2010 PA Super 158

ELIZABETH AND JOE COLEMAN, W/H,	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
Appellant	:	
	:	
v.	:	
	:	
WYETH PHARMACEUTICALS, INC., ET AL.,	:	
	:	
Appellee	:	No. 2678 EDA 2007

Appeal from the Order Entered September 24, 2007,
in the Court of Common Pleas of Philadelphia County,
Civil Division, at June Term, 2004 No. 3179.

PATRICIA MEDWID AND RICHARD MEDWID,	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
Appellant	:	
	:	
v.	:	
	:	
WYETH PHARMACEUTICALS, INC., ET AL.	:	
	:	
	:	
Appellee	:	No. 3026 EDA 2007

Appeal from the Order Entered October 3, 2007,
in the Court of Common Pleas of Philadelphia County,
Civil Division, at July Term, 2004 No. 00497.

MARY WEINBERGER,	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
Appellant	:	
	:	
v.	:	
	:	
WYETH PHARMACEUTICALS, INC., ET AL.,	:	
	:	
	:	
Appellee	:	No. 3089 EDA 2007

J. A19006/09

2010 PA Super 158

Appeal from the Order Entered October 12, 2007,
in the Court of Common Pleas of Philadelphia County,
Civil Division, at June Term, 2004 No. 004255.

JUDY A. REED AND GERALD W. REED, H/W,	:	IN THE SUPERIOR COURT OF PENNSYLVANIA
Appellant	:	
v.	:	
WYETH PHARMACEUTICALS, INC., ET AL.,	:	
Appellee	:	No. 3090 EDA 2007

Appeal from the Order Entered October 18, 2007,
in the Court of Common Pleas of Philadelphia County,
Civil Division, at June Term, 2004 No. 003605.

KATHLEEN TAW STEPHENSON AND MICHAEL R. TAW,	:	IN THE SUPERIOR COURT OF PENNSYLVANIA
Appellant	:	
v.	:	
WYETH PHARMACEUTICALS, INC., ET AL.,	:	
Appellee	:	No. 3091 EDA 2007

Appeal from the Order Entered October 18, 2007,
in the Court of Common Pleas of Philadelphia County,
Civil Division, at June Term, 2004 No. 003525.

DIANE MORALES,	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
Appellant	:	
	:	
v.	:	
	:	
WYETH PHARMACEUTICALS, INC., ET AL.,	:	
	:	
	:	
Appellee	:	No. 3092 EDA 2007

Appeal from the Order Entered October 18, 2007,
in the Court of Common Pleas of Philadelphia County,
Civil Division, at July Term, 2004 No. 000641.

VICKI LENZI AND RONALD J. LENZI,	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
Appellant	:	
	:	
v.	:	
	:	
WYETH PHARMACEUTICALS, INC., ET AL.,	:	
	:	
	:	
Appellee	:	No. 3093 EDA 2007

Appeal from the Order Entered October 18, 2007,
in the Court of Common Pleas of Philadelphia County,
Civil Division, at June Term, 2004 No. 003428.

ZANDA SCHIRN AND ROBERT W. SCHIRN, H/W,	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
Appellant	:	
	:	
v.	:	
	:	
WYETH PHARMACEUTICALS, INC., ET AL.,	:	
	:	
	:	
Appellee	:	No. 3094 EDA 2007

Appeal from the Order Entered October 18, 2007,
in the Court of Common Pleas of Philadelphia County,
Civil Division, at June Term, 2004 No. 004226.

PEGGY FLEMING-CRAIN,	:	IN THE SUPERIOR COURT OF PENNSYLVANIA
Appellant	:	
v.	:	
WYETH PHARMACEUTICALS, INC., ET AL.,	:	
Appellee	:	No. 3095 EDA 2007

Appeal from the Order Entered October 18, 2007,
in the Court of Common Pleas of Philadelphia County,
Civil Division, at June Term, 2004 No. 004343.

NANCY AND RICHARD HONAKER, H/W,	:	IN THE SUPERIOR COURT OF PENNSYLVANIA
Appellant	:	
v.	:	
WYETH PHARMACEUTICALS, INC., ET AL.,	:	
Appellee	:	No. 3096 EDA 2007

Appeal from the Order Entered October 12, 2007,
in the Court of Common Pleas of Philadelphia County,
Civil Division, at June Term, 2004 No. 003466.

VIRGINIA HANSEN,	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
Appellant	:	
	:	
v.	:	
	:	
WYETH PHARMACEUTICALS, INC., ET AL.,	:	
	:	
	:	
Appellee	:	No. 3097 EDA 2007

Appeal from the Order Entered October 18, 2007,
in the Court of Common Pleas of Philadelphia County,
Civil Division, at June Term, 2004 No. 003474.

HAZEL BLAYLOCK,	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
Appellant	:	
	:	
v.	:	
	:	
WYETH PHARMACEUTICALS, INC., ET AL.,	:	
	:	
	:	
Appellee	:	No. 3098 EDA 2007

Appeal from the Order Entered October 12, 2007,
in the Court of Common Pleas of Philadelphia County,
Civil Division, at June Term, 2004 No. 003721.

GRACIANA MANALO AND FELIPE MANALO,	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
Appellant	:	
	:	
v.	:	
	:	
WYETH PHARMACEUTICALS, INC., ET AL.,	:	
	:	
	:	
Appellee	:	No. 583 EDA 2008

2010 PA Super 158

Appeal from the Order Entered January 4, 2008,
in the Court of Common Pleas of Philadelphia County,
Civil Division, at June Term, 2004 No. 004503.

CAROL J. HESS,	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
Appellant	:	
	:	
v.	:	
	:	
WYETH PHARMACEUTICALS, INC., ET AL.,	:	
	:	
	:	
Appellee	:	No. 594 EDA 2008

Appeal from the Order Entered January 10, 2008,
in the Court of Common Pleas of Philadelphia County,
Civil Division, at June Term, 2004 No. 003973.

BEFORE: STEVENS, BOWES, and FITZGERALD,* JJ.

OPINION BY BOWES, J.: Filed: August 30, 2010

Elizabeth Coleman and her husband, Patricia Medwid and her husband, Mary Weinberger, Judy A. Reed and her husband, Kathleen Taw Stephenson and her husband, Diane Morales, Vicki Lenzi and her husband, Zanda Schirn and her husband, Peggy Fleming-Crain, Nancy Honaker and her husband, Virginia Hansen, Hazel Blaylock, Graciana Manalo and her husband, and Carol J. Hess (collectively referred to as Appellants[1] herein) appeal from the

* Former Justice specially assigned to the Superior Court.

[1] All husband litigants have asserted claims for loss of consortium. For ease of reference, "Appellants" will refer to wife-Appellants unless otherwise noted.

various orders granting summary judgment in favor of Wyeth Pharmaceuticals, Inc. and the other Wyeth parties, and in some cases Pharmacia & Upjohn (hereinafter collectively referred to as Appellees).[2] The appeals have been consolidated for purposes of our review. After careful consideration, we reverse the trial court's orders granting summary judgment.

Overview

Appellants are fourteen post-menopausal women who were diagnosed with breast cancer between 1998 and 2002. Prior to their diagnoses, Appellants' physicians prescribed hormone replacement therapy ("HRT" or "HT"), comprising estrogen and progestin in combination, to relieve symptoms associated with menopause such as hot flashes, irritability, and vaginal atrophy. Upjohn manufactured and distributed Provera, a synthetic progestin, until 1995 when it merged with Pharmacia to form the Pharmacia

[2] Ms. Coleman filed her action against Wyeth Pharmaceuticals, Inc., Wyeth-Ayerst Pharmaceuticals, Inc., Wyeth Ayerst International, Inc., Wyeth Laboratories, Inc., Wyeth Pharmaceuticals, Wyeth, Inc., Pharmacia & Upjohn, Inc. a/k/a Pharmacia & Upjohn Company, and Pfizer, Inc. Pfizer was dismissed by stipulation in December 2006 because it did not manufacture or sell Provera until it acquired Pharmacia & Upjohn, Inc. and Pharmacia & Upjohn Company in 2003. Wyeth-Ayerst Pharmaceuticals, Inc. and Wyeth Laboratories, Inc. are non-existent entities. Wyeth Pharmaceuticals, Inc. is the successor to these entities. For the sake of brevity, the Wyeth and Upjohn entities are referred to herein as simply "Wyeth" and "Upjohn."

& Upjohn entities. Premarin, a conjugated estrogen drug, and Prempro, a combination of Premarin and a progestin that is the chemical equivalent of Provera, were manufactured and distributed by Wyeth. The combination of estrogen and progestin was used by all Appellants because they had intact uteri and estrogen alone was found to cause endometrial cancer. These appeals arise from Appellants' claims that the pharmaceutical companies failed to adequately warn their physicians that HRT therapy caused or increased the risk of breast cancer.

Appellants Elizabeth and Joe Coleman commenced their lawsuit against Appellees on June 28, 2004, alleging negligent failure to warn, fraud, breach of express warranty, loss of consortium, and a violation of corporate responsibilities.[3] On September 24, 2007, after completion of some discovery, Appellees filed motions for summary judgment asserting that the statute of limitations on the claims began to run on October 20, 2000, when Ms. Coleman was diagnosed with breast cancer. Appellees argued that Ms. Coleman's lawsuit was barred by Pennsylvania's two-year statute of limitations set forth in 42 Pa.C.S. § 5524(2). That statute provides:

> The following actions and proceedings must be commenced within two years:

[3] Virtually identical allegations were made by the remaining Appellants herein.

(1) An action for assault, battery, false imprisonment, false arrest, malicious prosecution or malicious abuse of process.

(2) An action to recover damages for injuries to the person or for the death of an individual caused by the wrongful act or neglect or unlawful violence or negligence of another.

