THE FIRST JUDICIAL DISTRICT OF PENNSYLVANIA, PHILADELPHIA COUNTY
IN THE COURT OF COMMON PLEAS

ELIZABETH and JOE COLEMAN,	:	**TRIAL DIVISION - CIVIL**
	:	
Plaintiffs	:	**JUNE TERM, 2004**
	:	**NO. 3179**
VS.	:	
	:	
WYETH PHARMACEUTICALS INC., et al.	:	
	:	**CONTROL No. 020384**
Defendants	:	

FINDINGS AND ORDER

This matter comes before the Court by way of Defendant Wyeth's Motion for Summary Judgment[1] dated February 20, 2007 at Control #020384. The Court heard oral argument on this Motion on June 14, 2007 and the matter was taken under advisement. The Court now enters the following Findings and Order.

Plaintiff, Elizabeth Coleman ("Coleman") is a 67-year-old woman from Arkansas. She took one or more types of hormone replacement therapy ("HRT") medications continuously between November 1991 and October 2000, to treat vasomotor symptoms (hot flashes and irritability) related to menopause. (Short Form Complaint, ¶¶ 1, 3; Dep. of Elizabeth Coleman, 15:14-15). During these nine years, she took Premarin and Provera from November 1991 to November 1998; Prempro from November 1998 to April 2000; and Premarin again from April 2000 to October 2000. (Short Form

[1] This motion was joined by Defendant Pharmacia & Upjohn on February 21, 2007.

Complaint, ¶ 3.) Premarin and Prempro are products of Defendant Wyeth, Inc.[2] Provera is a product of Pharmacia & Upjohn, a successor company to the Upjohn Company.

Coleman was diagnosed with breast cancer on October 20, 2000, at which time she discontinued all HRT. As a treatment for the breast cancer, she chose to have surgery. Her surgeon wanted to do a lumpectomy. Plaintiff requested a mastectomy. (*Id* at 80:30-25, 81:1-4, 154:1-16, 156:4).

Coleman filed her action against the Wyeth[3] defendants, Pfizer, Inc.[4] and Pharmacia & Upjohn, Inc., on June 28, 2004. Coleman's husband also brings an action for loss of consortium. (Short Form Complaint, ¶ 7).

Coleman first sought out treatment for her menopausal symptoms from Dr. Haynes Jackson, Jr., in November of 1991. She had first been a patient of Dr. Haynes Jackson, Sr., for twenty (20) years prior to this time.[5] (Dep. of Elizabeth Coleman at 12-13). Although Coleman does not recall the conversation with Dr. Jackson, she does not dispute the accuracy of Dr. Jackson's record of that meeting which says, "Wants to discuss estrogen replacement. Complains of hot flashes." (*Id*. at 13-14).

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[2] Premarin is dispensed as tablets of 0.625 milligrams of conjugated estrogens plus inactive ingredients, such as colorants and binders. (1999 Physician's Desk Reference). The conjugated estrogens "are a mixture of sodium estrone sulfate and sodium equilin sulfate" and other chemical components. (Id.). Prempro is dispensed as "a single tablet containing 0.625 milligrams of the conjugated estrogens found in Premarin tablets and 2.5 or 5 milligrams of medroxyprogesterone acetate," (depending on the dosage) plus inactive ingredients. (Id.). "Medroxyprogesterone acetate is a derivative of progesterone." (Id.). Prempro's formulation provides for the release of estrogens "over several hours," as distinguished from formulations that are immediately "absorbed from the gastrointestinal tract." (Id.). Coleman's 1998 Prempro prescription was the "0.625/2.5" formulation. (See Defendant Wyeth's Motion for Summary Judgment Based on the Statute of Limitations, Exh. B).

[3] Plaintiff's complaint named as defendants, Wyeth Pharmaceuticals, Inc., Wyeth-Ayerst Pharmaceuticals, Inc., Wyeth Ayerst International, Inc., Wyeth Laboratories, Inc., Wyeth Pharmaceuticals and Wyeth, Inc. Hereinafter to be called "Wyeth".

[4] Defendant Pfizer was dismissed by agreement of the parties with approval of this Court on December 11, 2006.

[5] Any future reference to Dr. Jackson will be to Dr. Haynes Jackson, Jr., unless specifically noted.

Coleman did not recall any discussion with Dr. Jackson regarding the risk and benefits of hormone therapy for estrogen replacement. (*Id.* at 14-18). Dr. Jackson testified that at the time he was treating Coleman, he would typically mention to his HRT patients that the possible increased risk of breast cancer "was an unsettled issue," but that nonetheless it was a risk that he "included in [his] discussion because [t]he issue of whether or not hormone therapy was related to breast cancer was commonly discussed and was a common question from patients." (Dep. of Haynes Jackson, Jr., 32:20-25, 331-20). Dr. Jackson typically "told [patients] that there was conflicting information in different studies as to whether there was increased risk versus some protection, and that it was an ongoing actively-studied issue without a conclusion at that time." (*Id.*, at 66:4-8).

