In the Superior Court of Pennsylvania

Nos. 2678 EDA 2007, 3026 EDA 2007, 3089 EDA 2007, 3090 EDA 2007, 3091 EDA 2007, 3092 EDA 2007, 3093 EDA 2007, 3094 EDA 2007, 3095 EDA 2007, 3096 EDA 2007, 3097 EDA 2007, 3098 EDA 2007, 583 EDA 2008, and 594 EDA 2008

COLEMAN; MEDWID; WEINBERGER; REED; TAW; MORALES; LENZI; SCHIRN; FLEMING–CRAIN; HONAKER; HANSEN; BLAYLOCK; MANALO; and HESS,

Plaintiffs/Appellants,

v.

WYETH PHARMACEUTICALS, INC., et al.

CONSOLIDATED BRIEF FOR APPELLANTS

On Appeal from the Judgments of the
Court of Common Pleas of Philadelphia County, Pennsylvania,
Civil Trial Division

Howard J. Bashman
2300 Computer Avenue
Suite G–22
Willow Grove, PA 19090
(215) 830–1458

Fredric S. Eisenberg
Eisenberg, Rothweiler, Winkler,
Eisenberg & Jeck, P.C.
1634 Spruce Street
Philadelphia, PA 19103
(215) 546–6636
Counsel for Coleman

Counsel for Plaintiffs/Appellants

[The list of counsel for Plaintiffs/Appellants
continues on the next page]

Stephen A. Corr
Mellon, Webster & Shelly
87 N. Broad Street
Doylestown, PA 18901
(215) 348–7700
Counsel for Medwid

James A. Morris
Brian D. Ketterer
Brent Coon & Associates
1500 JFK Boulevard
Suite 1301
Philadelphia, PA 19102
(215) 564–9245
Counsel for Weinberger; Reed; Taw; Morales; Lenzi; Schirn; Fleming–Crain; Honaker; Hansen; and Blaylock

Tobias Millrood
Pogust Braslow & Millrood, LLC
8 Tower Bridge, Suite 1520
161 Washington Street
Conshohocken, PA 19428
(610) 941–4204
Counsel for Manalo

John J. Cord, Jr.
Robert K. Jenner
Janet, Jenner & Suggs, L.L.C.
1829 Reisterstown Road, Suite 320
Baltimore, MD 21208
(410) 653–3200
Counsel for Hess

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I. STATEMENT OF JURISDICTION

The plaintiffs in these 14 consolidated appeals filed timely notices of appeal within 30 days of the dates on which the trial court entered final, appealable orders granting summary judgment in their particular cases. Those orders were based on the supposed expiration of the two–year statute of limitations governing plaintiffs' claims that defendants' hormone therapy medications caused plaintiffs' breast cancer.

The Statement of the Case supplies the dates on which final orders and notices of appeal were filed in each case. This Court possesses appellate jurisdiction pursuant to Pennsylvania Rule of Appellate Procedure 341(a).

II. STATEMENT OF THE SCOPE AND STANDARD OF REVIEW

This Court exercises *de novo*, entirely non–deferential review of a trial court's order granting summary judgment. As the unanimous Supreme Court of Pennsylvania recently explained:

> Since the issue as to whether there are no genuine issues as to any material fact presents a question of law, our standard of review is *de novo*; thus, we need not defer to the determinations made by the lower tribunals. Our scope of review, to the extent necessary to resolve the legal question before us, is plenary.

Chanceford Aviation Properties, L.L.P. v. *Chanceford Tp. Bd. of Supervisors*, 592 Pa. 100, 107, 923 A.2d 1099, 1103 (2007). That decision recognizes that an appellate court "must view 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." *Id.*

Both this Court and the Pennsylvania Supreme Court have held that "[s]ummary judgment is to be entered only in the clearest of cases where there is not the slightest doubt as to the absence of a triable issue of fact." *See Wells Fargo Bank, N.A.* v. *Long*, 934 A.2d 76, 77 (Pa. Super. Ct. 2007); *see also Trowbridge* v. *Scranton Artificial Limb Co.*, 560 Pa. 640, 644, 747 A.2d 862, 864 (2000) ("Because this is an appeal from the grant of a motion for summary judgment, our standard of review is well settled. Summary judgment may be granted only in the clearest of cases where the record shows that there are no genuine issues of material fact and also demonstrates that the moving party is entitled to judgment as a matter of law.").