(3) An action for taking, detaining or injuring personal property, including actions for specific recovery thereof.

(4) An action for waste or trespass of real property.

(5) An action upon a statute for a civil penalty or forfeiture.

(6) An action against any officer of any government unit for the nonpayment of money or the nondelivery of property collected upon on execution or otherwise in his possession.

(7) Any other action or proceeding to recover damages for injury to person or property which is founded on negligent, intentional, or otherwise tortious conduct or any other action or proceeding sounding in trespass, including deceit or fraud, except an action or proceeding subject to another limitation specified in this subchapter.

(8) An action to recover damages for injury to a person or for the death of a person caused by exposure to asbestos shall be commenced within two years from the date on which the person is informed by a licensed physician that the person has been injured by such exposure or upon the date on which the person knew or in the exercise of reasonable diligence should have known that the person had an injury which was caused by such exposure, whichever date occurs first.

42 Pa.C.S. § 5524.

Ms. Coleman countered that the facts concerning the cause of her cancer were not known or knowable prior to the publication of the Women's Health Initiative ("WHI") study on July 9, 2002, and that the discovery rule operated to toll the limitations period until that time. The National Institutes of Health ("NIH") commissioned the WHI study to examine whether HRT decreased the risk of cardiovascular disease in post-menopausal women. The study was halted prematurely because an unusually high number of women who were taking HRT medications for purposes of the study developed breast cancer. The WHI study was the first large randomized study establishing a link between HRT medications and breast cancer. Consequently, its report was widely publicized. The trial court rejected Ms. Coleman's position and granted summary judgment for Appellees, holding that the discovery rule was inapplicable and that the two-year statute of limitations barred her claim. ***Coleman*** Opinion, 9/24/07, at 25.

The ***Coleman*** opinion and reasoning was subsequently adopted by the trial court in each of the remaining thirteen cases consolidated herein. Moreover, commencing with Appellant Medwid, the trial court held that the statute of limitations barred the action on an additional basis: that a response to Fact Sheet Question XI constituted a judicial admission, conclusively establishing that Ms. Medwid knew by June 1998 that there was

a correlation between her breast cancer and her use of HRT drugs.[4] The same finding was subsequently made in the ***Weinberger***, ***Reed***, ***Stephenson***, ***Morales***, ***Lenzi***, ***Schirn***, ***Fleming-Crain***, ***Honaker***, ***Hansen***, ***Blaylock***, and ***Manalo*** cases. In ***Hess***, there was no Fact Sheet response that could be construed as a judicial admission because Ms. Hess indicated that she did not recall what she was told.

While substantial discovery was completed in ***Coleman*** prior to the entry of summary judgment, virtually no discovery had been undertaken in the remaining cases, other than the completion of Fact Sheets. As the ***Coleman*** opinion served as the template for the remaining cases, we focus initially on the facts therein and then turn our attention to issues common to all. To the extent that the remaining cases present unique facts or legal issues, we address them individually.

Questions Presented on Appeal

The following issues have been raised for our review:[5]

> 1. Did the trial court err in holding that whether to apply the discovery rule to postpone the accrual of the statute of limitations applicable to plaintiffs' claims in these 14 cases did not present a question of fact for the jury to decide —

[4] Fact Sheets are form discovery documents utilized in mass tort litigation. Appellants herein were required to complete Fact Sheets upon filing their actions in the Court of Common Pleas of Philadelphia County.

[5] The issues have been renumbered for the convenience of the Court.

> notwithstanding Pennsylvania's strong preference for jury resolution of the discovery rules application; the absence of any developed factual record in 13 of these 14 cases; and the existence of genuine issues of material fact governing the discovery rule's application in all 14 cases?
>
> 2. Did the trial court err in holding on summary judgment that the statute of limitations applicable to plaintiffs' claims began to run — and in certain of these cases had in fact expired — before generally accepted scientific proof became available which was necessary to establish that ingesting defendants' combination hormone therapy drugs caused breast cancer?[6]

Appellants' Consolidated Brief at 4.

In their first issue, Appellants contend that the trial court erred and abused its discretion in granting summary judgment on the basis of the statute of limitations because there were genuine issues of fact as to when they should have realized the causal connection between HRT and their breast cancer. In asserting such error, they contend that the trial court failed to view the record in the light most favorable to the non-moving party, Appellants herein, and to draw all reasonable inferences in their favor. Appellants argue that their actions were not time-barred for two reasons: 1) the discovery rule tolled the limitations period until July 9, 2002, the date that they had reason to believe there was a causal connection between HRT medications and breast cancer, and 2) their causes of action did not accrue

[6] Pa.R.A.P. 2119(a) provides that argument in the brief is to "be divided into as many parts as there are questions to be argued." While Appellants' brief fails to strictly comply with this requirement and we have not been impeded in our review, counsel are strongly cautioned to adhere to the Rules of Appellate procedure, or risk waiver of their clients' claims.

until July 9, 2002, because, until then, they could not maintain an action to a successful conclusion.

Our standard of review on an appeal from the grant of a motion for summary judgment is well-settled:

> A reviewing court may disturb the order of the trial court only where it is established that the court committed an error of law or abused its discretion. As with all questions of law, our review is plenary.
>
> In evaluating the trial court's decision to enter summary judgment, we focus on the legal standard articulated in the summary judgment rule. Pa.R.C.P. 1035.2. The rule states that where there is no genuine issue of material fact and the moving party is entitled to relief as a matter of law, summary judgment may be entered. Where the non-moving party bears the burden of proof on an issue, he may not merely rely on his pleadings or answers in order to survive summary judgment. Failure of a non-moving party to adduce sufficient evidence on an issue essential to his case and on which he bears the burden of proof establishes the entitlement of the moving party to judgment as a matter of law. Lastly, we will review 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.

ADP, Inc. v. Morrow Motors Inc., 969 A.2d 1244, 1246 (Pa.Super. 2009) (quoting ***Shepard v. Temple University***, 948 A.2d 852, 856 (Pa.Super. 2008)).

Our Supreme Court recently cautioned that "the function of the summary judgment proceedings is to avoid a useless trial but is not, and cannot, be used to provide for trial by affidavits or trial by depositions." ***Stimmler v. Chestnut Hill Hospital***, 981 A.2d 145 (Pa. 2009). The Court

emphasized that in considering such a motion, a lower court must thoroughly examine the whole record to determine whether there is a genuine issue as to any material fact, with all doubts as to the existence of a genuine issue resolved against the moving party. ***Id***. at 154.

The trial court granted summary judgment on Appellants' negligent failure-to-warn claims based upon the expiration of the two-year statute of limitations for personal injury actions and the inapplicability of the discovery rule. ***Coleman*** Order, 9/24/07. The Judiciary Code, 42 Pa.C.S. § 5502(a), sets forth the general rule for the statute of limitations:

> The time within which a matter must be commenced under this chapter shall be computed, except as otherwise provided by subsection (b) or any other provision of this chapter, from the time the cause of action accrued, the criminal offense was committed or the right of appeal arose.

Actions or proceedings to recover damages for injury to person founded on negligent conduct must be commenced within two years, as measured from the time the cause of action accrued. ***See*** 42 Pa.C.S. § 5524(7), ***supra***, n.4. It is undisputed that none of Appellants instituted suit within two years of the diagnosis of her breast cancer; however, all filed suit within two years of the publication of the WHI study on July 9, 2002.

The Discovery Rule

Appellants allege that the trial court erred in granting summary judgment on the inapplicability of the discovery rule, holding as a matter of law that no reasonable jury could find that they initiated suit within two years from when they knew or should have known that Appellees' drugs caused their breast cancer. Appellants' brief at 28. Where, as here, there is conflicting evidence of when Appellants knew or reasonably should have known that their injuries resulted from the negligent conduct of Appellees, Appellants contend the applicability of the discovery rule is a jury question. Moreover, Appellants argue that there is sufficient evidence of record from which a jury could reasonably conclude that they neither knew nor should have known, despite reasonable diligence, that Appellees' combination hormone therapy caused their breast cancer until the WHI study was published on July 9, 2002. Thus, they urge us to hold that the discovery rule tolls the statute of limitations until that date. We agree and find our decision in ***Simon v. Wyeth Pharmaceuticals, Inc.***, 989 A.2d 356 (Pa.Super. 2009) to be controlling on this issue.[7]

In Pennsylvania, there are two well-recognized legal constructs that toll the running of the statute of limitations: the discovery rule and the doctrine of fraudulent concealment. While Appellants argued below that

[7] We recognize that the ***Simon*** decision was handed down after the trial court's decision in this matter.

both were applicable herein, on appeal they have chosen to rely solely on the discovery rule as the basis for reversal.

The discovery rule is a "judicially created device which tolls the running of the applicable statute of limitations until the point where the complaining party knows or reasonably should know that he has been injured and that his injury has been caused by another party's conduct." ***Crouse v. Cyclops Industries***, 745 A.2d 606, 611 (Pa. 2000). In ***Fine v. Checcio***, 870 A.2d 850 (Pa. 2005), our Supreme Court affirmed the applicability of the discovery rule in cases involving latent injuries or instances where the causal connection between an injury and another's conduct was not apparent. ***Accord Wilson v. El-Daief***, 964 A.2d 354, 361-62 (Pa. 2009). Our high court has looked favorably on "tying commencement of the limitations period to actual or constructive knowledge of at least some form of significant harm and of a factual cause linked to another's conduct, without the necessity of notice of the full extent of the injury, the fact of actual negligence, or precise cause." ***Wilson, supra*** at 364.