Coleman then began to visit with David Greathouse, M.D., as her gynecologist beginning in November 1998. (Dep. of David Greathouse, 40:11). She took Prempro prescribed by Dr. Greathouse from March 1999 through April 2000, when she had a hysterectomy. (*See Id.*, at 52:5-9). From that time forward, Coleman used estrogen-only Premarin. (*See Id.*, at 52:14-19). When discussing HRT with his patients, Dr. Greathouse "would have . . . discussed the possibility of DVT [deep-vein thrombosis], stroke, and perhaps even made mention of there being a possible concern of breast cancer." (*Id.*, at 40:22-25). "The risk of taking hormone, as I tell all of my patients, is that you possibly will develop a blood clot, you possibly will have a stroke, you possibly could develop breast cancer." (*Id.*, at 57:14-17).

Coleman's mail-order HRT prescription packages "always" included "a fact sheet" insert, which she would generally read, "[looking] for the side effects" of the drugs. (Dep. of Elizabeth Coleman, 18:15, 19, 22:10). The insert she received with her

Prempro prescription included a warning that "a possible increase in breast cancer risk" was "[an] additional risk [that] may be associated" with using that drug and directed the reader to read a paragraph entitled "*Cancer of the Breast*." (Patient Package Insert for Prempro, November 23, 1999) (emphasis in original). This paragraph warned that some studies had shown an increased breast cancer risk in women who used estrogen-only HRT; that some studies had shown no increased risk with estrogen-only HRT; and that "[t]he effects of added progestin on the risk of breast cancer are unknown." (*Id.*). Prempro is a combination estrogen and progestin HRT product. (*Id.*).

Studies indicating a possible elevated risk of breast cancer in long-term users of estrogen have been published "as early as 1961, when French animal studies linked exogenous [i.e., not naturally produced by the subject animal itself] hormones to mammary tumors." (*See* Plaintiff's Expert Report of Christina Clarke, Ph.D., MPH, at 8) (hereafter "Clarke").

One American example is the 1976 Hoover study, published in the *New England Journal of Medicine*. (*See* Plaintiff's Expert Report of Cheryl D. Blume, Ph.D., at 21, 39) (hereafter "Blume"). This study reported an increased "relative risk of breast cancer in patients taking conjugated estrogens" and that "the risk of breast cancer for women diagnosed after they started taking estrogen was 7 times greater than that of the general population." (*Id.* at 21-22). The 1989 Bergkvist study, also published in the *New England Journal of Medicine*, "directly link[ed] EPHT (combined estrogen-progestin HRT) use to breast cancer in Swedish women." (Clarke at 9; *see also* Blume at 41). The Bergkvist results "suggested that Swedish women taking EPHT for at least six years had [a]

strongly elevated risk (440%) of breast cancer than [sic] women who never took hormones." (Clarke at 9).

"A significant increase in the incidence of breast cancer in postmenopausal women taking estrogen was noted in a November 1990 JAMA [*Journal of the American Medical Association*] publication." (Blume at 24). This article reported "a prospective study on the risk of breast cancer in postmenopausal women taking estrogen replacement therapy" and "reported an elevated risk . . . among current users." (Blume at 41). A 1991 study published in JAMA "estimated that every year in the United States, [HRT] use could add about 4700 preventable cases of breast cancer." (Blume at 42). In January, 2000, JAMA published "Menopausal Estrogen and Estrogen-Progestin Replacement Therapy and Breast cancer Risk" by Dr. Schairer. (*See* Plaintiff's Expert Report of Dr. John Gueriguian, at 54) (hereafter "Gueriguian"). The article stated, "[T]he estrogen-progestin regimen increases breast cancer risk beyond that associated with estrogen alone." (*Id.*) The following month, the Journal of the National Cancer Institute published similar findings, by Dr. Ross, of "strong evidence that the addition of a progestin to HRT markedly enhances the risk of breast cancer relative to estrogen use alone. These findings have important implications for the risk-benefit equation for HRT in women using CHRT (combined HRT)." (*Id.*).

Articles about a possible causal link between HRT and breast cancer began to appear in the popular press by 1997. An article in *Good Housekeeping* discussed "risk-free alternatives to hormones" in February 1997, with a book excerpt that asserted, "We *do* know that [HRT] increases a woman's risk of developing breast cancer." (Wyeth's Supplemental Reply in Further Support of Summary Judgment, Exh. A-1) (emphasis in

original). National publications such as USA Today, Newsweek, and the New York Times released between 1997 and 2000, included similar articles warning of increased breast cancer risk associated with HRT. (*See Id.,* Exhs. A-1 - A-9). Locally to Coleman, the *Arkansas Democrat-Gazette* published at least two articles between 1998 and 2000 addressing HRT and an elevated risk of breast cancer. (*See Id.,* Exhs. A-10, A-11). The 1998 headline: "Drug could prove alternative to estrogen without the risk," assumed a proven causal relationship (*Id.,* Exh. A-10). The 2000 headline stated plainly, "Study: Hormone combo raises breast cancer risk." (*Id.,* Exh. A-11).

Similarly, reports regarding the long-term use of HRT and the occurrence of breast cancer surfaced in mainstream national news broadcasts and other news programs beginning in 1995, including evening network news shows and CNN. (*See Id.*, 5-7). As demonstrated in the examples above, much of the language used in the mainstream press reports, including reports prior to 2002, presumes a proven causal link between the use of HRT and an elevated risk of cancer.