III. TEXT OF THE ORDERS IN QUESTION

Judge Allan L. Tereshko of the Court of Common Pleas of Philadelphia County issued the summary judgment orders being challenged on appeal. The first case in which the trial court entered summary judgment based on the supposed expiration of the statute of limitations was *Coleman* v. *Wyeth*, No. 2678 EDA 2007. In granting summary judgment in the defendants' favor in the remaining 13 cases, Judge Tereshko relied heavily on his Order in *Coleman*, which states, in full:

> 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.

Attachments to Brief for Appellant ("Attachments") at 26.

IV. STATEMENT OF THE QUESTIONS PRESENTED

1. 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?

2. 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 — notwithstanding Pennsylvania's strong preference for jury resolution of the discovery rule's 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?

V. STATEMENT OF THE CASE

A. The medications and their warnings

The women who have sued as plaintiffs in these 14 consolidated appeals have alleged that defendants' prescription hormone therapy drugs caused their breast cancer. *See, e.g.,* R.1533a. Plaintiffs' physicians prescribed hormone therapy to treat vasomotor symptoms of menopause, such as hot flashes and vaginal dryness. The Wyeth defendants manufacture and market Premarin, a conjugated estrogen ("E") drug made from the urine of pregnant mares, and Prempro, a combination of Premarin and medroxyprogesterone acetate ("MPA"), a progestin that is the chemical equivalent of Provera. Defendant Upjohn manufactures and markets the prescription medication Provera, which is a synthetic progestin ("P"). Because plaintiffs had intact uteruses, and using estrogen alone can cause endometrial cancer, plaintiffs were given a combination of estrogen and progestin to reduce the risk of developing endometrial cancer. This combination of estrogen and progestin is referred to herein as "E+P."

The FDA–approved physician label in use in 1992 for Premarin, Wyeth's estrogen–only drug, 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.**

R.1678a (emphasis added).

The FDA–approved patient package insert for Premarin stated:

> *Cancer of the breast*. **The majority of studies have shown no association with the usual doses** 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.

R.1679a (emphasis added).

The patient insert explained that physicians may choose to prescribe a progestin in combination with Premarin, though the insert contained no mention of any increased breast cancer risk that could result from that combination therapy:

> Some physicians may choose to prescribe another hormonal drug to be used in association with estrogen treatment. These drugs, progestins, have been reported to lower the frequency of occurrence of a possible precancerous condition of the uterine lining. Whether this will provide protection from uterine cancer has not been clearly established. There are possible additional risks that may be associated with the inclusion of a progestin in estrogen treatment. The possible risks include unfavorable effects on blood fats and sugars. The choice of progestin and its dosage may be important in minimizing these effects.

R.1679a.

The patient insert and physician information provided with Provera, the progestin–only drug that Upjohn manufactured, contained no human breast cancer warning at any relevant time. The 1992 product information for Provera stated:

> 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.**

Attachments at 186 (emphasis added).

The 1996 FDA–approved label for Prempro (the combined estrogen/progestin pill ("E+P") manufactured by Wyeth), issued when this drug was first marketed, stated:

> *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 * * *, 5 new cases of breast cancer were detected among 1377 women who received the combination treatments * * *. **The overall incidence of breast cancer in this clinical trial does not exceed that expected in the general population**.

R.1682 (emphasis added).

The Prempro label contained its own beagle dog discussion with regard to that medication's progestin component:

> Beagle dogs treated with MPA 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 growth hormones in dogs. The growth hormones, 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**.

R.1683a (emphasis added).

The patient package insert for Prempro stated:

> *Cancer of the breast.* **Most studies have not shown a higher risk of breast cancer in women who have ever 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 time periods. **The effects of added progestin on the risk of breast cancer are unknown**. Some studies have reported a somewhat increased risk, even higher than the possible risk associated with estrogens alone. **Others have not**.

R.1684a (emphasis added).

