *see also Quinby v. Plumsteadville Family Practice, Inc.,* 907 A.2d 1061, 1074 (Pa. 2006).

When reviewing a trial court's decision to grant or deny a motion for judgment n.o.v., an appellate court's scrutiny is limited to determining whether there is sufficient competent evidence on the record to sustain the verdict. *Birth Center v. St. Paul Companies, In~,* 787 A.2d 376, 383 (Pa. 2001); *Carrozza,* 866 A.2d at 379. An appellate court will review all of the evidence in the light most favorable to the verdiet-wirmer and will give that party the benefit of every reasonable inference of fact arising therefrom, and any conflict in the evidence must be

383; *Campisi,* 915 A.2d at 119. An appellate court's scope of review is plenary concerning questions of law, while the fact-finder's determination of questions of credibility and the weight accorded the evidence is given great deference. *Carrar2a,* 866 A.2d at 379; *Birt~ Center,* 787

A.2d at 383. A lower court's decision to grant or denial of a judgment n.o.v., will be disturbed only for an abuse of discretion or an error of law. *Quinby,* 907 A.2d at 1074.

I. Statute of Limitations

As stated, this trial judge opines that Plaintiffs' civil action is time barred since it was filed after the statute of limitations period had expired. In general, an action to recover damages for personal injuries or for ne~igenee of another must be commenced within two years after the cause of action accrued. *See* 42 Pa. C.S. §§ 5502(a), 5524(2); *Fine v. Checchio,* 870 A.2d 850, 857 (Pa. 2005). A cause of action accrues when the plaintiff could have fi~t maintained the action to a successful conclusion. *Fine,* 870 A.2d at 857, *citing Kapil v. Association of Pennsylvania State College and University Faculties,* 470 A.2d 482, 485 (Pa. 1983); *see also Constantino v. Carbon County Tax Claim Bureau,* 895 A.2d 72, 74 (Pa. Commw. 2006), *allocatur denied,* 906 A.2d 544 (Pa. 2006). In a suit to recover damages for personal injuries, the right to institute and maintain a law suit arises when the injury is inflicted. *Fine,* 870 A.2d at 857, *citing Ayers v. Morgan,* 154 A.2d 788, 791 (Pa. 1959). Claims of mistake, misunderstanding, or lack of knowledge do not toll the running of the statute, *ld., citing Nesbitt v. Erie Coach Co.,* 204 A.2d 473, 475 (Pa. 1964); *Pocono International Raceway, Inc. v. Pocono Produce, lnc.,* 468 A.2d at 471 (Pa. 1983). Even though a person may not discover his injury until it is too late to take advantage of the appropriate remedy, this is incident to a law

^-t.:~..~! .... b-;,~, lanai r~a~l;~¢ t~ntlrlg~nt on merl~ lapse of time. *Pocono International,* 468 A.2d at 471. Once a cause of action has accrued and the prescribed statutory period has run, an injured party is barred from bringing a cause of action. *Fine,* 870 A.2d at 857, *citing Pocono International,* 468 A.2d at 471.

An exception to this general principal is the *discovery rule,* which essentially acts to toll the running of the statute of limitations so long as the injured party is reasonably unaware of his or her right to sue. *Fine,* 870 A.2d at 858; *Constantino,* 895 A.2d at 74-75; *Lesoon v.*

Metropolitan Life Insurance Co., 898 A.2d 620, 627 (Pa. Super. 2006), *allocator denied,* 898 A.2d 620 (Pa. 2006). In *Fine, the* Supreme Court reiterated the concepts the discovery rule:

> [W]hen a court is presented with the assertion of the discovery rule's application, it mus~ address the ability of the damaged party, exercising reasonable diligence, to ascertain that he has been injured and by what cause. Since this question. involves a factual determination as to whether a party was able, in the exercise of reasonable diligence, to know of his injury and its cause, ordinarily, a jury is to decide it. Where, however, reasonable minds would not differ in finding that a party knew or should have known on the exercise of reasonable diligence of his injury and its cause, the court determines that the discovery rule does not apply as a matter of law.

When the discovery rule applies, the statute of limitations, does not commence to run at the

instant that the fight to institute suit arises, i.e., when the injury occurs. Rather, the statute is tolled, and does not begin to run until the injured party discovers or reasonably should discover that he has been injured and that his injury has been caused by another party's conduct. Whether the statute of limitatiom has run on a claim is a question of law for the trial court to determine; but the question as to when a party's injury and its cause were discovered or discoverable is for the jury.