The Women's Health Initiative (WHI) is "a randomized, controlled trial of the benefits and risks of hormone replacement therapy." *See* Victoria Hendrick, M.D., *Hormones as Treatment for Perimenopausal and Postmenopausal Depression*, Geriatric Times 35 (January 1, 2004). "The study's duration had originally been planned for 8.5 years, but in 2002 the study's estrogen (Premarin) plus medroxyprogesterone acetate (Provera) arm was abruptly discontinued after 5.2 years because preliminary findings showed that this hormone combination appeared to increase rather than decrease the risk of coronary heart disease. In addition, this hormone combination was associated with an elevated risk of invasive breast cancer compared to placebo." *Id.; See also* J. E. Rossouw,

et. al, *Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women*, 288 JAMA 321 (July 17, 2002).

Prior to the WHI report, Coleman's OB/GYN, Dr. Greathouse, was

> "[V]ery aware of the potential increased risk of breast cancer with hormones. And so because that information was still there, even though I met Ms. Coleman prior to Women's Health Initiative, certainly I would have discussed with her there's a possibility of this risk in hormone users. Is it Premarin alone, is it Prempro, it's hormone users."

(Dep. of David Greathouse, 111:19-25, 112:1).

Use of HRT is contraindicated after a diagnosis of breast or uterine cancer. *See* Physician's Desk Reference 1999. In October 2000, when Coleman's breast cancer was diagnosed, her treating physician, Dr. Greathouse, told her to quit taking all HRT. **(**Dep. of Elizabeth Coleman, 43-44). Dr. Smith, Coleman's surgeon, concurred. **(***Id.* at 43). Coleman has discontinued use of HRT since her breast cancer diagnosis; she currently treats with Dr. Webb and has been taking Tamoxifen[6] as a follow-up treatment to her breast cancer. (*Id*. at 78:23-79:10).

Defendants have filed a Motion for Summary Judgment arguing that the statute of limitations began to run on Coleman's claim on October 20, 2000, the date she was diagnosed with breast cancer. Thus, this action, filed on June 28, 2004, almost four years after her diagnosis, is untimely and barred by Pennsylvania's two year statute of limitations applicable to her claim. *See 42 Pa.C.S. § 5524(2).*

Coleman argues in response that she did not and could not know the facts concerning the cause of her cancer prior to July 9, 2002, when a public announcement was made that the WHI study "had been prematurely terminated based on preliminary

[6] Tamoxifen is used to prevent the growth of cancer cells by interfering with the activity of estrogen. *See* National Cancer Institute Fact Sheet, http://www.cancer.gov/cancertopics/factsheet/Therapy/tamoxifen.

findings which revealed a significant increase in the risk of breast cancer in combination hormone therapy users." *See* Plaintiff's Brief in Opposition to Summary Judgment, p.3. Coleman further argues that even if she had reason to suspect that HRT may have caused her breast cancer, a "diligent investigation of the cause of her breast cancer would not have led Mrs. Coleman to reasonably conclude that hormone therapy was the cause of her breast cancer." *Id.* at p. 4 (emphasis in original). Coleman argues that the application of the discovery rule operates to toll the statute of limitations and thus her action was timely filed.

"After the relevant pleadings are closed, but within such time as not to unreasonably delay trial, any party may move for summary judgment in whole or in part as a matter of law." *Pa.R.C.P. 1035.2.* "In considering the merits of a motion for summary judgment, a court views the record in the light most favorable to the non-moving party, and all doubts as to the existence of a genuine issue of material fact must be resolved against the moving party." *Fine v. Checcio*, 582 Pa. 253, 870 A.2d 850, 857 (2005).

The statute of limitations to institute an action to recover damages for personal injury is two years. *See 42 Pa.C.S. § 5524(2).* The statute of limitations begins to run on an injury when a person knows or reasonably should know that he has been injured and by what cause. *See Fine v. Checcio*, 582 Pa. 253, 870 A.2d 850, 858 (Pa. 2005). It is a "well established principle that where the facts are so clear that reasonable minds cannot differ, the commencement period may be determined as a matter of law." *Cochran v. GAF Corp.*, 542 Pa. 210, 666 A.2d 245, 248 (1995). "Mistake, misunderstanding, or lack of knowledge in themselves do not toll the running of the statute." *Fine*, 870 A.2d at

857. "Once a cause of action has accrued and the prescribed statutory period has run, an injured party is barred from bringing his cause of action." *Id.* at 857. Notwithstanding this principal, there are certain exceptions which toll the running of the statute of limitations. *Id.* at 858. The discovery rule is the exception at issue in the immediate case.

"The discovery rule is applicable in situations where the injury or its cause was either unknown or not reasonably ascertainable to the injured party for a certain period of time." *Id.* "The purpose of the discovery rule has been to exclude from the running of the statute of limitations that period of time during which a party who has not suffered an immediately ascertainable injury or is reasonably unaware that he has been injured, so that he has essentially the same rights as those who have suffered such an injury." *Id.* (citing, *Hayward v. Medical Center of Beaver County*, 608 A.2d 1040, 1043 (Pa. 1992)). "[O]ne claiming the benefit of the exception bears the burden of establishing that she falls within it." *Cochran*, 666 A.2d at 249.