In sum, at the time when plaintiffs' physicians were prescribing these drugs in combination, the labels reassured them that the majority of studies showed no increased risk of breast cancer. R.1682a. According to the labels, the only data showing any risk involved using estrogen at high doses or for especially long durations. *Id.* The effect of adding progestins was admittedly unknown. *Id.* The label further alleviated any potential worry for risk of breast cancer by advising that a clinical trial using combination therapy (E+P) showed no higher rate of breast cancer than the expected background rate in the general population. *Id.* In other words, the Prempro label plainly stated that, according to Wyeth's own studies, women using a combination of estrogen and progestin had no greater risk of developing breast cancer than women who were not ingesting those drugs. *Id.*

The Premarin and Prempro labels contained a "contraindication" stating that women who **already have** breast cancer should not take estrogen–containing products. R.1678a, 1682a. It is not contested that estrogen can fuel the growth of an already existing tumor. Thus, women, like plaintiffs here, are removed from

hormone supplements as soon as they are diagnosed with breast cancer. *See, e.g.,* R.1337a, 1666a, 1672a, 1674a. This contraindication does not suggest or imply that hormones caused the cancer to exist in the first instance. The defendants offer no evidence otherwise, much less evidence establishing their entitlement to summary judgment as a matter of law.

Thus, when these women were receiving combined hormone therapy treatment, doctors and patients had no reason to believe that E+P caused breast cancer based on the FDA–approved labeling, so long as the patients were not taking either "higher doses" of estrogen or estrogen for extended periods of time. In seeking summary judgment in these 14 cases, defendants did not assert that any of the plaintiffs ingested estrogen in high doses or for an atypically long duration, nor did the trial court so find in granting summary judgment in defendants' favor.

B. Publication of the Women's Health Initiative ("WHI") results

A reliable link to alert women that there was a causal connection between E+P and breast cancer was first established on July 9, 2002. On that date, the results from the Women's Health Initiative ("WHI") study's estrogen plus progestin arm were released early at the web site of the Journal of the American Medical Association, publicizing the groundbreaking findings that Prempro could cause breast cancer.[1] Attachments at 187–99. The WHI was a randomized controlled trial

[1] *See* "Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women: Principal Results From the Women's Health Initiative Randomized Controlled Trial," Journal of the American Medical Association, Volume 288, No. 3, at page 321 (July 17, 2002). The complete text of this article can be freely accessed via the web site of the Journal of the American Medical

sponsored by the National Institutes of Health ("NIH") to "assess the major health benefits and risks of the most commonly used combined hormone preparation in the United States." Attachments at 187. ("Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women" at 321).

Writing in the Journal of the American Medical Association, the authors of the WHI study explained the context of the study as follows: "Despite decades of accumulated observational evidence, the balance of risks and benefits for hormone use in healthy postmenopausal women remains uncertain." *Id.* The article also explained the study's objective: "To assess the major health benefits and risks of the most commonly used combined hormone preparation in the United States." *Id.* According to the article's authors:

> The WHI is the first randomized controlled trial to confirm that combined estrogen plus progestin does increase the risk of incident breast cancer and to quantify the degree of risk.

Attachments at 196 (*Id.* at 330). The authors noted that "[t]he trial was stopped early based on health risks that exceeded health benefits over an average follow–up of 5.2 years." Attachments at 187 (*Id.* at 321).

The results of the WHI received widespread attention from the popular media. By way of example, the National Cancer Institute of the NIH ("NCI") reported the groundbreaking nature of the WHI study's results as follows:

> Hormone therapy, either estrogen alone or estrogen combined with progestin, has been the subject of numerous studies over the past two

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Association at the following two links: http://jama.ama-assn.org/cgi/content/full/288/3/321 and http://jama.ama-assn.org/cgi/reprint/288/3/321.pdf. For the Court's convenience, the article is attached to this brief at Attachments 187–199.

> decades. Some of the findings have suggested benefits to hormone use; others have suggested risks.
>
> Recently, however, one definitive study has convinced experts that the risks of estrogen plus progestin outweigh the benefits. This large randomized trial, conducted as part of the Women's Health Initiative (WHI) at the National Institutes of Health, was stopped early when it became clear that estrogen plus progestin increased the risk of heart disease, blood clots in the legs and lungs, and breast cancer.