Recognizing that a plaintiff's awareness of an injury and its cause is fact-intensive, our courts have held that ordinarily this is an issue "best determined by the collective judgment, wisdom and experience of jurors." ***Crouse***, ***supra*** at 611 (quoting ***White v. Owens-Corning Fiberglas***

Corp., 683 A.2d 885 (Pa.Super. 1996). ***Fine***, ***supra***. It is the factfinder who must focus on whether the plaintiff was reasonably diligent in discovering his injury and that it was caused by a third party. Even though this is an objective standard, it is to be applied with reference to individual characteristics. ***Wilson***, ***supra***; ***Crouse***, ***supra***. Our courts maintain that the standard "is sufficiently flexible . . . to take into account the differences between persons and their capacity to meet certain situations and the circumstances confronting them at the time." ***Burnside v. Abbott Laboratories***, 505 A.2d 973, 988 (Pa.Super. 1985). Where there are factual and credibility determinations to be made regarding the reasonable diligence of the plaintiff, that issue should be submitted to the finder of fact. ***Crouse***, ***supra***; ***Fine***, ***supra***.

The common thread in our jurisprudence, as articulated in ***Crouse***, ***Fine***, and ***Wilson*** is the recognition that at some point, a plaintiff should become sufficiently aware of his injury and that it was caused by another to trigger or "awaken inquiry." ***Hayward v. Medical Center of Beaver County***, 608 A.2d 1040, 1043 (Pa. 1992). Knowledge of an injury alone is not sufficient to trigger such inquiry. One must have some reason to suspect that the injury was caused by a third party to impose a duty to investigate further. Where the injury is one that may result from non-tortious conduct, such as a disease, that point may be difficult to discern

without resolving factual issues. Subjective differences among persons and the situations in which they find themselves are relevant in making that determination.

In ***Fine***, ***supra***, the plaintiff suffered facial numbness following wisdom tooth extraction. The record revealed that the condition could have been a temporary physical consequence of the surgery or a manifestation of Fine's injury, a permanent condition that resulted from underlying nerve damage. We refused to apply the discovery rule, holding that Fine knew when the surgery ended that he was hurt, and that he was experiencing unexpected numbness. The Supreme Court reversed, recognizing that

> until conflicts in the record were resolved and inferences from relevant facts were drawn, the issue of whether Fine knew, or should have known through the diligence that a reasonable person would have exercised under the circumstances, that the numbness he was experiencing . . . was a manifestation of injury, as, opposed to, or in addition to, the typical condition that dental surgery produces, remained disputed.

Id. at 862. In refusing to apply the discovery rule in that situation, the Court held that we had erroneously undertaken "the fact resolution and inference-drawing functions" when our proper role was to decide whether there was an issue to be tried. It is only when "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" that a court may determine

that the discovery rule does not apply as a matter of law. ***Id.*** at 858 (quoting ***Hayward***, ***supra*** at 1043.)

More recently, in ***Simon v. Wyeth Pharmaceuticals, Inc.***, ***supra***, at 365-366, we examined the discovery rule, and specifically the reasonable diligence component, in the context of an HRT case:

> If the injured party could not ascertain when he was injured and by what cause within the limitations period, "despite the exercise of reasonable diligence," then the discovery rule is appropriate. ***Pocono International Raceway, Inc. v. Pocono Produce, Inc.***, 468 A.2d 468, 471 (Pa. 1983). The test is objective but takes into account individual capacities and society's expectations of "attention, knowledge intelligence and judgment" for citizens to protect their own interests. ***Fine***, ***supra*** at 858. The party who invokes the discovery rule has the burden of proving its applicability by establishing he acted with reasonable diligence in determining the fact and cause of his injury but was unable to ascertain it. ***Wiek v. Estate of Brown***, 794 A.2d 907, 909 (Pa.Super. 2005) (citing ***Fine***, ***supra*** at 858).
>
> This determination is a factual one as to whether the party, despite the exercise of reasonable diligence, was unaware of his injury and unable to determine its cause. ***Id***. Where the rule's application involves a factual determination regarding whether the plaintiff exercised due diligence in discovering his injury, the jury must decide whether the rule applies. ***Crouse v. Cyclops Industries***, 745 A.2d 606 (Pa. 2000).

We reversed JNOV for Upjohn entered on statute of limitations grounds in ***Simon*** because we found sufficient competent evidence of record to support the jury's finding that Ms. Simon's cause of action accrued when the WHI study was published on July 9, 2002. Until that time, Ms. Simon

had no reason to suspect a link between her use of HRT and breast cancer. ***Simon***, ***supra*** at ¶ 26.

The trial court, in granting summary judgment herein, held that Ms. Coleman "failed to provide sufficient evidence that she did not know nor reasonably could have known that HRT could cause breast cancer before the WHI study." ***Coleman*** Opinion, 9/24/07, at 25-26. It also found that she "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 she falls within the exception of the discovery rule." ***Id***. at 10. In the view of the trial court, there was no factual issue for the jury since Ms. Coleman "failed to make even a single attempt" to investigate her injury. ***Id***. In essence, the trial court concluded that reasonable minds could not differ in finding that Ms. Coleman knew or should have known, with the exercise of reasonable diligence, of her injury and its cause, and the discovery rule did not therefore apply.

An understanding of the state of medical warnings regarding HRT therapy during the relevant time period is fundamental to our analysis of the trial court's ruling because the application of the discovery rule involves issues of Appellants' constructive and actual knowledge of a causal relationship between HRT therapy and breast cancer. We begin our inquiry with the physician-labeling information published annually in the Physicians'

Desk Reference ("PDR") and patient package inserts for the medications at issue.

The FDA-approved physician labeling information that was provided in 1992 with Premarin, Wyeth's estrogen, identified a potential risk of endometrial cancer with estrogen-only therapy. Regarding breast cancer risk, the label stated:

> Some studies have suggested a possible increased incidence of breast cancer in those women on estrogen therapy taking higher doses for prolonged periods of time. The majority of studies, however, have not shown an association with the usual doses used for estrogen replacement therapy.

Physicians' Desk Reference, 1992; Weinberger Brief in Opposition to Wyeth's Motion for Summary Judgment, Exhibit 10. The patient package insert for Premarin at the same time dismissed any association between estrogen and breast cancer, except perhaps with long-term use at higher dosages, stating:

> Cancer of the breast. The majority of studies have shown no association with the usual dose used for estrogen replacement therapy and breast cancer. Some studies have suggested a possible increased incidence of breast cancer in those women taking estrogens for prolonged periods of time and especially if higher doses are used.

Id.

The 1992 PDR listing for Provera, Upjohn's progestin-only drug, contained the following warning:

> Beagle dogs treated with medroxyprogesterone acetate [the active ingredient in Provera] developed mammary nodules some of which were malignant. Although nodules occasionally appeared in control animals, they were intermittent in nature, whereas the nodules in the drug-treated animals were larger, more numerous, persistent, and there were some breast malignancies with metastases. Their significance with respect to humans has not been established.

As to Prempro, the combined estrogen-progestin medication, the 1998 PDR stated, "unopposed estrogen therapy has been associated with an increased risk of endometrial adenocarcinoma," but the "results of clinical studies indicate that the addition of a progestin to an estrogen replacement cycle . . . reduces the incidence of endometrial hyperplasia and the attendant risk of adenocarcinoma in women with intact uteri." Coleman Brief in Opposition to Wyeth's Motion for Summary Judgment, Exhibit F. Under "Contraindications," the 1998 PDR listing for Prempro advised that:

> Estrogens/progestin combined should not be used in women under any of the following conditions or circumstances:
>
> > 1. Known or suspected pregnancy, including for missed abortion or as a diagnostic test for pregnancy (see Boxed Warning). Estrogen or progestin may cause fetal harm when administered to a pregnant woman.
> >
> > 2. Known or suspected cancer of the breast.
> >
> > 3. Known or suspected estrogen-dependent neoplasia.
> >
> > 4. Undiagnosed abnormal genital bleeding;

5. Active or past history of thrombophlebitis, thrombolic disorders, or stroke.

6. Liver dysfunction or disease.

Id. The information described as "WARNINGS" stated as follows:

ALL WARNINGS BELOW PERTAIN TO THE USE OF THIS COMBINATION PRODUCT.

Based on experience with estrogens and /or progestins:

1. *Induction of malignant neoplasms*

Breast cancer. Some studies have reported a moderately increased risk of breast cancer (relative risk of 1.3 to 2.0) in those women on estrogen replacement therapy taking higher doses, or in those taking lower doses for prolonged periods of time, especially in excess of 10 years. The majority of studies, however, have not shown an association in women who have ever used estrogen replacement therapy. The effect of added progestins on the risk of breast cancer is unknown, although a moderately increased risk in those taking combination estrogen/progestin therapy has been reported. Other studies have not shown this relationship. In a one year clinical trial of PREMPRO, PREMPHASE and Premarin alone, 5 new cases of breast cancer were detected among 1377 women who received the combination treatments, while no new cases were detected among 347 women who received Premarin alone. The overall incidence of breast cancer in this clinical trial does not exceed that expected in the general population.

In the three year clinical Postmenopausal Estrogen Progestin Intervention (PEPI) trial of 875 women to assess differences among placebo, unopposed Premarin, and three different combination hormone therapy regimens, one (1) new case of breast cancer was detected in the placebo group (n=174), one in the Premarin group alone (n=175), none in the continuous Premarin plus continuous medroxyprogesterone acetate group (n=174), and two (2) in the continuous Premarin plus cyclic medroxyprogesterone acetate group (n=174).

> Women on hormone replacement therapy should have regular breast examinations and should be instructed in breast self-examination, and women over the age of 50 should have regular mammograms.