870 A.2d at 858-859, citations and quotations omitted; *see also Lesoon,* 898 A.2d at 627; ***Gustine Uniontown Associates, LteL v. Anthony Crane Rental, In~,* 892 A.2d 830, 836 n. 2 (Pa.**

Super. 2006).

An exercise of reasonable diligence necessitates a reasonable effort to discover the cause of an injury under the facts and circumstance present in the case. *Cochran v. GAF Corp., 666* A.2d 245, 249 (Pa. 1995); *Sell v, Workers" Compensation.Appeal Board,* 771 A.2d 1246, 1251

(Pa. 2001). In this context, reasonable diligence is not an absolute standard, but is what is expected from a party who has been given reason to inform himself or herself of the facts upon which the right to recovery is premises. *Fine,* 870 A.2d at 858. While there are very few facts which diligence cannot discover, there must be some reason to awaken inquiry and direct diligence in the channel in which it would be successful. *Id., citing Crouse v, Cyclops Industries,* 745 A.2d 606, 611 (Pa. 2000). Therefore, although the reasonable diligence standard

is flexible enough to take into account differences between persons and their capacity to meet

certain situations, a plaintiff must exercise the level of diligence that a reasonable person would employ under the facts and circumstances presented in a particular case. *Fine,* 870 A.2d at 858, *citing Crouse,* 745 A.2d at 611.

In the instant case, a critical issue is whether Plaintiff-wife's claims against Defendants accrued when she was diagnosed with breast cancer on May 21, 2002, or, as she argues, when she learned of the published findings of Will study some time aiter July 9, 2002. Plaintiff-wife contends that she had no reason to know or even think that there was a link between her use of HRT and breast cancer until the WHI report was released. Plaintiff-wife further contends that at the time of her diagnosis, a dul. y diligent investigation of the came of her breast cancer would not have led her to conclude that the use of the combined HRT was the culprit became a randomize controlled clinical trial focusing on combination HRT and breast cancer, such as WHI study, had not yet been reported. Plaintiff-wife concludes that because of the totality of circumstances, which included the facts that her physicians did not tell her there was a causal link between HRT and breast cancer, the product labels were similarly disrnissive, and the media was equally non-informative, she was unaware of any causal connection between the HRT use and her breast c~cer ,,_nti! a.~.er the pub!i_eation of the WHI study.

However, Plaintiff-wife's contention that there was no scientific evidence showing a link between combined HRT and breast cancer until the WHI report was published, conflicts with the evidence of record Plaintiffs presented, including opinions offered by their experts, Dr. Blume and Dr. Colditz. In part, Dr. Blume testified that scientific evidence showing a connection between combined HRT and breast cancer, *albeit* not as publicly disseminated as the WHI

report, began mounting as early as 1989. In 1989, *the New England Journal of Medicine*

published Dr. Bergkvist's article entitled *Breast Cancer after Estrogen and Estrogen-Progestin Replacement* which found that women taking combined estrogen and progestin HRT for long periods of time had a significantly increased risk of developing breast cancer. These results were reproduced in numerous clinical studies, including Dr. Colditz' 1998 paper *Plasma Sex Hormone Concentrations and Subsequent Risk of Breast Cancer Among Women Using Postmenopausal Hormones,* published in the *Annals of Internal Medicine, as* well as Dr. Schaixer's article *Menopausal Estrogen and Estrogen-Progestin Replacement Therapy and Breast Cancer,* published in 2000 in the *Journal of the American Medical Association* (JAMA).

In addition, Plaintiffs' argument is faulty since the labeling/package information sheet provided inside the packaging of *Prempro, the* combined HRT drug Plaintiff-wife took continuously from 1996 until she was diagnosed with breast cancer in 2002 provided, in its relevant section:

> RISKSOF ESTROGEN AND/OR PROGESTIN However, additional risks may be associated with the inclusion of a progestin in estrogen treatment. The possible risks include.., a possible increase in breast cancer risk (see *Cancer of the breast,* below). Usually, the smaller the dose and the shorter the duration of treatment, the more these effects are minimized. Check with your doctor to make sure you are using the lowest effective dose and only for so long as you need it.
>
> *Cancer of the bre~_vt-* Most studies have not shown a higher risk of breast cancer in women who have ever used estrogen. However, some studies have reported that breast cancer developed more often (up to twice the usual rate) in women who used estrogen for long periods of time (especially more than 10 years), or who used high doses for shorter time periods. The effects of added progestin on the risk of breast cancer are unknown. Some studies have reported a somewhat increased risk, even

higher than the possible risk associated with estrogen alone. Others have not. Regular breast examinations by a health professional and monthly self-examination are recommended for all women. Regular mammograms are recommended for all women over 50 years of age.