See Summary of the Evidence of the Risks and Benefits of Postmenopausal Use of Hormones, BenchMarks (Aug. 20, 2002) (available online at: http://www.cancer.gov/newscenter/archive/benchmarks-vol2-issue8/page2). The NCI explained that "[t]he highest level of evidence for a causal association between hormone exposure and disease or condition is achieved with a randomized, controlled, blinded, clinical trial," which is the very type of study that the WHI represented. *Id.*; *see also* R.1706a–07a ("The WHI proved definitively what 30 earlier studies could not: HRT does indeed raise the risk of developing invasive breast cancer.").

C. The relevant facts and procedural history of the cases consolidated on appeal

Plaintiffs claim that E+P caused their breast cancer. While it is true that each plaintiff commenced her suit more than two years after receiving her breast cancer diagnosis, each sued within two years of the publication of the WHI study's results on July 9, 2002. Plaintiffs thus sued within two years from the date on which a reliable causal connection between E+P and breast cancer was made known to them, to the medical community, and to general public.

Judge Tereshko granted summary judgment in favor of defendants in all 14 of these cases, holding that plaintiffs' claims were time–barred due to expiration of

the applicable two–year statute of limitations. He concluded that plaintiffs had known or reasonably should have known that E+P had caused their breast cancer on being diagnosed with that disease. In his view, the discovery rule did not and could not toll the start of the two–year limitations period in any of these cases.

In 13 of the cases (all but *Coleman*), the trial court granted summary judgment in the absence of any discovery whatsoever, based solely on the plaintiff's complaint and associated "fact sheet," consisting of written responses to a court–approved written questionnaire. In many of these cases, the plaintiffs submitted affidavits in response to the summary judgment motions to make clear that their fact sheet answers should not be misconstrued to entitle defendants to summary judgment on statute of limitations grounds.

The specific facts and procedural history of the 14 cases are set forth below:

Manalo

Plaintiff Graciana Manalo was diagnosed with breast cancer in November 2000. R.2967a. She and her husband filed suit against Wyeth only on July 2, 2004. R.2947a. On her fact sheet, she indicated that sometime in November 2000 she was told that her condition "may be related" to the use of hormone therapy medications. R.3060a.

By affidavit, Mrs. Manalo explained that her "may be related" statement on the fact sheet referred to the fact that, in 2001, she had asked the physician who had diagnosed her breast cancer what had caused the disease. R.3013a. Her physician responded that it may have been caused by any number of things,

including hormone therapy. *Id.* The same physician told Mrs. Manalo at that time that there was no way to confirm what actually caused her breast cancer. *Id.* Mrs. Manalo further testified that she did not learn that hormone therapy could cause breast cancer until early 2004, when she saw a television advertisement reporting that the Woman's Health Initiative study had established a causal link between breast cancer and Wyeth's hormone therapy medications. R.3014a.

Wyeth filed its motion for summary judgment on November 15, 2007, arguing that plaintiff's action was time–barred. R.2953a. The trial court granted Wyeth's motion for summary judgment on statute of limitations grounds on January 7, 2008. R.3314a. Plaintiffs filed a timely appeal on February 1, 2008. R.3315a.

Blaylock*, *Fleming–Crain*, *Hansen*, *Honaker*, *Lenzi*, *Morales*, *Reed*, *Schirn*, *Stephenson*, and *Weinberger

The plaintiffs in these 10 cases are residents of California. While California law imposed a one–year statute of limitations at the time these plaintiffs filed suit, a law enacted thereafter extended the limitations period to two years for all claims not yet time–barred. *See* Calif. Code. Civ. P. §335.1 (extending statute of limitations to two years effective January 1, 2003); *Andonagui* v. *May Dep't Stores Co.*, 128 Cal. App. 4th 435, 440, 27 Cal. Rptr. 3d 145, 148 (Cal. Ct. App. 2d Dist. 2005) (recognizing, under longstanding precedent from the Supreme Court of California, that "[a] new statute that enlarges a statutory limitations period applies to actions that are not already barred by the original limitations period at the time the new statute goes into effect"); *Mojica* v. *4311 Wilshire, LLC*, 131 Cal. App. 4th 1069, 1072–73, 31 Cal. Rptr. 3d 887, 889 (Cal. Ct. App. 2d Dist. 2005) (same).