"The salient point giving rise to the equitable application of the exception of the discovery rule is the inability, <u>despite the exercise of diligence</u> by the plaintiff, to know of the injury." *Pocono Int'l Raceway, Inc. v. Pocono Produce, Inc.*, 468 A.2d 468, 471 (Pa. 1983) (emphasis supplied). "Reasonable diligence is just that, a reasonable effort to discover the cause of an injury under the facts and circumstance present in the case." *Cochran*, 666 A.2d at 249. "Reasonable diligence is an objective, rather than a subjective standard." *Id.* However, "plaintiff is not under an absolute duty to discover the cause of his illness. . . [but] must exercise only the level of diligence that a reasonable [person] would employ under the facts and circumstances presented in a particular case." *Id.*

We find based on the record that Coleman failed to exercise the level of diligence that a reasonable person would employ under the facts of her case and therefore, has failed to establish that that she falls within the exception of the discovery rule.

Coleman was diagnosed with breast cancer on October 20, 2000. Coleman filed suit on June 28, 2004. Coleman claims that she could not have known that the hormone replacement therapy that she received was responsible for her breast cancer until the publication of the results of the Women's Health Initiative Study in July 2002.

> It is Mrs. Coleman's unwavering testimony that at no time prior to July 9, 2002 was she warned by any of her doctors, friends, family, or the media that hormone replacement therapy was associated with breast cancer. Why? The reason is simple. There was no definitive association between hormone replacement therapy and breast cancer until the abrupt termination of the WHI Study on July 9, 2002.

See Plaintiff's Brief in Opposition to Summary Judgment, p. 6 (emphasis supplied).

First, Coleman's assertion that she was never told that there may be a connection between HRT and breast cancer is not supported by the record. When Coleman was diagnosed with breast cancer in October 2000, she admits to having a conversation with her treating doctor in which the relationship between her breast cancer and her hormone therapy was discussed.

> Q. Have any of your doctors told you that they think your breast cancer was caused by taking hormone therapy?
> A. Not in so many words, no.
> Q. Have they told you in any way?
> A. Well, I was told it was estrogen positive.
> Q. Do you interpret that to mean -- by somebody telling you "estrogen positive" do you interpret that to mean that they think your breast cancer is caused by hormones?
> A. I don't know.

Q. Well, when I asked the first question, "Has your doctor told you that your breast cancer is caused by hormone therapy," and you said, "Not in so many words" right? Is that right?
A. Is that what I said?
Q. And then, my next question was, "Well, in what words are you thinking they told you that?" And you said, "They told me it was estrogen receptor positive"; right?
A. And it is -- it was.
Q. Absolutely, that's what the records say about it?
A. That's right.
Q. It is estrogen receptor positive. Did you think that meant that your breast cancer was caused by hormone therapy?
A. Yes, I guess. Yes.

Dep. of E. Coleman at 127-128.

Assuming arguendo, that the above conversation at the time Coleman was advised of her injury was not a *per se* notice to her of the nexus between her cancer and HRT, then given her level of understanding (as evidenced by the above testimony), notice of her injury was more than sufficient to trigger her duty to investigate a possible link between HRT and her breast cancer.

Coleman argues that the *sine qua non* for triggering the running of the statute of limitations in Pennsylvania is a requirement that Plaintiff know of a definitive association between her injury and the hormone therapy she received.[7]

This has never been the law in Pennsylvania.

In *Ayers v. Morgan*, 397 Pa. 282, 154 A.2d 788 (1959) our Supreme Court established that it was the discovery of the injury that began the running of the statute of limitations in tort claims. The Court emphasized that "[t]he statute. . . . says that the suit

[7] This Court will not now address the subsidiary issue of if, when and how the Plaintiff became aware of the WHI Study.

must be brought within two years from the time when the injury was done." *Id.* at 792 (emphasis supplied). "The injury is done when the act heralding a possible tort inflicts a damage which is physically objective and ascertainable." *Id.*

Here, there is no dispute that damage was ascertainable when Coleman was diagnosed with breast cancer. Therefore, Coleman's statute of limitations began to run on that date.

Once the injury has been determined, what duty is imposed upon Plaintiff by the statute of limitations? One duty is obvious; bring the action within two (2) years. If this is not accomplished, can the time period be extended? Yes, but only if within the exercise of due diligence, the Plaintiff could not have discovered that the conduct of another was the possible cause of the injury. *See DeMartino v. Albert Einstein Medical Ctr. N.D.*, 313 Pa. Super. 492, 460 A.2d 295 (1983).

In *Groover v. Riddle Memorial Hospital*, 357 Pa. Super. 420, 516 A.2d 53 (1986), our Superior Court rejected one aspect of Coleman's argument here; that she could not have known of a definitive association between her breast cancer and HRT because her doctors did not know that there was a definitive connection between the two.

As part of Plaintiff's Response to this Motion, she presented the following testimony of her treating doctor, Dr. Haynes Jackson, Jr.

> Q. And the note here states that: "Wants to discuss estrogen replacement. Complaining of hot flashes." Do you see that there?
> A. Yes.
> Q. Do you have an independent recollection of this appointment with Mrs. Coleman? Or is it, you're basing your recollection on what's in the chart?
> A. I'm basing my own -- of what's in the chart.
> Q. At that time period in 1991, when you first prescribed a woman hormone therapy, did you have any

discussion with her at the time of that as to the potential risks and/or benefits of hormone therapy?
A. Yes.
Q. Could you tell me what the content of that discussion that you typically had in that time period was?
A. Typically, I would tell a patient that we were treating symptoms with this hormone therapy. In her case, basal motor symptoms that, in as much as we knew at the time, there might be some risk with hormone therapy and there might be some benefits that had as yet been uncovered. The issue of whether or not hormone therapy was related to breast cancer was commonly discussed and was a common question from patients. And at that time, the information I had to share with a patient was simply that it was an unresolved issue in dispute. There were some studies to suggest possible breast protection and some studies to suggest increased risk, and it was an unsettled issue.
Q. So it was your practice in that time period, when discussing hormone replacement therapy with a woman about to start it, to discuss with her that there was an unresolved issue as to whether or not there could be an association with hormone therapy and increased risk of breast cancer?
A. Yes.
Q. And that was something that you included in your discussion?
A. Yes.