14

REDUCING THE RISKS OF ESTROGEN/PROGESTIN If you decide to take an estrogen/progestin ~ombination, you can reduce your risks by carefuLly monitoring your treatment.i See your doctor regularly. While you are taking PREMPRO or PREMPHASE~ it is important to visit your doctor at least once a year for a checkup .... If membe.' rs of your family have had breast cancer or if you have ever had breast lumps ~r an abnormal mammogram (breast x ray), you need to have more frequent breast examinations.

Be alert for signs of trouble. If any of these ~warning signals (or any other unusual symptoms) happen while you are using ¢strogen/progestin, call your doctor immediately: ... breast lumps (possible bre ,a~t cancer; ask your doctor or health professional to show you how to examine yout~ breasts monthly).

Exhibit D-43, emphasis in the original information sheet.

Although *Prempro's* information sheet is not defini~ve in explaining the breast cancer risk associated with long-term combined HRT usage, it doe~ indicate that some clinical studies had found an increased risk for breast cancer with its use. Tlj~e information sheet also encourages *Prempro* users to perform frequent breast self-examinations! receive yearly mammograms, and expeditiously alert a doctor if any breast lumps are discovered,.

Based on the evidence of record, this trial judge opin~ that Plaintiffs claim is time barred as the discovery rule exception to the statute of limitations does not apply as a matter of law. In

this trial judge~s opinion, Plaintiff-wife knew or should l have known by the exercise of reasonable diligence of her injury and its cause when she w~s diagnosed with breast cancer on May 21, 2002. Clearly, the *Prempro* package information ~.sheet, which Plaintiff-wife admitted came with each and every prescription received and which ~he read the f~st time she took the [1] drug, was sufficient to put her on notice of the causal connection between her ~ of combined HRT and her breast cancer.~ Without reiterating the entire ~arnmg information, suffice to say that while the *Prempro* package information sheet may app,ear to underestimate the mounting

[1] 4o 4/25/07, A.M. Tr. at 80:17 - 81:23.

evidenc~ linking the use of combined HRT with an increase of breast cancer risk, it did not conceal the fact that "some studies have reported breast caner had developed with the use of estrogen for long periods of time", and that "some studies have reponexl a somewhat increased risk" when also using progestin. This warning also alerted Plaintiff-wife of the potential risks associated with her prior use of Defendant Upjohn's product *Provera with Premarin* since the patient package information sheet warns in terms of estrogen and progestin combined HRT use generally and not in terms of Defendant Wyeth's specific drug, *Prempro.* This trial judge opines that by the exercise of reasonable diligence, Plaintiff-wife should have associated her long-term use of HRT to her breast cancer. Tiffs association was apparent when her treating physicians ordered her to discontinue the HRT regimen once the diagnosis of breast cancer was made. A reasonable person would have at least inquired at the time of the diagnosis why the HRT regimen

was being discontinued or what, if any, was the relationship between the HRT regimen and the breast cancer diagnosis. Plaintiff-wife, however, would have us believe that she did a thorough investigation of any potential genetic component to her sister's diagnosis of breast cancer years earlier, and yet did nothing when she was diagnosed.4z Because this civil action was filed on July 1, 2004, and not by May 21, 2004, when the diagnosis was made, this action is barred by the two-year statute

Ol lllilitattOm.

"- :'-':-"

This trial judge notes that this opinion is consistent with the *Findings and Order* issued on September 24, 2007, by the Honorable Allan L. Tereshko in the unrelated yet similar matter of *Coleman v. Wyeth Pharmaceuticals, Inc.,* 2007 Phila. Ct. Com. P1. LEXIS 262, which is presently under appellate review. In *Coleman,* plaintiff used combined HRT continuously from November 1991 until October 2000, when she was diagnosed with breast cancer. Id~ at "1-'2. She commenced an action on June 28, 2004, against the manufacturers of the combined HRT

4t 4/24/2007 P.M. Tr. at 84:11-17.

drugs she took during said time, including Defendants Wyeth and Upjohn. I~L at *11.

Defendant Wyeth moved for summary judgment arguing that plaintiff's lawsuit was time barred. IaL In response, plaintiff contended that she did not and could not have known the facts concerning the causation of her cancer prior to the release of t~e WHI report. I~ Judge Tereshko granted summary judgment finding that the plaintiff "failed to exercise the level of diligence that areasonable person would employ under the facts of her case and therefore, [has] failed to establish that she falls within the exception of the discovery rule." I~ at '14.