Under California law, as under Pennsylvania law, the discovery rule operates to postpone the commencement of the statute of limitations applicable to a cause of action. *See Fox* v. *Ethicon Endo–Surgery, Inc.*, 35 Cal. 4th 797, 810–11, 110 P.3d 914, 922–23, 27 Cal. Rptr. 3d 661, 670–71 (2005). And in California, as in Pennsylvania, whether to apply the discovery rule ordinarily presents a question of fact for the jury. *See id.* at 810, 110 P.3d at 922, 27 Cal. Rptr. 3d at 670.

Judge Tereshko ruled that the claims of these 10 California plaintiffs were time–barred using either State's prescriptive period because, in his view, the plaintiffs could not invoke the discovery rule. *See* Attachments at 41–117. If plaintiffs could invoke the discovery rule, their claims would be timely under the two–year statute of limitations that would apply under both California and Pennsylvania law.

Plaintiff Hazel Blaylock was diagnosed with breast cancer in December 2000. R.2874a. She filed suit against Wyeth and Upjohn in June 2004, within two years of the WHI study's results. R.2850a. On the fact sheet filed shortly after her complaint, Ms. Blaylock checked a line indicating that, in November 2001, her physician informed her that her breast cancer "is related" to hormone therapy drugs. R.2900a. The fact sheet contained no definition for the phrase "is related to" and does not even suggest that defendants intended to interpret this phrase to mean that the plaintiff was aware of what "caused" her breast cancer.

If defendants had wanted to know on what date the plaintiff knew the cause of her breast cancer, defendants could have asked that question. Instead, the

defendants asked a question that requests the plaintiff to explain any conversations with physicians about breast cancer and use of hormones, including any discussion about being removed from hormone therapy when the plaintiff was diagnosed with breast cancer (because of the contraindication of continuing these drugs after diagnosis). R.2900a. Checking the "is related" or "may be related" line on the fact sheet does not necessarily confirm anything more than that the plaintiff was told to stop taking hormone therapy drugs when she was diagnosed with breast cancer because of the relationship between continued use of such drugs and growth of her tumor.

Indeed, in an affidavit that Ms. Blaylock filed in opposition to defendants' summary judgment motion, she explained just this: that she checked the "is related" line on the fact sheet because, "[w]hen I was diagnosed with breast cancer, my doctor told me that I should stop taking the hormone replacement therapy." R.2924a. Ms. Blaylock further testified:

> My doctor never told me that the HRT caused the tumor in the first place. The first time I became aware that the HRT was an actual cause of my breast cancer was after the Women's Health Initiative report was released in July of 2002. I did not discover the cause of my injury until sometime after that date. My lawsuit was filed within two years of the date that I discovered the cause of my injury.

R.2924a.

Similarly, plaintiffs Nancy and Richard Honaker, Vicki Lenzi, Judy and Gerald Reed, Zanda and Robert Schirn, Kathleen Taw Stephenson and Michael Taw, and Mary Weinberger also filed their complaints within two years of publication of the WHI study's results but more than two years after those women

were diagnosed with breast cancer. R.1526a–33a, 1849a–56a, 2008a–15a, 2308a–12a, 2416a–23a, 2642a–46a. They also completed fact sheets in which they indicated that they had discussed with a physician a relationship between their breast cancer and hormone therapy. R.1568a, 1873a, 2045a, 2342a, 2451a, 2682a.

These women likewise signed affidavits explaining that they checked the "related" box on the fact sheet because they thought the question referred to discussions with their physicians about being taken off of hormone therapy drugs when they were diagnosed with breast cancer. R.1666a, 1939a, 2122a, 2369a, 2482a, 2704a. Each of these plaintiffs affirmed that they did not discover what caused their breast cancer until after publication of the WHI study's results in July 2002. *Id.*

Even though no discovery had been conducted in these cases, and the plaintiffs' affidavits raised clear questions of material fact, the trial court granted summary judgment in each case, holding that the actions were filed too late under either Pennsylvania or California law.

In addition, plaintiffs Peggy Fleming–Crain, Virginia Hansen, and Diane Morales all filed suit against defendants within two years of the publication of the WHI study's results. R.2147a, 2507a, 2729a. These plaintiffs also indicated on their fact sheets that they had discussed with their physicians a relationship between their breast cancer and hormone therapy medications. R.2207a, 2555a, 2785a. Even though no discovery was conducted in any of these cases, summary judgment was granted in favor of defendants, and against each plaintiff, based on the trial court's

conclusion that the actions were time–barred under either Pennsylvania or California law.