Dep. of Haynes Jackson, Jr., M.D., 11/18/05, pp.32-33.

Q. Now, can we agree that at least as far as your notes are concerned, that we've gone through here today -- and I don't want to go back through all of them unless we need to -- but can we agree that there is no mention in your progress notes of a specific consultation where you mentioned to Mrs. Coleman the issue of breast cancer?
A. I don't see it in writing.
Q. All right. And in that time frame back in 1991, I think we've established in your direct examination that it was your routine practice to speak to women concerning that issue of breast cancer. As I understand your testimony and appreciate your testimony, your position, at least in 1991, was it was a matter that was still in dispute and no definitive advice could be given regarding that; is that correct?
A. That's correct.

> Q. Sitting here today, do you remember having a specific conversation with Mrs. Coleman on that issue?
> A. I don't recall a specific conversation.
> Q. Through the seven years that you treated her up until 1998, do you recall your opinion changing in terms of whether or not there was a relationship that had been definitively established?
> A. A relationship?
> Q. Between the hormone therapy and the breast cancer. I'm sorry.
> A. No.
> Q. All right. So as of the time that you ceased treating her in 1998, was it your opinion that that issue, whether or not breast cancer was related to hormone therapy, was still a matter in dispute?
> A. That's correct.

Dep. of Haynes Jackson, Jr., M.D., 11/18/05, pp. 57-58.

It is evident from Dr. Jackson's testimony that those in the medical profession were aware that HRT increased the risk of breast cancer. Despite the lack of consensus regarding whether HRT definitively causes breast cancer, most doctors, including Dr. Jackson, were aware of the studies suggesting an increased risk of breast cancer and routinely discussed that information with their patients.

The *Groover* Court had before it a case in which the plaintiff claimed she consulted with numerous doctors who could not tell what was causing her pain and thus she was entitled to have the statute of limitations tolled until she could discover the cause of her pain:

> Appellant maintains that the discovery rule delayed the running of the statute. She argues that from the time she received the painful injection in the spring of 1979 until June of 1983, she continuously sought help concerning the pain in her right leg, and that she attempted to determine the type of injury she suffered and the cause of that injury. She contends that she saw numerous doctors who did not know what was wrong with her leg.

Groover, 516 A.2d at 57

The Court rejected plaintiff's argument and responded to plaintiff's claim by holding that:

> Appellant need not have known the precise medical cause of the injury in order to commence the running of the statute of limitations. She need only to have known that she was *injured.* "An injury is done when the act heralding a possible tort inflicts a damage which is physically objective and ascertainable." *Ayers v. Morgan*,
> 397 Pa. 282, 290, 154 A.2d 788, 792 (1959).

Id. at 57.

Here, as in *Groover,* Coleman "alleges that the physicians with whom she consulted told her that they did not know what the problem was." *Id.* at 57. If we read Coleman's "allegations in a common sense fashion, we believe that [she] knew or reasonably should have known . . . . the cause of her problem." *Id.* at 57. Any "statements by [Coleman's] physician[s] should not be read to mean that they did not know, or suspect [what] caused the injury." *Id.* at 57. "Rather, common sense suggests that the statements should be read to mean that the physicians were not medically certain as to the precise medical reason that . . . triggered the problem . . ." *Id.* at 57.

The *Groover* court rejected the same argument made by Plaintiff herein; to wit—that all of the doctors she saw did not know the cause of her injury. The *Groover* court opined:

> In her counter-affidavit to appellee's motion for summary judgment, appellant alleged that all of the doctors she saw did not know the cause of her injury until one doctor, in December of 1982, began to suspect that the cause may be related to the injections. This does not alter our

> holding. From the facts related, *supra*, at the very least, appellant reasonably should have known that her problems were caused by the injection. One need only know (or reasonably should know) that he is injured and that the injury was caused by the conduct of another. . . . . [I]it is only essential that the injured party know or reasonably should know that the conduct of another has caused the injury.

Id. at 57-58 (internal citations omitted) (emphasis in the original).

The *Groover* court then reviewed the operative duty of a plaintiff in these cases:

> Thus, once the patient is aware or should reasonably have become aware that medical treatment is causing him personal injury the statute begins and the prospective plaintiff is required to begin doing those things for which the statute of limitations specifically provides time: "an opportunity to select and consult with a lawyer, investigation, initiation of suit, discovery, joinder of additional parties, etc." *Keating v. Zemel,* 281 Pa. Superior Ct. 129, 134 n.4, 421 A.2d 1181, 1184 n.4 (1980). It is during this two year period that the medical malpractice plaintiff, like any other plaintiff pursuing any other legal claim, makes the decision whether or not to pursue any legal rights he may possess.

Id. at 58 (citing *DeMartino* 460 A.2d at 300).