Physicians' Desk Reference, 1998; Coleman Brief in Opposition to Wyeth's Motion for Summary Judgment, Exhibit F. There was mention in the 1998 PDR of an increase in pancreatic islet cell tumors and a decreased incidence of spontaneous mammary gland tumors in female rats with Prempro. ***Id***. The 1998 PDR for Prempro contained a warning regarding the beagle dog study, providing:

> Beagle dogs treated with MPA [medroxyprogesterone, the active ingredient in Provera] developed mammary nodules, some of which were malignant. Although nodules occasionally appeared in control animals, they were intermittent in nature, whereas the nodules in the drug-treated animals were larger, more numerous, persistent, and there were some breast malignancies with metastases. It is known that progestogens stimulate synthesis and release of the growth hormone in dogs. The growth hormone, along with the progestogen, stimulates mammary growth and tumors. In contrast, growth hormone in humans is not increased, nor does growth hormone have any significant mammotrophic role. Therefore, the MPA-induced increase of mammary tumors in dogs probably has no significance to humans. No pancreatic tumors occurred in dogs.

Id. The 2000 PDR contained virtually identical language regarding Prempro.

The 1998 package insert for Prempro under "Risks of Estrogens and/or Progestins," provided:

> *Cancer of the breast.* Most studies have not shown a higher risk of breast cancer in women who have used estrogens. However, some studies have reported that breast cancer developed more often (up to twice the usual rate) in women who used estrogens

> for long periods of time (especially more than 10 years), or who used high doses for shorter 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.

Wyeth's Reply in Further Support of Its Motion for Summary Judgment Based on the Statute of Limitations, 3/29/07, at Exhibit A.

Thus, the literature distributed to physicians and patients through 2000 did not causally link HRT therapy with breast cancer. The reported studies involving women were inconclusive. Studies conducted on rats and beagle dogs were dismissed as being of little or no significance to humans.

The certified record herein contains articles that appeared in the popular print media in the late 1990s, including an article authored by Susan Love, a breast cancer specialist, entitled, "Estrogen Therapy: Should You or Shouldn't You?," in the February 1997 issue of *Good Housekeeping*. Wyeth's Supplemental Brief in Further Support of its Motion for Summary Judgment Based on the Statute of Limitations (Coleman), Exhibit 1. The article addressed estrogen therapy and its risks and alluded to contradictory medical advice and doctor confusion. In an article appearing in the June 19, 1997 issue of *USA Today*, it was explained that if a woman had a budding cluster of estrogen-dependent breast cancer cells, estrogen replacement

could promote the tumor's growth. ***Id***. at Exhibit 2. A *Newsweek* article appearing in the June 30, 1997 issue touted the benefits of estrogen therapy for heart, skin, and bones, but cautioned against long-term use of estrogen. ***Id***. at Exhibit 3. A December 23, 1997 *New York Times* article recited that women doctors were more likely to use HRT despite studies suggesting a link with a higher incidence of breast cancer. ***Id***. at Exhibit 5. An article in the *Arkansas Democrat Gazette* appearing on January 27, 2000, explained the dilemma, noting that "[s]ome previous studies have linked estrogen supplements, either alone or in combination with progestin, with higher risks of breast cancer. Other research has found no increased risk." ***Id***. at Exhibit 10.

Reference is made in the record to an article appearing in the *Journal of the American Medical Association* ("*JAMA*") in January 2000 discussing three studies: the Breast Cancer Detection Demonstration Project ("BCDDP"), the National Health and Nutrition Examination Study ("NHANES"), and the Iowa Women's Health Study. Coleman's Brief in Support of Motion for Reconsideration, Exhibit 18. The studies were characterized as showing "different conclusions and reaffirming the majority of data that have not shown an association between hormone use and overall increased breast cancer risk in most women." ***Id***. The *JAMA* article heralded that, "More definitive information is anticipated at the conclusion in

2006 of the National Institutes of Health: Women's Health Initiative, the largest prospective clinical trial of postmenopausal women and estrogen use. . . ." ***Id***.

On July 9, 2002, the WHI study was made public. This document was the first large randomized study establishing a definitive causal link between combined estrogen and progestin in healthy post-menopausal women and breast cancer. *Journal of the American Medical Association*, "Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women." It was touted to be the "biggest bombshell in the history of HRT." Sari Harrar, *HRT: Answers, Not Panic; Breast Cancer. Heart attacks. Stroke. And – Surprise! - A Window of Safety*. Vol. 54 *Prevention* 46 (October 1, 2002). Coleman Brief in Opposition to Wyeth's Motion for Summary Judgment Based on the Statute of Limitations, Exhibit I (hereinafter "Coleman Brief"). The study was halted three years early because results indicated that the risks of taking HRT medications clearly outweighed the benefits. The study found that HRT did not protect against heart disease or Alzheimer's, as advertised; rather, it increased the risk of developing invasive breast cancer. The study acknowledged, however, that further research was needed to

determine whether different dosages and combinations impacted breast cancer.[8]

We have reviewed the record, which is replete with articles, product labeling information, physician resources, and excerpts from expert testimony proffered by Appellees and plaintiffs in other litigation involving HRT medications. The patient package inserts either do not mention or largely dismiss a connection between breast cancer and HRT medications. The physicians' product labeling information during the relevant time period offered no conclusive connection or specifically downplayed a causal link. Articles in popular magazines alluded to a possible correlation but acknowledged that no reliable studies confirmed one. Wyeth's expert in another HRT case, ***Nelson v. Wyeth et al.,*** 2007 Phila.Ct.Com.Pl. LEXIS 316 (2007), Raquel D. Arias, M.D., opined that when she reviewed the literature in its totality, it showed "no cause association" between hormone therapy and breast cancer. Coleman's Brief in Opposition to Summary Judgment, Exhibit P. The record herein contains numerous excerpts, submitted by Appellants, from Appellees' expert reports in other cases, such as the report of Gretchen M. Ahrendt, M.D., F.A.C.S., to the effect that "HT is not a cause of breast cancer," (Manalo Brief in Opposition to Wyeth's Motion for Summary Judgment, Exhibit 6 at 2) and the fact that "a breast

[8] Alice Park, *What Did the Study Show?,* 160 *Time Mag*. 38 (July 22, 2002), Coleman Brief, Exhibit A.

cancer is ER+ and PR+ does not mean that HT has any effect on that cancer." ***Id***. at 4.

After reviewing the record in ***Coleman*** in light of the above facts, we conclude that there are genuine issues of material fact for the jury. Ms. Coleman's diagnosis of breast cancer did not automatically place her on notice that her injury was caused by a third party. In fact, one could reasonably conclude, based upon the record before us, that diagnosis would not likely trigger inquiry into a third-party cause of her injury. There are factual inconsistencies as to what Ms. Coleman was told and by whom and what was generally known and understood about HRT and breast cancer. We hold that until these conflicts are resolved and inferences are drawn from relevant facts by the factfinder, the determination of what Ms. Coleman knew or should have known with reasonable diligence under the circumstances remains a matter of dispute as in ***Fine***, ***supra***. Those factual determinations and inferences drawn by the trial court were erroneously undertaken.

Viewed in the light most favorable to Ms. Coleman, the non-moving party, the facts of record reveal that she was prescribed Premarin and Provera from November 1991 through November 1998 by Dr. Haynes Jackson and his son, Dr. Haynes Jackson, Jr. Thereafter, in November of 1998, Dr. David Greathouse prescribed first a combipatch, a patch worn on

the skin that released estrogen and progestin, and then Prempro. In April 2000, following a hysterectomy, Dr. Greathouse prescribed Premarin. Coleman Short Form Complaint ¶3. On or about October 20, 2000, Ms. Coleman was diagnosed with infiltrating ductal carcinoma in her right breast. ***Id***. at ¶4. Ms. Coleman averred that she "first learned that her injuries described herein were related to the ingestion of an HT medication on or about July 9, 2002." ***Id***. at ¶4(a).

Dr. Jackson, Jr. testified at his deposition that he would routinely discuss risks and benefits of HRT medications with his patients, but he had no recollection of such a discussion with Ms. Coleman. Deposition, Haynes Jackson, Jr. M.D., 11/18/05, Exhibit "B" at 58. The information Dr. Jackson typically shared at that time 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." ***Id***. at 33. When he ceased treating Ms. Coleman in 1998, it was Dr. Jackson's opinion that whether or not breast cancer was related to hormone therapy was still a matter in dispute. ***Id***. at 57-58.

Dr. Greathouse testified that, "I would have, you know, discussed the possibility of DVT, stroke, and perhaps even made a mention of there being a possible concern of breast cancer." Deposition, David Greathouse, M.D. 11/09/05 at 110-111. He had no independent recollection of any

conversation with Ms. Coleman regarding the risks of hormone therapy generally or breast cancer specifically. His records were devoid of any mention of such a discussion. ***Id.*** at 113. Dr. Greathouse added, "And if she [Ms. Coleman] were to say under oath that I never specifically discussed breast cancer risks with her with regard to Prempro, then all I would have to say to that is that's possible." ***Id***. at 153. Dr. Greathouse denied that he became more focused on the link between hormone therapy and breast cancer after the WHI report was issued in 2002, insisting that it only provided "more clarity of what those risks are." ***Id***. at 112. However, he later admitted that the WHI impacted the way he counseled patients prior to prescribing HRT medications; that post-WHI he was conscious about using the lowest effective dose for the shortest duration. ***Id***. at 129-132. While unsure if the study affected his prescribing practices, Dr. Greathouse acknowledged that after the revelations of the WHI, he recommended that his patients periodically cease such therapy due to his concern over the risks of long-term use. ***Id***. at 133-136. He noted that his counseling at the time of the deposition in 2005 differed from his counseling in March 1999 because he knew something that he did not know then: that there is no cardio benefit from the medications and that there is an increased risk in combination usage. ***Id***. at 137. Prior to the WHI study, it was common

practice to prescribe HRT prophylactically for women entering menopause and today, as a rule, he would not do so. ***Id***. at 141.