* * * * *

Wyeth moved for summary judgment on statute of limitations grounds in each of these ten cases on June 7, 2007. R.1511a, 1834a, 1993a, 2155a, 2290a, 2401a, 2514a, 2632a, 2736a, 2835a. On October 12 and 18, 2007, the trial court granted summary judgment in favor of Wyeth, holding that plaintiffs' claims in all 10 cases were time–barred. R.1815a, 1980a, 2137a, 2273a, 2384a, 2496a, 2615a, 2719a, 2818a, 2939a. On November 6, 2007, the court entered an order recognizing that Upjohn had earlier joined in various of Wyeth's statute of limitations summary judgment motions and that Upjohn was likewise entitled to summary judgment. R.1816a. Plaintiffs filed timely notices of appeal in all ten cases on November 7, 2007. R.1818a, 1981a, 2138a, 2274a, 2385a, 2497a, 2616a, 2720a, 2819a, 2940a.

Medwid

Plaintiffs Patricia Medwid was diagnosed with breast cancer in April 1998. R.1263a. She and her husband filed suit against Wyeth only on July 7, 2004. R.1259a. On her fact sheet, Mrs. Medwid indicated that in 1998 she was told that her condition "is related" to the use of hormone therapy medications. R.1312a.

By affidavit, Mrs. Medwid explained that her "is related" statement on the fact sheet referred only to the fact that she was told that estrogen would make her breast cancer tumor grow more rapidly. R.1337a. Mrs. Medwid further testified that she was not told in 1998 that her breast cancer was caused by hormone therapy

medications. *Id.* In fact, she did not learn that "Prempro could have been a cause of my breast cancer" until after July 9, 2002. R.1338a.

When Wyeth moved for summary judgment in the *Medwid* case on the statute of limitations in August 2007, no discovery had occurred in that case. The trial court granted Wyeth's motion on October 4, 2007. R.1495a. Plaintiffs filed their timely notice of appeal on November 2, 2007. R.1496a.

Hess

Plaintiff Carol Hess was diagnosed with breast cancer in April 2002. R.3346a. She filed suit against Wyeth in June 2004. R.3342a. On her fact sheet, Ms. Hess did not disclose that any physician had told her that her breast cancer was related to hormone therapy medication. R.3431a. Ms. Hess also testified by affidavit that she did not learn that her breast cancer may be related to Wyeth's hormone therapy medication until after the release of the results of the WHI study on July 9, 2002. R.3389a.

Wyeth filed its motion for summary judgment on October 22, 2007, arguing that plaintiff's action was time–barred. R.3331a. The trial court granted Wyeth's summary judgment motion on January 10, 2008. R.3656a. Plaintiff filed a timely notice of appeal on February 7, 2008. R.3657a.

Coleman

Plaintiff Elizabeth Coleman was diagnosed with breast cancer on October 20, 2000. R.437a. She and her husband filed suit against Wyeth and Upjohn on June 28, 2004. R.8a. The *Coleman* action was selected as a bellwether case for the first

round of hormone therapy trials in the Court of Common Pleas of Philadelphia County. Thus, unlike the other cases, in *Coleman* a substantial amount of discovery has occurred.

On September 24, 2007, shortly before trial in the *Coleman* case was to begin, Judge Tereshko granted Wyeth's motion for summary judgment on statute of limitations grounds, which had been filed in February of that year. Attachments at 26. Plaintiffs filed their timely notice of appeal on October 9, 2007. R.1158a.

In granting Wyeth's motion, Judge Tereshko relied on the following deposition testimony by Mrs. Coleman:

> 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 that 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.

Attachments at 10–11.

Later in her deposition, however, Mrs. Coleman clarified her response:

> Q: Is there anything about your answer you want to change?
>
> A: 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.
>
> Q: All right. So, is your testimony now that when the doctor told you that your cancer was estrogen receptor positive, is your testimony, now, after this break, that you don't think that meant it was related to hormones?
>
> A: At the time, I — we did not discuss it, and I — I never gave it a thought as to that.

R.188a.

The summary judgment record in *Coleman* also contains the deposition testimony of the two gynecologists who had prescribed E+P for Mrs. Coleman. Dr. Haynes Jackson, Jr., who served as Mrs. Coleman's gynecologist from 1991 through 1998, testified under oath that, in his opinion, whether combination hormone replacement therapy caused breast cancer was an unresolved matter that remained in dispute between 1991 and 1998. R.161a–64a.