In the instant case, Coleman maintains that at the time of her diagnosis and surgery she was not told anything by her doctors that would lead her to believe that HRT caused her breast cancer. *See* Plaintiff's Response at p. 3. However, there is no doubt that Coleman knew of her injury as she was diagnosed with breast cancer on October 20, 2000. As the *Groover* court makes clear, Plaintiff need not know the exact medical cause of her injury to start the running of the statute of limitations. Rather, it's the knowledge that Plaintiff has been injured that triggers the statute of limitations and imposes on her a duty to investigate her claim. *See also*, *Connors v. Upjohn Co*., 1989 Pa. Super. LEXIS 4096, *8 ("The exact cause of injury is not a controlling factor in tolling the Statute of

Limitations. Rather, the statute begins to run when a plaintiff claimant knows or reasonably should have known of the injury and that a third person caused it").

Nonetheless, it is clear from the record that at the time of her injury, both Coleman (and her doctors) had sufficient information about the increased risk of breast cancer associated with HRT to "begin doing those things for which the statute of limitations specifically provides time," such as investigating the basis for her claim. *Groover*, at 58. Coleman asserts that there was no way for her to have known nor should she have known, that HRT was responsible for her injury until the publication of the WHI. However, "[t]he polestar of the Pennsylvania discovery rule is not a plaintiff's actual acquisition of knowledge but whether the information, through the exercise of due diligence, was knowable to the plaintiff." *Bradley v. Ragheb,* 429 Pa. Super. 616, 633 A.2d 192, 196 (1993).

We find that despite Coleman's assertions, there was available sufficient information at the time she was diagnosed with breast cancer, such that she was under a duty to diligently investigate its cause.

Coleman contends that the dissemination of the WHI study was an event that changed the way medical professionals and citizens alike thought about HRT and breast cancer. *See* Plaintiff's Response to Summary Judgment at p. 3. However, this contention can be disproved by Plaintiff's own witness, Dr. David Greathouse, who previously testified at his deposition to the complete contrary:

> Q: Do you agree that after the Women's Health Initiative report was issued in July of 2002 that OB/GYNs like yourself certainly became more focused on the issue as to whether or not the hormone therapy causes breast cancer?
>
> A: I don't agree with that. And the reason I don't is the Women's Health Initiative study did not bring new evidence to light, in my opinion.

Dep. of David Greathouse, pp.110:23-111:5.

By many accounts, the results of WHI showed a much lower rate in the risk of breast cancer for women on HRT than had been reported in previous studies. In fact, many of the early studies showed a relative risk of 2.0 or higher for women who took HRT (as did the package insert supplied by Wyeth during the time Coleman took the drug), while data from the WHI reported a relative risk of only 1.24 compared to placebo. *See* Clarke at 4.

In *Meehan v. Archdiocese of Phila.*, 2005 Pa. Super. 91, 870 A.2d 912 (2005), plaintiffs, victims of sexual abuse by priests, claimed that "the coverage of the Catholic Church abuse scandal constituted new harm that should . . . . toll the statute of limitations." *Id.* at 919. The court found however, that plaintiffs "knew they were injured by their abusers at the time of the abuse" which had occurred between twenty-one and forty-seven years earlier and rejected plaintiffs' argument "that they did not know that the Church was a possible cause of their injury until 2002." *Id.* at 920, *see also, Baselice v. Franciscan Friars Assumption BVM Province*, 2005 Pa. Super. 246, 879 A.2d 270 (2005). In holding that "that the discovery rule is inapplicable" the court opined:

> "Neither the plaintiffs' lack of knowledge of the Archdiocese's conduct, nor the plaintiffs' reluctance, as members of the Catholic Church, to investigate the possible negligence of the Archdiocese of Philadelphia after having been abused by one of its priests or nuns, tolls the statute of limitations when the plaintiffs had the means of discovery but neglected to use them."

Id. at 921.

The argument made by the plaintiffs in *Meehan* is strikingly similar to the argument presented by the Plaintiff herein. As in *Meehan*, Plaintiff claims that the

international release of the WHI study in 2002 was the event that put her on notice of a possible connection between her breast cancer and her HRT ingestion and thus started the running of the statute of limitations in the instant case. However, as in *Meehan*, Plaintiff knew of her injury almost two years prior to the release of WHI and had she chosen to investigate the cause of her cancer, would have found ample information linking it to HRT.

Based on the entire record before this Court, we find that there was sufficient evidence available to the public on October 20, 2000, regarding the connection between HRT and breast cancer to put Coleman on notice of a possible cause of her injury. As thoroughly discussed in the facts above, numerous widely publicized clinical studies, as well as articles in the mainstream press, regarding the increased risk of breast cancer in women who took HRT were published years before the WHI. Coleman's contention that a diligent investigation would have been fruitless is unfounded and factually incorrect. Coleman's testimony clearly shows that she was aware of the possible connection between HRT and breast cancer prior to the WHI. Coleman admitted that she received HRT prescriptions monthly and it "always" came with a "fact sheet insert" which she read "looking for the side effects." (Dep. of Elizabeth Coleman, 18:15, 19, 22:10). Refuting her claim that the information she needed was unavailable to her, Coleman testified as follows:

> Q: Prior to 2000, did you make it a practice to read any information that was provided by the manufacturer of a medicine before you took it, or not?
>
> A: I always scanned it and looked for the side effects, but not- after you have been taking it a while, you don't read it every time, but it is there.