Specifically, Judge Tereshko reasoned that widely publicized clinical studies, articles available in the mainstream press, and the fact sheet the came with plaintiff's prescription all put her on notice that taking combined estrogen and progestin HRT increased her risk of breast cancer. at *28-*31.

IL Proximate Causation

The other equally important reason/ground for granting Defendant Upjohn's post-trial motion for judgment n.o.v., lies on this trial judge's opinion that Plaintiff-wife failed to meet her *prima facie* burden of establishing proximate causation. Specifically, Defendant Upjohn convincingly argued that Plaintiffs did not prove that any of Plaintiff-wife's physicians would have altered their prescribing habits and would not have prescribed *Premarin with Provera* and/or *Prempro* to her knowing what they now know about the causal link between the long-term use of HRT and the increased risk of breast cancer. On the contrary, Plaintiff-wife's physicians were adamant that they continue to prescribe the HRT regimen combination and have not changed their prescribing practices when it comes to HR.T.

Under Pennsylvania law, strict liability is imposed oft the manufacturer and/or seller of a product in a defective condition unreasonably dangerous to the user or consumer. *Incollingo v.*

Ewing, 282 A.2d206, 219 (Pa. 1971); *Dernmler v. SmithKline Beecham Corp.,* 671 A.2d 1151, 1153-1154 (Pa. Super. 1996), *affirmed without opinion,* 684 A.2d 557 (Pa. 1996). A product may be deemed defective if it lacks adequate warnings or instructions necessary for the safe use of the product. *Dernmler,* 671 A.2d at 1154, *citing Fletcher v. Raymond Corp.,* 623 A.2d 845,

848 (Pa. Super. 1993); *see also Gigua v. Giles & Ransome, Inc.,* 868 A.2d 459, 462 (Pa. Super. 2005), *allocatur denied,* 895 A.2d 550 (Pa. 2006).

However, Pennsylvania courts have repeatedly refused to impose strict liability on manufacturers of presCription drugs. *See Hahn v. Richter,* 673 A.2d 888, 889-890 (Pa. 1996), *adopting* RESTATEMENT (SECOND)OF TORTS § 402A, comment k;42 *Creazzo v. Medtronic, Inc.,* 903 A.2d 24, 30-31 (Pa. Super. 2006). A drug rnanufaeturer will be held liable for a plaintiff's injury only if it fails to exercise reasonable care to inform those, for whose use the article is supplied, of the facts which make the product dangerous. *E.g., White v. Weiner,* 562 A.2d 378, 384 (Pa. Super. 1989), *affirmed without opinion,* 583 A.2d 789 (Pa. 1991); *Brecher v. Cutler,* 578 A.2d 481,485 (Pa. Super. 1990); *Rosci v. Acromed,* 669 A.2d 959, 969 (Pa. Super. I995). This concept, otherwise known as the *learned intermediary doctrine,* holds that the duty to

> RESTATEMENT (SF_,COND) OF TOItTS § 402A, comment k provides: *~,,a'vo,,'abl) ur,.r.-fe pr_~l_~cts.* _'/'here are some vroducts 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 produet~ 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 physieiart It is also true in partienlar of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical expc.rience, there can be no assurance of safely, 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.

inform runs only from the drug manufacturer to the prescribing physician, not to the patient or to the general public. *See Incollingo,* 282 A.2d at 220; *Denunler,* 671 A.2d at 1154. This is because in deciding whether to prescribe a drug, it is a physician's responsibility to use his own medical judgment, taking into account the data supplied to him from the drug manufacturer, other medical literature, and any other source available, and weigh this information against the personal medical history of the patient. *Leibowitz v. Ortho Pharmaceutical Corp.,* 307 A.2d 449, 457 (Pa. Super. 1973), Hoffman, J., conctming. Stated differently:

> As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medieai judgment bottomed on a knowledge of both patient and palliative.

Demmler, 671 A.2d at 1154, *citing Windham v.* ***Wyeth Laboratories,*** 786 F. Supp. 607, 611 (S.D. Miss. 1992).

In learned intermediary cases, assuming that a plaintiff has established that a defendant drug .manufacturer had a duty to warn and that defendant breached its duty, plaintiff must further establish proximate causation, by showing that had the defendant drug manufacturer issued a proper warning to the learned intermediary, *(i.e.* plaintiff's physician), the physician would have altered his/her prescribing behavior and plaintiff's injury would have been avoided. *Demmler,*

671 A.2d at 1155. The *Demmler* court further explained that:

> In the event that a warning is inadequate, proximate cause is not presumed. 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.** Absent proof that a more thorough or more explicit warning would have prevemed [plaintiff's] use of [the drug], [plaintiff] .cannot establish that [defendant's] alleged failure to warn was the proximate cause of [plaintiff's] injuries.