Ms. Coleman testified that neither Dr. Jackson, Jr. nor Dr. Greathouse ever advised her that HRT caused or increased the risk of breast cancer. Deposition, E. Coleman, 10/19/05, at 15.[9] She deferred to the doctor who was knowledgeable of the risks as, "I'm not a pharmacist or a doctor so I have no way of knowing." ***Id***. at 16. "He prescribed it so I took it." ***Id***. Ms. Coleman stated that she scanned the product insert that came with the prescription looking for side effects, admitting that, "lots of it I do not understand." ***Id***. at 18. She did not recall reading anything about cancer in the information provided by Appellees prior to 2000. ***Id***. at 22. When Dr. Greathouse prescribed Prempro in March 1999, she scanned its information pack. ***Id***. at 34. At the time of her deposition, Ms. Coleman

[9] The physicians' knowledge and what they communicated to their patients, Appellants herein, is relevant at this juncture in determining whether Appellants knew or should have known of a causal connection between their ingestion of HRT medications and their breast cancer for purposes of application of the discovery rule. At trial, the physicians' understanding of the warnings provided by the manufacturers becomes the focus as the "learned intermediary" doctrine provides that the manufacturer of a prescription drug must direct warnings to the prescribing physician, not to the patient. ***Taurino v. Ellen***, 579 A.2d 925, 927 (Pa.Super. 1990). The jury will be asked to determine whether the warnings were adequate to permit the physician to exercise his or her informed judgment in the patient's best interest in deciding whether to prescribe HRT medications. ***See Simon v. Wyeth***, 989 A.2d 356 (Pa.Super. 2009). This involves proof that a different warning would have altered the prescribing physician's actions such that a failure to warn was the proximate cause of the injuries.

had no recollection of what Dr. Greathouse told her about Prempro except that it was one pill. ***Id***. at 35.

Following an abnormal mammogram on October 4, 2000, Dr. Greathouse directed Ms. Coleman to see A.D. Smith, M.D., a surgeon, and not to take any more of her medication. ***Id***. at 43. Ms. Coleman did not relate her cancer to the HRT therapy, thinking that she was told to stop taking the medication because "you never know if it is going to affect your surgery. . . ." ***Id***. at 44. Dr. Webb, her surgeon, told her that her cancer was "estrogen receptor positive." "In [Ms. Coleman's] mind, it meant that the estrogen was in the cells or whatever they do when they biopsy you." ***Id***. at 46. Ms. Coleman checked the box on the Fact Sheet that a physician had discussed that her "condition was related to the use of HRT medications" because "he told me it was estrogen positive." ***Id***. at 148.

The trial court focused on the following excerpt from Ms. Coleman's deposition, finding it more than sufficient to trigger her duty to investigate a possible link between HRT medications and her breast cancer:

> 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 – 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 positive. Did you think that meant that your breast cancer was caused by hormone therapy?

A. Yes, I guess. Yes.

Deposition, E. Coleman, 10/19/05 at 127-128.

Just moments later, Ms. Coleman was asked if there was anything about her answer that she wanted to change. She responded, "The doctor and I never discussed hormone therapy as a cause. I have seen it in the medium – media, 2003 or so, and that was my recollection of when I thought it was – might have been breast cancer related – you know, related." ***Id***. at 129.

We view this exchange as further evidence that would permit a reasonable person to conclude that Ms. Coleman was confused and uncertain about the significance of the fact that her cancer was "estrogen positive." Moreover, the deposition questions were not sufficiently time specific so as to ensure that the answers truly reflected her knowledge and understanding at the time of the original conversation with her physician in October of 2000, rather than the knowledge she subsequently acquired. A jury could reasonably find that Dr. Webb's comment that Ms. Coleman's breast cancer was "estrogen receptor positive" did not constitute notice to her that the etiology of her cancer was the HRT medications. In fact, as discussed *infra*, Appellees' own experts have opined that the fact that a tumor is "estrogen receptor positive" is no indication that HRT had any effect on it.

Moreover, one could reasonably infer from the record that neither Dr. Jackson, Jr. nor Dr. Greathouse advised Ms. Coleman that taking Premarin and Provera, or Prempro, increased her chances of developing breast cancer. Both believed that the connection was inconclusive at that time and that nothing in the labeling suggested that Ms. Coleman would be at risk for breast cancer. When Ms. Coleman was diagnosed with breast cancer, Dr. Greathouse directed her to see Dr. Webb and to stop her medications. Ms. Coleman thought that surgery necessitated ceasing her medications. There

is no evidence that Dr. Greathouse knew or that he told Ms. Coleman that the use of HRT medications may have contributed to the development of her breast cancer.

The record herein is factually indistinguishable from that in ***Simon***, ***supra***. Ms. Simon's first treating physician was unaware of any increased risk of cancer with HRT medications. The physician only learned of the increased risk when the WHI study was published. Ms. Simon's subsequent physician explained that, at the time she prescribed HRT, she did not believe the literature supported an increase in breast cancer. Ms. Simon's third physician, like Dr. Greathouse herein, denied that the WHI study made any difference in her prescribing practices, but later acknowledged that "the dialogue had to change. . . ." She acknowledged that the results of the WHI study had to be explained to patients and there was education that needed to be undertaken. In ***Simon***, we reversed the trial court's grant of judgment NOV on the statute of limitations, holding:

> based upon the evidence of record, the jury reasonably found that Appellant's cause of action failed to accrue until the WHI study was published on July 9, 2002. Appellant had no reason even to suspect that there was a link between her use of HRT and breast cancer until the WHI report was released. . . . .
>
> It defies logic, contrary to the trial court's suggestion, that Appellant should have been aware of the risk of taking HRT through her own due diligence. It is entirely unreasonable that a lay person, completely lacking in medical training, would make the logical connection between HRT and breast cancer prior to

> the release of the WHI study, when three trained medical doctors believed there was no such connection.

Simon, ***Id***. at 367. In reversing, we recognized that the trial court in ***Simon*** had ascribed to the appellant therein a prior awareness not only of a possible connection between HRT and breast cancer, but that a causal connection was probable. On the basis of the record, the jury could reasonably have concluded that a lay person would not make the connection.

In reaching our conclusion herein, we find first that the trial court failed to view the record, together with all reasonable inferences therefrom, in the light most favorable to the non-moving party as required in a motion for summary judgment. The trial court held 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." ***Coleman*** Opinion, 9/24/07, at 22.[10] Such a holding can only flow from an impermissible inference that Ms. Coleman understood this to mean that there was a causal connection between the two, an inference that is refuted by her pleadings,

[10] This reasoning was rejected by the Court of Appeals for the Eighth Circuit in ***Scroggin v. Wyeth (In re Prempro Products Liability Litigation)***, 586 F.3d 547 (8th Cir. 2009). Knowledge of a causal connection could not be assumed on Scroggin's part due to her physician's instruction to stop taking hormone replacement therapy when he diagnosed her with breast cancer because Premarin and Prempro labels stated that women already known to have breast cancer should not use Premarin or Prempro. The record contained expert testimony that the label included that instruction because estrogen can exacerbate existing breast cancer, not because it suggested a causal connection.

affidavit, and deposition testimony. Nor do we find factual support for the trial court's conclusion that it was "evident from Dr. Jackson's testimony that those in the medical profession were aware that HRT increased the risk of breast cancer." ***Id***. at 14. Dr. Jackson testified that studies were inconclusive. The court's conclusion that "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," is an inference that was not drawn in favor of the non-moving parties herein as required. ***Id***. Dr. Jackson was equally aware of the studies suggesting possible breast protection and testified that it was "an unsettled issue." The information he typically shared with his patients at the time was, "simply that it was an unresolved issue in dispute." Deposition, Haynes Jackson, Jr. M.D., 11/18/05, Exhibit "B" at 58.

On the basis of the record before us, a jury could reasonably believe that Ms. Coleman had no reason to suspect that there was a causal link between her breast cancer and her ingestion of HRT medications until the WHI study was published and triggered inquiry. ***See Simon***, ***supra***. The issue of her reasonable diligence is a factual one for the jury. We believe that the recent pronouncements of our Supreme Court in ***Fine*** and ***Wilson*** reveal a strong judicial preference for the submission of such fact-intensive inquiries to the jury. A jury can properly apply a standard that is

"sufficiently flexible . . . to take into account difference[s] between persons, their capacity to meet certain situations and the circumstances confronting them at the time in question." ***Petri v. Smith***, 453 A.2d 342, 347 (Pa.Super. 1982).

Nor do we find ***Love v. Raymark Indus., Inc.***, 633 A.2d 1185 (Pa.Super. 1993), relied upon by the trial court, applicable to the facts herein. ***Coleman*** Opinion, at 23-24. Mr. Love, unlike Ms. Coleman, *suspected* that his lung cancer was related to his occupational exposure to asbestos. Furthermore, the causal connection between lung cancer and occupational exposure to asbestos was "neither obscure nor unascertainable." ***Love***, at 1187. On those facts we held that Love's failure to inquire of his physicians as to the results of his lung biopsy was unreasonable as a matter of law where the presence of asbestos would have confirmed the cause of his cancer.

Appellants contend further that, even if Ms. Coleman and the other Appellants suspected that HRT may have caused their breast cancer, "a diligent investigation" of the cause would not have led them to reasonably conclude that hormone therapy was the cause of their breast cancers. Appellants' brief at 4. Appellants maintain that the FDA apparently concluded when it approved Wyeth's warnings that the majority of studies showed no increased risk. ***Id***. at 26. Ms. Coleman's doctors were unsure of

the risk. The product information that came with the HRT medications did not advise of the risk and studies were inconclusive of any causal link or increased risk of breast cancer. Even Appellees' own experts acknowledge that the literature showed no causal connection between HRT medications and breast cancer. For all these reasons, we hold that there are genuine issues of fact as to whether, with the exercise of due diligence, the causal connection between HRT and breast cancer was knowable until the results of the WHI study were revealed. Thus, summary judgment was improperly granted on this ground.