Dep. of Elizabeth Coleman, 22:5-11

Additionally, the testimony of Plaintiff's own experts refutes her claim that a diligent investigation would not have revealed a causal relationship between HRT and breast cancer. Plaintiff's expert, Christina Clarke Ph.D, MPH, an epidemiologist and research scientist, testified that a possible elevated risk of breast cancer was known "as early as 1961, when French animal studies linked exogenous hormones to mammary tumors." *See* Clarke at p. 8, ¶10.

Another of Plaintiff's experts, Cheryl D. Blume, Ph.D., retained most likely because of her many years supervising and evaluating the scientific and regulatory aspects of the pharmaceutical industry, testified that the 1976 Hoover Study reported that "the risk of breast cancer for women diagnosed after they started taking estrogen was 7 times greater than that of the general population." *See* Blume at 22, 39.

The above-mentioned are merely two of many studies preceding Coleman's injury, and were known by her experts prior to the release of WHI. As evidenced by the exhibits in Defendants' Supplemental Reply, an untold number of articles in the popular press alerted the general public to the association between HRT and breast cancer. *See* Wyeth's Supplemental Reply in Further Support of Summary Judgment, 5/25/07. Yet Plaintiff now disingenuously claims that there was no viable information available to learn of the correlation between HRT and breast cancer in October 2000, when she was diagnosed. Public availability of these publications prior to WHI, however, refutes Plaintiff's claim that a reasonable effort to discover the cause of her cancer would have been fruitless.

This Court finds it significant that Plaintiff failed to inquire about the cause of her breast cancer even after being instructed to stop taking HRT. Coleman testified that after

being diagnosed, her surgeon, Dr. Smith, instructed her to stop taking HRT. She then consulted with Dr. Greathouse who concurred with those instructions due to fear of "promoting or spreading the cancer" (Dep. of David Greathouse 145:5-9).

In *De Martino, supra,* a medical malpractice case, the court found that the plaintiff's injury (pain in his tooth after surgery) was not enough to trigger the plaintiff's knowledge of its cause. *See* 460 A.2d at 303. The court found, however, that once another doctor told him that whoever performed the surgery "must not have been watching what he was doing" plaintiff was "then cognitive of the operative cause and the relationship between the cause and the injury." *Id.* The court recognized that although the other doctor "could not be positive of what had occurred, [plaintiff] was no longer oblivious to the possibility that there may be more to his persistent problems than a natural progression of his disease." *Id.* The court held that "[plaintiff] had sufficient empirical information at his disposal to begin an investigation into suspicions which should reasonably have arisen out of [the doctor's] observations" and thus trigger the statute of limitations. *Id.* at 303-04. The court further found that "the alleged failure of other physicians to inform [plaintiff] of the cause of his dental problems [was] irrelevant to the start of the statute." *Id.* at 305.

Here, as in *DeMartino*, Plaintiff was told by both Dr. Smith and Dr. Greathouse to cease taking HRT after she was diagnosed with breast cancer. Dr. Greathouse was especially concerned about "promoting or spreading the cancer." (Dep. of David Greathouse 145:5-9). Yet, despite these instructions, Plaintiff still failed to inquire of her doctors whether HRT caused her cancer. This Court finds, however, that the instructions of Coleman's doctors to discontinue the HRT after her diagnosis put her on notice of a

link between the drug and her cancer. As in *DeMartino*, although Coleman's doctors "could not be positive of what had occurred," they provided her with enough information to realize "that there may be more to [her] . . . . problems than a natural progression of [her] disease." *Id.* at 303. Thus, Plaintiff's selective ignorance regarding the cause of her disease fails to toll the statute of limitations.

"Failure to make inquiry when information is available is failure to exercise reasonable diligence as a matter of law." *Bradley v. Ragheb,* 429 Pa. Super. 616, 633 A.2d 192, 196 (1993). In *Cochran v. GAF Corp., supra*, plaintiff's decedent quit smoking in response to being diagnosed with lung cancer. *See* 666 A.2d at 247. Although there was ample evidence to support a diagnosis of asbestos related lung cancer at the time of his diagnosis, plaintiff, working under the mistaken belief that his cancer was brought on by his smoking, failed to "seek additional legal or medical help to ascertain the precise cause of his cancer" until four years later. *Id.* at 250. Our Supreme Court found that "[t]he decedent's failure to ascertain the cause of his injury was the result of 'somnolence,' rather than 'blameless ignorance'" and thus held that "decedent's mistaken belief cannot toll the statute of limitations." *Id.* (quoting *Ayers, supra*).

In *Love v. Raymark Indus., Inc.,* 430 Pa. Super.155, 633 A.2d 1185 (1993), the plaintiff was exposed to asbestos throughout his employment as a laborer, welder, sandblaster and shotblaster. *Id.* at 1186. In 1982, plaintiff was told by the plant physician that he had a "dirty lung" and should surrender his position as a shotblaster. *Id.* Although plaintiff failed to inquire with the physician regarding the cause of his condition, he later conceded that he thought it to have been work related. *Id.* Later that year, plaintiff was diagnosed with lung cancer, which he suspected was work related, and

subsequently underwent surgery. *Id.* Following surgery, plaintiff consulted a lawyer who sent him to a specialist who concluded there was a causal connection between plaintiff's lung cancer and his asbestos exposure. *Id.* However, plaintiff failed to file suit until 1985. *Id.* The Superior Court affirmed the trial court's decision not to toll the statute. *Id* at 1187. The court found that because plaintiff "suspected that it was related to his occupational exposure to asbestos" that [u]nder these circumstances, even if the physicians did not inform [plaintiff] of the cause of his lung condition, it was unreasonable as a matter of law for [plaintiff] not to make inquiry." *Id.* The court held that the causal connection between asbestos and cancer was known and failure to inquire with his physicians about the cause of his cancer "was unreasonable as a matter of law". *Id.* at 1187. Further the court opined:

> "If, as appellants allege, Love did not have actual knowledge of the causal connection between his lung cancer and his exposure to asbestos, it is clear that, as a matter of law, he failed 'to use all reasonable diligence to be properly informed of the facts and circumstances upon which a potential right of recovery [was] based and to institute suit within the prescribed statutory period'."