671 A.2d at 1155,as emphasis added, citations and quotations omitted.

In Demmler, plaintiff's physician testified that he pms~ribed the drug to plaintiff based upon his years of clinical experience and his review of medical literature, rather than upon any information supplied to him by defendant mannfaeturer, laY. at 1155-1156. Pursuant to this testimony, the court held that summary judgment, for defendant was appropriate because the record was devoid of any evidence that a different warning to plaintiff's physician would have altered plaintiff's use of the drug in accordance with her physician's instructions. Id. at 1156.

In recent years, the appellate court has been presented with several learned intermediary issues similar and relevant to the present issue. Among these, the matter *ofLineberger v. Wyeth,* 72 Pa. D.&C.4th 35 (C.P. Philadelphia 2005) (hereinafter *"Lineberger 1"'), affirmed on other grounds,* 894 A.2d 141 (Pa. Super. 2006) (hereinafter *"Lineberger IF'),44* wherein plaintiff brought a failure to warn claim against the manufacturer of the drug *Phen-Fen,* which plaintiff claimed caused damage to her heart valve. *1,inebe~'ger I,* at 36. Defendant moved for summary

judgment arguing that plaintiff was unable to prove that a different warning regarding the association be .t~.__een the drug and heart valve damage would have prevented her physieiah from prescribing the diet drugs. Id~ at 36-37. Defendant drug manufacturer further argued that without evidence that "a warning that the use of the drug caused heart valve damage" would have resulted in her physician altering his prescribing practices, plaintiff was unable to establish that defendant's failure to warn was the proximate cause of her alleged injuries. Id~ at 37. In

> Although *Deramlet's* discussion of proximate causation in learned intermediary eases is authoritative, it should be noted that that ease dealt with the trial court's decision to grant summary judgment. Notwithstanding, the rationale is applicable. This trial judge purposefully analyzes the decision of the trial court rather than the Superior Court. *As* noted in the learned eono~rring and dissenting statement fried by the Honorable Kate Ford Elliot, the Superior Court's decision in this matter regarding the application of the learned intermediary doctrine is of questionable preeedental value, because the court, as a threshold matter, found that plaintiff/appellant waived her appellate issues by filing a vague and overbroad Pa. 1LA.P. 192503) statement. *Lineberger,* 894 A.2d at 151 (J. Ford Elliot, concurring and dissenting).

response, the *Lineberger* plaintiff asserted several arguments, *inter alia,* that she was entitled to a rebuttable presumption, or "heeding presumption", that either she or her physician (or both) would have followed an adequate vv~mxing had defendant provided one. Id~ at 44. A "heeding presumption" shiPts the burden of production to a defendant manufacturer of a defective product where warnings or instructions are required to make a product non-defective and such a warning had not been given, *ld. citing Coward v. Owens-Coming Fiberglas Corp.,* 729 A.2d 614, 621

(Pa. Super. 1999),

The Lineberger trial court, however, rejected plaintiff's "heeding presumption" argument concluding that such presumptions are only available in strict liability, not negligence actions, such as the case at bar. *Id.* at 45. It farther reasoned that plaintiff was not .entitled to a "heeding presumption" because Pennsylvania does not have a weakened version of the learned intermediary doctrine, such as other jurisdictions which permit plaintiffs to apply the presumption. *Id.,* at 45-46, *citing De Luryea v. Winthrop Laboratories, Division of Sterling Drug, Inc.,* 697 F.2d 222, 225 (Sth Cir. 1983). Rather, it opined that Pennsylvania courts have strictly interpreted the learned intermediary doclrine, enforcing a policy which has been designed to protect manufacturers of prescription drugs from liability. *Id.* at 46. The *£ineberger trial* court granted summary judgment finding that pursuant to Pennsylvania's well established learned intermediary doctrine, plaintiff was unable to show that defendant manufacturer's alleged failure to warn was the proximate cause of her injuries because plaintiff proffered no evidence that her physician would not have prescribed the diet drugs even if the *Phen-Fen* label was adequate. *Id.,* at 43-44. On appeal, Superior Court agreed with the trial court's reasoning, however, affirmed on other grounds. *Lineberger II,* 894 A.2d at 151.

Likewise, in *Berry v. Wyeth,* 2005 Phila. Ct. Com. PI. LEXIS 271, *appeal dismissed,* No. 1220 E.D.A. 2005 (Pa. Super., Sept. 6, 2006), the trial court granted summary judgment to defendant drug manufacturer in another *Phen-Fen* case finding that plaintiff had not satisfied

her

burden of establishing proximate causation and, further, was not entitled to a rebuttable presumption that a reasonable doctor would have heeded a warning had defendant drug manufacturer provided one. Id~ at "14. The *Berry* trial court also rejected plaintiff's argument that had either of her physicians informed her of the risk of heart valve disease associated with drugs, she would not have taken them. *ld.* at * 14-* 16.