Following ***Coleman***, the trial court granted summary judgment in the thirteen other cases presently before us on the same basis: as a matter of law, Appellants knew or should have known of a connection between their breast cancer and their ingestion of HRT medications had they exercised reasonable diligence. The records in these cases, however, do not contain depositions of the parties or treating physicians, being limited to pleadings, Fact Sheets, affidavits, and medical and popular literature. On the basis of the records before us, we hold that there are genuine issues of material fact that preclude the entry of summary judgment.

Each Appellant pled in her complaint that she "first learned that her injuries described herein were related to the ingestion of an HT medication on or about July 9, 2002." Appellants' Complaints at either ¶4 or ¶5. All of

the Appellants except Ms. Hess responded in the affirmative to the Fact Sheet Question XI, asking whether they had a conversation with at least one of their physicians following diagnosis in which they were told that their condition was "related to" or "may be related to" their use of HRT. Many of the Appellants filed affidavits clarifying that the conversation with their physicians did not include any discussion that HRT caused their breast cancer and that they did not suspect a causal connection until publication of the WHI study. For the reasons that follow, the trial court erred in disregarding or discrediting these affidavits. This evidence, together with inconclusive medical studies, contradictory literature, and conflicting expert medical opinions, is sufficient to raise genuine issues of material fact as to when or whether Appellants knew or should have known of a causal link between HRT medications and breast cancer.

We agree with Appellants that the trial court further erred in supporting its entry of summary judgment by drawing impermissible inferences from their Fact Sheet responses to Question XI and then in treating them as judicial admissions. Specifically, each Appellant (with the exception of Ms. Hess) placed an "X" next to a form response that she had discussions with a medical professional that her "condition" "is related to" or "may be related to" ingestion of HRT medications. Appellees argued that the Fact Sheet responses constituted judicial admissions conclusively

establishing that Appellants knew or should have known of a causal link and urged the court to disregard Appellants' affidavits to the contrary.

Fact Sheet question XI provided:

> XI. INJURY CLAIMS
>
> A. Have you had discussions with any physician(s) about whether your condition is related to the use of HT medications?
>
> Yes ____ No _____ Don't know _____
>
> If yes, please identify:
>
> Name of Doctor: _____
> Address: _____
> Specialty:_____
> Date of discussion:_____
> *and*, check one of the following
>
> 1.____ I was told my condition is related to the use of HT medications.
>
> 2.____ I was told my condition is not related to HT medications.
>
> 3.____ I was told my condition may be related to HT medications.
>
> 4.____ I was told by the doctor that he or she does not know whether my condition is related to the use of HT medications.
>
> 5.___ I don't recall what I was told.
>
> ____Other: (describe discussion regarding HT)

Most of the Appellants had placed an "X" next to the "related to" or "may be related to" option. Later, in their affidavits, they explained why

they marked that option: that the tumor was estrogen positive, or that estrogen fed the tumor, or that they should stop taking their HRT medications. They averred that they were never told that HRT medications caused their breast cancer.

Relying upon ***Stephens v. Paris Cleaners, Inc.***, 885 A.2d 59 (Pa.Super. 2005) and ***Stone v. Wyeth***, 2005 Phila.Ct.Com.Pl. LEXIS 371, *aff'd memorandum*, 905 A.2d 1056 (Pa.Super. 2006),[11] the trial court agreed with Appellees that the responses to Question XI constituted judicial admissions conclusively establishing that Appellants knew of the causal link and held their affidavits to be "wholly incredible as they contradicted prior facts in evidence." ***Medwid*** Trial Court Opinion, 12/9/08, at 6-7. The result was a finding that there was no genuine issue of material fact and thus, summary judgment was proper. ***Id***.

Ms. Medwid explained that she placed an "X" on the line beside "is related to" because she was told by her oncologist several months after her

[11] The trial court may rely on trial court decisions. However, neither a trial court decision nor an unpublished Superior Court memorandum is binding on us. "An unpublished Superior Court memorandum decision shall not be relied upon or cited by a Court or a party in any other action or proceeding, except that such a memorandum decision may be relied upon or cited (1) when it is relevant under the doctrine of law of the case, res judicata, or collateral estoppel, and (2) when the memorandum is relevant to a criminal action or proceeding because it recites issues raised and reasons for a decision affecting the same defendant in a prior action or proceeding." ***Schaaf v. Kaufman***, 850 A.2d 655, 662 (Pa.Super. 2004), quoting Superior Court Internal Operating Procedures, § 65.37(A.), 21 Pa.Code § 65.37.

mastectomy that her cancer was "estrogen positive which meant that hormones fed the tumor and made it grow faster." Medwid Affidavit, Medwid's Brief in Opposition to Wyeth's Motion for Summary Judgment, Exhibit 7. She stated further that "at no time did any physician state or imply that her breast cancer could have been caused by her use of Prempro." ***Id***.

Ms. Weinberger's physician told her that estrogen was causing her cancer to grow, explaining why she placed an "X" next to "related to." However, he never suggested that HRT medications caused her cancer in the first place. Nor did he explain whether it was her own hormones or the HRT that was feeding the tumor. The first time she became aware that HRT may have caused her breast cancer was when she saw a commercial on television after the WHI study was released. Weinberger Affidavit, Weinberger's Brief in Opposition to Wyeth's Motion for Summary Judgment on the Statute of Limitations, Exhibit 7.

Ms. Reed placed an "X" next to "related to" because her doctor told her to stop taking HRT when she was diagnosed with breast cancer. She, like Ms. Weinberger, did not know whether her own hormones or the HRT medications were feeding the tumor. She did not suspect that HRT medications caused her breast cancer until after the WHI study was published. Reed Affidavit, Reed Brief in Opposition to Wyeth's Motion for

Summary Judgment, Exhibit 7. Ms. Stephenson had a similar understanding. Stephenson Affidavit, Stephenson Brief in Opposition to Wyeth's Motion for Summary Judgment, Exhibit 7. Appellants' confusion was plausible considering the expert medical testimony of Suzanne Klimberg, M.D., provided via deposition, 4/10/06, 104:22-107:6, to the effect that a woman's endogenous hormones can potentially affect the tumor; that is the reason why tamoxifen is prescribed after surgery. Weinberger Opposition to Wyeth's Motion for Summary Judgment, Exhibit 9.

Ms. Morales checked "Yes," that she was told by Dr. Sam Oronan on September 14, 2001 that "her condition was related to" the use of HT medications. Exhibit C to Wyeth's Motion for Summary Judgment at XI. No specifics or explanation was provided.

Ms. Lenzi stated she had a discussion with her OBGYN/surgeon in July of 2000 wherein she was told that her condition was related to the use of HRT medications. Lenzi Brief in Opposition to Wyeth's Motion for Summary Judgment, Exhibit 6. In her affidavit, Ms. Lenzi explained that this was a reference to a conversation during which she was instructed to stop taking her HRT medications. She was not informed whether her own hormones or the hormone replacement therapy was feeding the tumor. ***Id***. at Exhibit 7. Ms. Lenzi offered the *curriculum vitae* and an excerpt of a deposition of Dr. Mary Jane Minkin, board-certified in Obstetrics and Gynecology, to the

effect that most people recommend that one cease taking an estrogenic substance with estrogen-receptor-positive tumors because they promote growth of the tumor. ***Id***. at Exhibit 8.

Ms. Schirn responded that she had discussions after her cancer was diagnosed in 2001, but she could not remember with whom. On the Fact Sheet, she placed "X"s next to "is related to" and "may be related to" HT medications. Schirn Brief in Opposition to Wyeth's Motion for Summary Judgment, Exhibit 6. She, too, was directed to cease taking her HRT medications but she was not advised whether it was her own hormones or the HRT medications that would feed the tumor. ***Id***. at Exhibit 7.

Ms. Fleming-Crain was informed by her physician in approximately March of 2001 that her condition was related to the use of HRT. Fleming-Crain Brief in Opposition to Wyeth's Motion for Summary Judgment, Exhibit 6. On dates unknown, she had discussions with doctors and was told that HRT increased the risk of breast cancer. ***Id***. In a subsequent affidavit, however, Ms. Fleming-Crain stated that her doctor never told her that HRT caused her tumor and that she did not discover the cause of her breast cancer until after publication of the WHI study. ***Id***. at Exhibit 7.

Ms. Honaker answered in the affirmative in response to Question XI of the Fact Sheet that she had a discussion with her oncologist on an unknown date that her condition "is related to" and "may be related to" her HRT

medications. That response was later supplemented to provide a date of approximately September 1999. Wyeth's Brief in Support of Summary Judgment, Exhibit B. In her affidavit, she explained that her doctor directed her to stop taking her HRT medications, but that she was not told that HRT caused the tumor in the first place. She did not become aware of the cause until after release of the WHI report. Honaker Brief in Opposition to Wyeth's Motion for Summary Judgment, Exhibit 7.

Ms. Hansen responded to question XI that she had a discussion with her oncologist in June 1999 that her condition "is related" to her ingestion of HRT medications. Hansen Brief in Opposition to Wyeth's Motion for Summary Judgment, Exhibit 6.

Ms. Blaylock answered "Yes," to Question XI that she had a discussion with a physician wherein she was advised that her condition "was related to" HRT medications. Blaylock Brief in Opposition to Wyeth's Motion for Summary Judgment, Exhibit 6. Ms. Blaylock explained further that the discussion took place in November 2001 with her oncologist who informed her that her breasts, "are estrogen receptive and now I must take medication for five years to ensure my estrogen is low." ***Id***. In her affidavit, Ms. Blaylock stated that she was told to stop taking HRT after her diagnosis. She did not know whether her own hormones or the HRT were feeding the tumor and she was not told that HRT caused her cancer. She

was not aware of the cause until the WHI study was released. ***Id***. at Exhibit 7.