*Id. (*quoting *Pocono* 468 A.2d at 471).

In the instant case, Plaintiff was informed by her surgeon, Dr. Smith, and her gynecologist, Dr. Greathouse, that she had cancer and was to cease taking HRT. Similar to the Plaintiff in *Love* who was instructed to stop shotblasting, Plaintiff herein was instructed to cease taking HRT. The information regarding the causal link between HRT and breast cancer, similar to the link between asbestos and lung cancer, was available if a diligent investigation had been undertaken by the Plaintiff. This Court holds that the rationale in *Love* applies here, and the fact that Plaintiff failed to use reasonable diligence to inform herself

of available information important to a possible cause of action cannot toll the statute in her favor.

In order to toll the two year statute of limitations, Plaintiff must show that she made a reasonably diligent effort to obtain information regarding her injury and why it was unobtainable at that time. This Court finds that not only did Plaintiff not undertake a diligent investigation of the causes of her injury, but that she undertook no investigation whatsoever.

Between 1991 and 2000, Coleman was alerted both by her doctors and monthly through prescription package inserts (provided by Wyeth and approved by the FDA) that HRT possibly increased the risk of breast cancer. On October 20, 2000, Coleman was instructed to cease taking HRT due to her diagnosis of breast cancer. Yet despite these warnings, Coleman failed to ask her treating doctors about the possible causes of her diagnosis. This Court concludes that an objectively reasonable person, informed by her doctors, prescription fact sheet inserts, and national and local media that the HRT medicine she was taking for nine years could cause breast cancer who is later diagnosed with breast cancer, is under a duty to investigate the correlation between HRT and breast cancer at the time she is told she has breast cancer.

The Plaintiff misinterprets *Burnside v. Abbott Laboratories*, 251 Pa. Super. 264, 505 A.2d 973 (Pa. Super. Ct. 1986). Plaintiff argues that *Burnside* supports her contention that the statute of limitations should be tolled in this case. However, *Burnside* addresses a different prong of the discovery rule than the case *sub judice*. The issue in the present case is whether Plaintiff had a duty to diligently investigate possible causes of her disease at the date of her diagnosis. In contrast, the plaintiff in *Burnside* immediately

began to ask questions upon being diagnosed with cervical stenosis. *Id.* at 988. Her questions persisted upon learning of a possible causal link between DES and her cervical stenosis which continued even after she was rebuffed. *Id.* at 989. The rebuffing by the doctors is relevant to the second prong of the discovery rule, which the plaintiff in *Burnside* reaches because she followed her duty to diligently investigate her injury. *Id.* at 989-90. This Court finds that the Plaintiff herein failed to diligently investigate any correlation between the HRT and breast cancer, and therefore the second prong as to her claim why discovery was impossible by her, is misplaced and dehors the factual record here.

The Plaintiff fails to present any viable support for her contention that knowledge of the possible correlation between HRT and breast cancer was not available before the WHI. Accordingly, Plaintiff fails to prove that through reasonable diligence beginning at the date of diagnosis, she would not have been able to find the information necessary to sustain her case and toll the statute of limitations. This court holds that as of October 20, 2000, a diligent investigation would have revealed ample evidence to support Plaintiff's claim and the discovery rule is not available to her.

Numerous studies conducted before WHI have been documented regarding the link between HRT and breast cancer. The FDA relied on studies conducted as early as 1990 to approve the warnings that accompanied HRT prescriptions. Plaintiff's own doctors relied on these same studies to inform patients who were considering HRT medications for menopausal symptoms.

Further, Plaintiff was provided with the information that a possible causal link existed between HRT and breast cancer upon being prescribed HRT. This Court finds

that Plaintiff was put on notice of the connection between HRT and breast cancer before the Women's Health Initiative was published, yet independently chose not to investigate its association to her cancer.

The law is clear; Plaintiff was responsible for investigating the correlation between HRT and breast cancer, especially after she was told that her breast cancer was estrogen receptor positive and warned it could possibly have been caused by HRT. As such, Plaintiff has failed to provide sufficient evidence that she did not know nor reasonably could have known that HRT could cause breast cancer. Therefore, the statute of limitations cannot be tolled in this case.

ORDER

AND NOW, to wit, this 24TH day of September 2007, it is hereby Ordered and Decreed that this Court finds that Plaintiff's statute of limitations began to run on October 20, 2000, when she was diagnosed with breast cancer and that the discovery rule does not apply. Therefore, the Plaintiff's claim is dismissed as untimely and thus Wyeth's Motion for Summary Judgment is GRANTED.

BY THE COURT:

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ALLAN L. TERESHKO, J.