In the instant ease, it is undisputed that sometime in 1992, Plaintiff-wife complained to Dr. Dollinger that she was experiencing post-menopausal symptoms. To combat and alleviate her post-menopausal symptoms, Dr. Dollinger prescribed Defendant Wyeth's drug *Premarin, a* synthetic estrogen, and Defendant Upjohn's drug *Provera,* a synthetic progestin. The expressed and only reason Dr. Dollinger prescribed *Provera was* because Plaintiff-wife had a uterus, and was therefore needed to oppose the estrogen and to prevent an increased risk of endometrial bleeding and, ultimately, endometrial cancer. Plaintiff-wife took the combination of *Premarin and Provera* HRT continuously until 1996 when Dr. Somers, who replaced Dr. Dollinger when he retired in 1994, changed Plaintiff-wife's medication to *Prempro,* Defendant Wyeth's drug which combined the two (2) components of estrogen and progestin HRT in one (1) pill. Thereafter, Plaintiff-wife took *Prempro* continuously, including while she treated with Dr. Sladowski, until she was diagnosed with breast cancer on May 21, 2002. It is also undisputed that the drugs *Premarin, Prempro, and Provera are* available only by prescription.

In light of the totality of evidence presented, this trial judge Opines that Plaintiffs failed to prove proximate causation. Clearly, under the controlling case law, Defendants' duty to warn of

any risks of the drugs was directly to Plaintiff-wife's treating physicians. In this trial judge's opinion, the labels of the drugs provided such warnings to the treating physicians, *albeit* not as extensive as Plaintiffs claim should have been done. The evidence of record also established that Plaintiff-wife's physicians had independent knowledge, prior to the release of the WHI report, that combined estrogen and progestin HRT posed anincrease risk for a woman to develop breast cancer and, yet, did not hesitate to prescribe the HRT regimen. Specifically, Dr. Dollinger, one of Plaintiff-wife's treating physicians, testified:

> Qo Would you agree, Dr. Dollinger, that in the early 1990s there was a controversy about whether or not hormone therapy could cause breast cancer?
>
> Ao There was really never a controversy. It was a discussion. The general consensus was, however, that it did not.
>
> But there were people out in the medical community who espoused the view that hormone therapy could cause breast cancer; is that right?
>
> Ao Oh, sure, there are people in the community now who say aspirin causes brain cancer. You could always find somebody on the other side.
>
> And there were reports in the published literature in which there was a possible association between hormone therapy and breast cancer, were there not?
>
> Ao I'm not aware of an association. As a matter of fact, I would say that there was never really proven to be an association. It was always discussed. The final line was always nobody has ever proven it. It requires a big study, which is what prompted this world study.4~

Dr. Sladowski, another treating physician, testified that she also had knowledge of pre-WH/medical research that suggested that usage of HRT increased a woman's risk of breast cancer and still prescribed HRT.4~ The evidence of record also established that Plaintiff-wife's treating physicians were aware, through sources other than the literature provided to them by

45 Kenneth Dollinger, M.D., Video Tr. 39:23 -40:19. ~

Catherine Sladowski, M.D., Video Tr. 116:20 - 126:23.

Defendants and prior to the release of the WHI report, of the possible risks of cancer when prescribing HRT. Therefore, as a matter of law and under the circumstances in this ease, no liability can be found against Defendant Upjohn because Plaintiffs did not prove that additional information and/or a more complete labeling of *Premarin, Provera,* and/or *Prempro* would have altered the prescribing practices of the physicians and Plaintiff-wife's use of the drug.47

Moreover, the jury heard no testimony from Plaintiff-wife's treating physicians that they would *not* have prescribed to her the estrogen and progestin combination HRT. The physicians' testimony was unequivocal *even with* their personal kno~vledge of the WHI report's findings that casually linked long-term HRT usage with an increased breast cancer risk. Specifically, the jury heard Dr. Dollinger testify that although he now advises his patients complaining of menopausal symptoms of the WHI report's conclusions and attempts to interpret the report's results for his patients, he does not hesitate to prescribe a-combination estrogen and progestin HRT regimen. The trial transcript reveals, in part:

> A. [Dr. Dollinger]: ... It wasn't until the study came out in, I believe it was 2002 that we became aware of the increased [breast cancer] risk. Some people believe that study, some people do not.