Ms. Manalo responded to the Fact Sheet question that she had a discussion in November 2000 that her "condition may be related" to HRT. Manalo Brief in Opposition to Wyeth's Motion for Summary Judgment, Exhibit 3. In her affidavit, she explained that she was told that her breast cancer may be related to several different factors, including hormone replacement therapy, but that it was impossible for anyone to pinpoint or prove the cause of the breast cancer with any assurance. ***Id***. at Exhibit 2. Ms. Manalo understood that her breast cancer may or may not have been caused by hormone replacement drugs, "but that I would never be able to know for certain." ***Id***. That is why she checked "may be related," understanding it to mean may or may not be related. Ms. Manalo averred that she did not see any news reports or read the study regarding estrogen replacement. The first time she knew that HRT posed a "significantly increased risk" of breast cancer was in the early part of 2004, after she saw an advertisement regarding the release of the WHI study. ***Id***. at Exhibit 2.

The trial court inferred from the Fact Sheet responses that "related to" meant "caused by," and held that these responses constituted judicial admissions that conclusively established Appellants' knowledge of a causal relationship shortly after their respective surgeries. Therefore, the trial

court disregarded Appellants' affidavits as "contradictory" and "wholly incredible."

We find the undefined term "related to" to be ambiguous and capable of multiple meanings. It may mean causally related; it may mean correlated with, or having some relation to after the fact. We agree with Appellants that the trial court's conclusion equating "related to" with "caused by" required the drawing of an impermissible inference in Appellees' favor. The court then held that it constituted a judicial admission, giving it conclusive effect. For the following reasons, we disagree.

Statements of fact by one party in pleadings, stipulations, testimony, and the like, made for that party's benefit, are termed judicial admissions and are binding on the party. ***Nasim v. Shamrock Welding Supply Co.***, 563 A.2d 1266, 1267 (Pa.Super. 1989) ("It is well established that a judicial admission is an express waiver made in court or preparatory to trial by a party or his attorney, conceding for the purposes of trial, the truth of the admission."). As we held in ***John B. Conomos, Inc. v. Sun Co.***, 831 A.2d 696, 712 (Pa.Super. 2003),

> For an averment to qualify as a judicial admission, however, it must be a clear and unequivocal admission of fact. Judicial admissions are limited in scope to factual matters otherwise requiring evidentiary proof, and are exclusive of legal theories and conclusions of law. ***Glick***, 458 F.2d at 1291. The fact must have been unequivocally admitted and not be merely one interpretation of the statement that is purported to be a judicial admission. ***Jones v. Constantino***, 429 Pa.Super. 73,

> 631 A.2d 1289, 1293-94 (Pa.Super. 1993) (finding no admission where "the evidence could be reasonably construed to admit of more than one meaning"); ***see also***, ***Phila. Reinsurance Corp. v. Employers Ins. of Wausau***, 61 Fed. Appx. 816, 2003 U.S. App. LEXIS 6198 (3d Cir. 2003) ("An unequivocal statement is one that is clear, unambiguous and expresses only one meaning."); ***Glick***, 458 F.2d at 1291; ***The Doyle***, 105 F.2d 113, 117 (3d Cir. 1939) (holding that "admissions to be binding must be unequivocal, . . . and anyway they may be disregarded in the interests of justice"). An admission is not conclusively binding when the statement is indeterminate, inconsistent, or ambiguous. ***Greater Valley Terminal Corp. v. Goodman***, 405 Pa. 605, 176 A.2d 408, 410 (Pa. 1962); ***Dible v. Vagley***, 417 Pa. Super. 302, 612 A.2d 493, 499 (Pa.Super. 1992) (finding no admission in a statement in which "pronouns are burdened with ambiguous antecedents, and syntax is opaque" and that "to be an admission, a statement must at least be intelligible [and its] subject matter . . . readily determinable"); ***Astrazeneca AB v. Mutual Pharm. Co.***, 250 F. Supp. 2d 506, 518 (E.D. Pa. 2003). When there is uncertainty surrounding a conceded fact, it is the role of the judge or jury as fact finder to determine which facts have been adequately proved and which must be rejected. ***See Oscanyan v. Arms Co.***, 103 U.S. 261, 263-64, 26 L. Ed. 539 (1880).

The answers herein were not made for Appellants' benefit. Nor are they clear and unequivocal and capable of only one meaning because of the ambiguity inherent in the terms used. The responses were not factual because the question invited the respondent to draw a conclusion from words uttered. Thus, we find that Appellants' Fact Sheet responses do not meet the well-established criteria for judicial admissions.

The trial court cited ***Stone v. Wyeth***, ***supra***, a case for personal injuries arising out of the use of the diet drug, "phen fen," as a basis for its decision herein; however, ***Stone*** does not support a finding that the Fact

Sheet responses herein constituted judicial admissions. Stone asserted in her **complaint** that she learned of her heart valve injury and its related cause on March 21, 2000, more than two years before she filed her complaint. Stone later sought to contradict that assertion by denying that she knew the cause of her injury at that time so that she could argue that her action was not time-barred due to the discovery rule. Wyeth argued that the allegations in Stone's complaint, consistent with her later discovery responses, constituted binding judicial admissions that could not later be contradicted by the party who had made them. The court agreed that Stone was bound by the assertions in her complaint and fact sheet and therefore unable to contradict her earlier admission, thus losing the benefit of the discovery rule.

If we were to apply the court's analysis in ***Stone***, ***supra***, on the facts at bar, we would be compelled to conclude that the averments in Appellants' complaints (Paragraphs 4 or 5) that they "did not know that their breast cancer was related to their ingestion of HRT medications until July 9, 2002, the publication of the WHI study," are the operative "judicial admissions." Adopting the ***Stone*** reasoning herein, the complaint controls. The affidavits are then admissible to explain what each Appellant understood the phrase "is related to" to mean.

Nothing in the Rules of Civil Procedure nor in our case law supports the construction of Fact Sheet responses as judicial admissions. The Fact Sheet involved herein was prefaced with the statement that it was "completed pursuant to the Pennsylvania Rules of Civil Procedure governing discovery." It consisted of open-ended questions much like interrogatories to a party as described in Pa.R.C.P. 4005. Rule 4005 provides that responses to interrogatories can be supplemented and "used to the same extent as provided in Pa.R.C.P. 4020 for the use of a deposition of a party." Rule 4020 provides that all or part of a deposition (and hence interrogatory responses), so far as admissible under the Rules of Evidence, may be used against any party for purposes such as impeachment or as party admissions. However, "[a]t trial or hearing, any party may rebut any relevant evidence contained in a deposition whether introduced by that party or by any other party." Pa.R.C.P. 4020(d). Thus, under the Pennsylvania Rules of Civil Procedure, depositions and interrogatory answers are not binding admissions.

Requests for admission, in contrast, are governed by Pa.R.C.P. 4014. They are requests submitted to the opposing party that certain matters be admitted or denied. Matters admitted under Pa.R.C.P. 4014 are "conclusively established" unless they are withdrawn or admitted with court permission. However, our Supreme Court in ***Stimmler***, ***supra***, faced with

summary judgment granted on the basis of untimely responses that were deemed admitted, discouraged an inflexible application of Pa.R.C.P. 4014. This Court was criticized for being "quick on the trigger" in determining that summary judgment on the basis of "deemed admissions," was appropriate. The Supreme Court, finding that the factual foundations for the requests for admission were insufficient to support the conclusion that appellees wished to reach, reversed the grant of summary judgment. In so holding, the Court cautioned that Rule 4014 was designed to ensure that a case was determined on its merits, not disposed of summarily.

Our examination of the Fact Sheet question at issue confirms that it is not a request for admission and that it is not conclusive. More importantly, however, the instant case presents an even more compelling example of a court "too quick on the trigger" in treating an ambiguous Fact Sheet question and answer as a binding judicial admission and granting summary judgment based upon it.

Applying the Pennsylvania Rules of Civil Procedure governing discovery to determine the effect to be given to the Fact Sheet responses, we conclude that the answers therein should be accorded the weight of interrogatory responses: admissible when otherwise permitted under the rules of evidence, but subject to rebuttal. The Fact Sheet responses do not constitute binding admissions in the nature of judicial admissions. We note that our finding is

consistent with the effect given to the Fact Sheet responses in the Prempro multi-district litigation in Arkansas, where the court determined that the plaintiffs' verifications to Fact Sheet information had "the same legal significance as responses to interrogatories or requests for production." ***In re Prempro Products Liability Litigation***, 2010 U.S. Dist. LEXIS 23832 (E.D. Ark. February 23, 2010).

Furthermore, in construing the Fact Sheet responses as conclusive on the issue of Appellants' knowledge or notice of the cause of their breast cancer, the trial court again drew impermissible inferences in favor of Appellees. The error was compounded when the trial court then refused to consider, or held "wholly incredible," the affidavits submitted by Appellants clarifying their responses. The trial court erred in granting summary judgment where there were genuine issues of fact for the jury.

Ms. Hess presented a unique factual situation. Her breast cancer was diagnosed on April 19, 2002. In her complaint, she pled that she "first learned that her injuries described herein were related to the ingestion of a HRT medication on or about July 9, 2002." Hess Complaint ¶4(a). In response to Question XI of the Fact Sheet, Ms. Hess stated that she could not remember her conversation with her physician. Thus, the record contained no "judicial admission" that conclusively established notice or knowledge of the cause of her breast cancer and no basis for refusing to

consider Ms. Hess's affidavit. In her affidavit dated November 30, 2007, Ms. Hess stated that neither her doctor nor anyone else told her that hormone therapy could cause breast cancer. She had two aunts with breast cancer and, at the time, thought her sister also had breast cancer. Ms. Hess wondered if her family history was the cause of her breast cancer. She had no awareness that her use of Prempro may have been the cause of her breast cancer until she saw an advertisement on television shortly after the release of the WHI study suggesting such a link. Affidavit, Hess Brief in Opposition to Summary Judgment, Exhibit 2.