Q. [Defense Counsel]: Do you believe that study?

A. I don't think so. I have mixed feelings about it, but I can't say I don't believe it. If you ever read the study, it was really, I think it was a flawed study, but that's only my own opinion. If you look at the numbers, there were I believe 28 more cancers of the breast per 100,000 people. Percentagewise [sic], it made a big_difference. It was a bigpercentage,but in real numbers it was 28 women.~

This conclusion is not to be confused with Defendant Upjolm's argument for a new trial pr~mised on the theory that Defendant Upjohn could not be liable for a failur~ to warn of dangers associated with its drug *Provera* because Defendant Wyeth's drug *Pi, eraarin* carded a warning adequate enough encompass both drugs. *See* Defendant's Upjohn's Motion for Post-Trial Relief at 5-9 (Part If). Kenneth Dollinger, M.D., Video Tr. at 19:4-17,

24

Qo Dr. Dollinger, knowing everything that you know today about hormone therapy, would you still have prescribed Premarin to Merle Simon?

Well, it depends what her symptoms were. I don't remember what she complained about, but if she complained about menopausal symptoms of hot flushes and flashes, sure I would.. If she was not, if she were now 65 years old or 60--1 don't know how old Merle is, I assume she's in her sixties--there would be no reason for me to prescribe it now.

Qo Let me ask it a different way. Knowing what you know now and today, would you still have prescribed Premarin to Mere Simon in 19927

A° Not without Progestin if she has a uterus. In 1992 was before I knew about the WHI study. Absolutely I would.

Let me try it again.. Knowing what you know today about hormone therapy and the information that you'~'e gained from reviewing the WHI, if you knew that information in 1992 when Merle Simon came to you with symptoms of menopause, hot flashes and night sweats, Would

you have prescribed her Premarin and Progestin at that time?

I would then have had a long. discussion with her about how bad her symptoms were. I would tell her about the study. I would try to interpret the study for her. The decision would be hers, not mine now. She would .have to weigh the risks. And ff she still was confused by it, I said, "Well, why don't we try it for three or four months and see how much better you feel?" The decision would be hers. I would have no qualms about it, but I would still have to warn somebody about the study, which, by the way, is what I do now.49 (Emphasis added.).

Likewise, the j~y. heard Dr. Sladowski testify, as follow:

Qo [Defense Counsel]:. In your opinion, did the publicity surrounding the WHI result in a decrease in the number of prescriptions for hormone therapy?

[Dr. Sladowski]: Initially, yes. Then I think they came back a little bit, probably not as popular as they were before the WHI report, but I think when the analysis of the WHI report found that there were a lot of women in their late sixties and who had been on the hormones for longer periods of time, and then we reevaluated the situation and said perhaps let's try to use it in the immediate postmenopausal time for women who were really having the majority of their symptoms and maybe let's try to set a four- year window, try to just go on the hormones for four years and try to wean

Kenneth Dollinger, M.D., Video Tr. at 35:24 - 37:8.

them off and put them on the lowest possible does [sic], at least for relief of the symptoms. It was much more acceptable to both the physicians and the patients, at least to me.5°

Although Dr. Sladwoski's testimony is not as explicit as Dr. Dollinger's, it suggests that Dr. Sladowski's continues to prescribe a combined HRT regimen, when needed, as there is no evidence to the contrary. Plaintiffs did not introduce any evidence from Dr. Somers relevant to establishing proximate causation.

With Drs. Dollinger's and Sladowski's acknowledgment that after the WHI findings were

published, they counsel patients, such as Plaintiff-wife, on the report's findings and continue to prescribe the combined estrogen and progestin HRT regimen, Plaintiffs failed to meet the requisite proximal cause burden of proof. That is, in order to prove proximate causation, Plaintiffs were required to establish that Plaintiff-wife's treating physicians would not, under any circumstances, prescribe the dangerous drug HRT combination. That evidentiary threshold was not met and, therefore, in this trial judge's opinion, a judgment n.o.v., was properly entered in favor of Defendant Upjohn.

Notwithstanding this legal conclusion, Plaintiffs proffered additional yet unconvincing arguments that competent evidence exists to support the jury's finding that they satisfied their *prima facie* burden of establishing proximate causation against Defendant Upjohn. Plaintiffs incorrectly argued that it is enough that Plaintiff-wife testified that she never would have taken combined estrogen and progestin HRT if she knew that it would later cause her to develop breast cancer. That is not an argument applicable in a case against a drug manufacturer under the learned intermediary doctrine. Plaintiffs further argue that Defendant Upjohn, in bad faith, withheld information that HRT is tied to an increased breast cancer risk, that Defendant Upjohn failed to conduct the proper tests of its HRT drugs and, in essence, remained willfully ignorant of

~o Catherine Sladowski, M.D., Video Tr. at 77:2-21.

its product's true risk profile, and failed to heed the findings of its own commissioned analysis, *the Degge Report.* These arguments are also without merit as to their burden to prove proximate causation. As a final comment, this trial judge notes that. the opinion on this issue is consistent with

the Opinion issued on December 5, 2007, by the Honorable Rieardo C. Jackson, in the matter of *Nelson v. Wyeth,* No. 0401-1670 (Dee. 5, 2007), a similar HRT ease. Therein, Judge Jackson found that the plaintiff did not establish proximate causation because her physician relied on independent medical research, rather than information provided by the defendant drug manufacturers, when prescribing combined HRT to patients. Slip op. at 4-7. This decision is also presently under appellate review.

IlL Evidentiary rulings

Lastly, Plaintiff argues that this trial judge improperly granted numerous motions in *limine* and precluded evidence from trial that, if presented, would have assisted Plaintiffs in proving proximate causation as a matter of law. In light of these exclusions, Plaintiffs argue that their case would have been bolstered if, *inter alia,* this trial judge, would have permitted evidence of post-WHI report developments, such as the post-2002 label warnings for Defendant Wyeth and Defendant Upjohn's respective drugs *Prempro and Provera; as* well as evidence of market trends suggesting that usage of combined HRT generally declined after the WHI study was publicly disseminated; that Defendants hired independent researches to draft and publish reports minimizing the mounting pre-WHI findings that combined HRT usage was found to be linked to increas6d breast cancer risk; a letter from the FDA to the counsel for Defendant Upjolm accusing Defendant Upjolm of engaging in fraud and violating FDA regulations; studies showing that the sale of combined HRT was a lucrative business for Defendants; and finally, supplement

reports of various experts listing hundreds of newly reviewed and relied upon scholarly articles,

which had been submitted to Defendants' counsel one month prior to the commencement of trial.

Without addressing the merits or lack of merits of each one of these numerous motions in *limine,* (over 80 motions in *limine* were decided) suffice to state that this trial judge opines that these motions were properly decided. This trial further opines that what Defendants did or did not do after Plaintiff-wife ceased taking their HRT drugs is irrelevant to the critical issues of this case. While Plaintiffs argue, for example, that they could not present charts showing a decrease in the sales of these drugs after the WHI study results were released, this information was made public to the jury through other means. Scholarly articles published after May, 2002 were also deemed not relevant to the instant cause of action. In sum, none of the instances cited by Plaintiffs address the learned intermediary proximate causation issue, clearly their burden of proof. It is also immaterial, under the ease law, the assertion that Plaintiff-wife would not have taken combined estrogen and progestin HRT if she knew it would later cause breast cancer. Instead,. the controlling law overwhelmingly holds that under the learned intermediary doctrine, a plaintiff may only establish proximate causation by showing that her physicians would never have prescribed the HRT drugs if the physicians knew that the drugs were hazardous. Not one of Plaintiff-wife's treating physicians provided this required testimony. Accordingly, this trial judge opines that no error was committed in the manner these motions in *limine* were ruled.

II~. Defendant Upjohn's Request for New Trial

Defendant Up John filed a cross-appeal in the event the appellate court reversed this trial judge's opinion. Defendant Upjohn correctly notes that this trial judge deemed the motion for a new trial moot since judgment n.o.v., was granted In its cross appeal, Defendant Upjohn

requests that this trial judge enumerate reasons for denying or granting a new trial. **Pa. R.C.P.** 227. l(e) provides that ifa new trial and the entry of judgment n.o.v, are sought in the alternative and the trial court directs the enlry ofjudgment~ the trial court shall be required to specify the grounds for granting or denying the request for a new trial should the appellate court vacate or overrule the trial court's decision. This trial judge interprets this Rule to mean that an opinion will be needed on the issue of a new trial/fthe appellate court vacates or overturns the granting of the judgment n.o.v. In light of this interpretation, this trial judge for judicial brevity will not provide herewith the reasons sought, but will await the final appellate decision on this appeal.

CONCLUSION

Based on the foregoing discussion, this trial judge is of the opinion that no errors and/or abuse of discretion were committed in granting Defendant Upjohn's post-trial motion and entering judgment n.o.v., in.its favor. This trial judge respectfully requests that this appeal be dismissed and that the Order dated September 7, 2007, granting Defendant Upjohn's post- trial motion be affirmed.

BY THE COURT