In granting summary judgment for Appellees, the trial court held that Ms. Hess's claims were time-barred as of June 29, 2004, for the reasons enunciated in ***Coleman***. The trial court found that there was sufficient information available at the time of Ms. Hess's diagnosis which warned of the risk of developing breast cancer from the ingestion of HRT drugs, and that as a matter of law, she knew or should have known of the causal connection. The court further held that her affidavit failed to raise an issue of material fact as to when she learned that HRT was related to her breast cancer; she had the ability, "exercising reasonable diligence, to ascertain the fact of a cause of action" and thus, was under a duty to investigate the possible causes of her injury at the time she was diagnosed in April 2002. ***Hess*** Trial Court Opinion, 12/8/08 at 8. Had Ms. Hess exercised due

diligence, the court continued, she would have discovered the reports and studies and been placed on notice of the causal connection within the two-year statute of limitations.

The trial court, in essence, held as a matter of law that a diagnosis of breast cancer alone was sufficient to trigger inquiry into whether it was caused by a third party. Furthermore, the inability of Ms. Hess to discover the causal connection within two years was a failure to exercise due diligence as a matter of law.

We hold that such a conclusion flies in the face of our highest court's decisions in ***Fine*** and ***Wilson***, ***supra*** and stands contrary to our recent holding in ***Simon***, ***supra***. The trial court failed to "take into account the differences between persons and their capacity to meet certain situations and the circumstances confronting them at the time in question." ***Fine***, at 858. We find that Ms. Hess's complaint, Fact Sheet, affidavit, and the reams of product information, articles, medical studies, and popular literature discussing HRT that are contained in the record before us, raise genuine issues of material fact as to when she knew or should have known that her breast cancer was caused by the ingestion of HRT medications. Consequently, the issue should have been submitted to the jury. The trial court failed to view the record in a light most favorable to Ms. Hess, as it was required to do, and drew impermissible inferences from her failure to

make a causal connection within two years of her diagnosis. Therefore, summary judgment was improper.[12]

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[12] Ms. Coleman is a resident of Arkansas and Ms. Manalo is a resident of Illinois. In addition, ten of the Appellants are from California. The trial court did not reach the issue of whether the Arkansas, California, or Illinois statutes of limitations were applicable, or whether, under Pennsylvania's borrowing statute, Pennsylvania law applied.

Pennsylvania's borrowing statute governs claims accruing outside the Commonwealth. The Uniform Statute of Limitations on Foreign Claims Act, 42 Pa.C.S. § 5521, provides in pertinent part:

> (b) General Rule – The period of limitation applicable to a claim accruing outside this Commonwealth shall be either that provided or prescribed by the law of the place where the claim accrued or by the law of this Commonwealth, whichever first bars the claim."

Prior to January 1, 2003, the California statute of limitations in personal injury actions was one year. On that date, California increased the limitations period for personal injury actions to two years. However, the new statute enlarging the limitations period applied only to actions not already barred by the original limitations period as of January 1, 2003. ***Andonagui v. May Dept. Stores Co.***, 27 Cal. Rptr. 3d 145 (2008). California, like Pennsylvania, has a discovery rule that postpones accrual of a cause of action until a plaintiff discovers, or has reason to discover, the cause of action." ***Norgart v. Upjohn***, 21 Cal. 4th 383, 397, 981 P.2d 79 (1999); ***Fox v. Ethicon Endo-Surgery***, ***Inc.***, 35 Cal. 4th 797, 110 P.3d 914 (2005). If the discovery rule delayed accrual until July 9, 2002, as Appellants contend, then Appellants' actions were not barred by California's one-year statute of limitations, and the two-year statute governed. Under our borrowing statute, we would apply Pennsylvania law.

The applicable prescriptive period in Arkansas is three years; in Illinois, two years. Both states have discovery rules that are virtually identical to Pennsylvania's. ***Martin v. Arthur***, 3 S.W.3d 689, 690 (Ark. 1999). (statute does not run until the plaintiff knew, or by the exercise of reasonable diligence, should have discovered the causal connection between the product and the injuries suffered); ***Healy v. Owens-Illinois, Inc.***, 359 Ill. App. 3d

The *Frye* Argument

Appellants argue alternatively that the trial court erred in granting summary judgment because, under Pennsylvania law, their claims did not accrue and the statute of limitations did not even begin to run until they were capable of proving each element of their claims. Appellants rely upon our Supreme Court's decision in ***Fine***, ***supra***, which holds that a cause of action accrues when the plaintiff could have first maintained the action to a successful conclusion.

Generally, the statute of limitations begins to run as soon as the right to institute and maintain a suit arises, normally when the plaintiff's injury is inflicted. ***Id***. Appellants assert that their "claims did not accrue until at least July 9, 2002 because before that date [they] could not establish by a preponderance of the evidence that hormone therapy causes breast cancer." Appellants' brief at 23. In support of their argument, they allege that Wyeth's pre-July 2002 labeling for Premarin and Prempro reassured physicians and patients that there was no likely risk of breast cancer from using the drugs. Weinberger Brief in Opposition to Wyeth's Motion for

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186 (Ill.App.Ct. 2005); ***Roper v. Markle***, 59 Ill. App. 3d 706, 713, 375 N.E.2d 934 (1978) ("the limitations period does not begin to run until there exists actual or constructive knowledge of both a physical problem and that someone is or may be at fault for its existence"). Thus, Pennsylvania's two-year statute applies.

Summary Judgment, Exhibit 10. Warnings on Upjohn's Provera labels pre-July 2002 were limited to the presence of mammary nodules in beagle dogs.

Appellants argue that neither Wyeth nor Upjohn provided adequate warnings on their labels about the possibility of a causal link between hormone therapy and an increased risk of breast cancer although their approved labels "collectively reflected the state of scientific knowledge within the medical community at that time." Appellants' brief at 24.

Appellants insist that it was not until publication of the WHI study that it became generally accepted within the scientific community that estrogen plus progesterone caused breast cancer because the approach utilized was "much more scientifically reliable than the preceding studies that had examined the question." Appellants' brief at 27. Prior to that date, Appellants argue that they would have been unable to procure expert scientific testimony to establish that Appellees' medications caused their breast cancer because the scientific community had not reached consensus as to the reliability of the expert's approach under ***Frye v. United States***, 293 F. 1013 (D.C. Cir. 1923), (adopted in Pennsylvania in ***Commonwealth v. Topa***, 369 A.2d 1277 (Pa. 1977)). ***See also Blum v. Merrell Dow Pharmaceuticals, Inc.***, 764 A.2d 1 (Pa. 2000). Without such testimony, Appellants contend that no cause of action could be maintained to a successful conclusion. Therefore, Appellants assert that no cause of action

accrued until publication of the WHI study on July 9, 2002 because only at that time was there generally accepted scientific evidence under ***Frye*** to support expert testimony.[13] Appellees counter that this argument is waived because it was not made below nor raised in Appellants' Pa.R.A.P. 1925(b) statements.

Our review of the record in these consolidated cases confirms that this issue was not raised in the trial court nor identified in Appellants' Pa.R.A.P. 1925(b) statements. Hence, we agree that it is waived under both Pa.R.A.P. 302(a) and Pa.R.A.P. 1925(b).[14]

[13] This argument is premised on the construction of the statutory language in 42 Pa.C.S. § 5502(a), "from the time the cause of action accrued."

[14] As this argument was not advanced in the trial court, the record is devoid of any evidence that, prior to the WHI study, no expert testimony would have been available to Appellants that would meet the ***Frye*** general acceptance standard. Thus, even if this issue were properly preserved, the record is inadequate to permit us to review whether ***Frye*** would have presented an insurmountable barrier to Appellants' successful maintenance of actions within two years of their diagnoses. We note that on August 16, 2006, the ***Coleman*** trial court denied Wyeth's motion, pursuant to Pa.R.C.P. 207.1, to exclude plaintiff's novel expert testimony under ***Frye***.

Conclusion

For all of the foregoing reasons, we reverse the trial court's orders granting summary judgment and remand for proceedings consistent with this opinion.[15]

Orders granting summary judgment reversed. Cases remanded. Jurisdiction relinquished.

[15] We note that our holding is consistent with the majority of courts in other jurisdictions who have found that genuine issues of material fact precluded entry of summary judgment on statute of limitations grounds in hormone replacement therapy cases. In ***Scroggin v. Wyeth (In re: Prempro Products Liability Litigation)***, 2007 WL 3228125, at *1 (E.D. Ark. 2007), the district court denied summary judgment on statute of limitations grounds finding genuine issues of material fact. Then, following a jury verdict for plaintiff, Wyeth's motion for judgment as a matter of law on statute of limitations grounds was denied by the trial court. The Court of Appeals for the Eighth Circuit affirmed, holding that on the basis of the evidence a jury could find that Scroggin's cause of action accrued at some point after the publication of the WHI study's results, noting change in product labeling and widespread publicity following publication of the WHI study. ***Scroggin v. Wyeth (In re Prempro Products Liability Litigation)***, 586 F.3d 547 (8th Cir. 2009). Motions for summary judgment based on the statute of limitations were also denied in ***Rush v. Wyeth*** (***In re Prempro Products Liability Litigation***), Case No. 4:05CV00497-WRW (E.D. Ark. 2005) (Order, May 12, 2006) and ***Deutsch v. Wyeth***, MID-L-998-06 MT (N.J. Super. Ct. June 14, 2007).