In November 1998, Dr. David Greathouse became Mrs. Coleman's gynecologist. He continued to prescribe E+P for Mrs. Coleman until April 2000, when she had a hysterectomy. R.224a. After her uterus was removed in April 2000, until she was diagnosed with breast cancer in October 2000, Mrs. Coleman took Premarin, Wyeth's estrogen–only medication. *Id.* Dr. Greathouse testified under oath at his deposition that the breast cancer risk from combined hormone replacement therapy was confusing, conflicting, and essentially unknown before the results of the WHI study were released on July 9, 2002. R.221a, 238a.

VI. SUMMARY OF THE ARGUMENT

The trial court's entry of summary judgment based on the supposed expiration of the statute of limitations applicable to plaintiffs' claims in these fourteen cases is erroneous and must be reversed for two separate and independent reasons.

First, under Pennsylvania law, a plaintiff's claim does not even accrue, and therefore the statute of limitations applicable to that claim does not begin to run, until the plaintiff is capable of proving each of the elements of her claim. Before the results of the WHI study became public on July 9, 2002, these plaintiffs were unable to establish by a preponderance of the evidence, using generally accepted scientific proof, that ingesting defendants' combination hormone therapy drugs caused breast cancer. Until plaintiffs were capable of proving that ingesting defendants' hormone therapy drugs causes breast cancer, plaintiffs could not prove that *their* ingestion of defendants' hormone therapy drugs caused *their* breast cancer.

Accordingly, under Pennsylvania law, plaintiffs' claims did not accrue until, at the earliest, July 9, 2002, when reliable scientific evidence first became available establishing a scientifically accepted causal link between combination hormone therapy and breast cancer. Because all 14 of these cases were initiated within two years of July 9, 2002, the trial court erred as a matter of law in holding that any of these plaintiffs' claims were time–barred.

Second, under Pennsylvania law it is well–established that whether to apply the discovery rule to postpone the start of the statute of limitations applicable to a claim generally presents a jury question. The factual record in these 14 cases, when viewed in a light most favorable to the plaintiffs, establishes that whether combination hormone therapy did or did not cause breast cancer remained a seriously disputed issue within the medical community until at least July 9, 2002. None of the plaintiffs in these 14 cases has unambiguously admitted that she knew, before July 9, 2002, that defendants' combination hormone therapy drugs caused her breast cancer. And a reasonable jury could easily conclude that these women neither knew nor should have known — more than two years before they filed suit — that their breast cancer had been caused by defendants' combination hormone therapy drugs.

For all of these reasons, as examined in more detail below, the trial court erred in holding, on summary judgment, that plaintiffs' claims were time–barred. The judgments appealed from should be reversed, and these cases should be remanded for further proceedings in the trial court.

VII. ARGUMENT

A. The Trial Court Erred In Holding, On Summary Judgment, That Plaintiffs' Claims For Negligent Failure To Warn Were Time–Barred Because Plaintiffs Did Not Initiate Suit Within Two Years Of Being Diagnosed With Breast Cancer

1. Plaintiffs' claims did not accrue until at least July 9, 2002, because before that date plaintiffs could not establish by a preponderance of the evidence that hormone therapy causes breast cancer

Wyeth's pre–July 2002 labeling for Premarin and Prempro actually reassured physicians and patients that there was likely no risk of breast cancer from using the drugs at issue in this case by stating:

- The majority of studies show no breast cancer risk from **any** use of estrogen;
- The only studies showing a risk involved estrogen use at high doses or for long duration (10 years or more);
- The effect of adding progestins to estrogen was unknown;
- Some studies suggest adding progestins has no effect on the risk from estrogen, if any; and
- A clinical trial of combination therapy (E+P) showed no greater incidence of breast cancer among E+P users than the expected breast cancer rate of the general population.

R.1678a–79a, 1682a–84a.

Furthermore, Upjohn's pre-July-2002 Provera labeling contained no human breast cancer warning at all, instead referring only to mammary nodules in beagle dogs and then immediately clarifying that these findings have no bearing on human breast cancer risk. Attachments at 186.

The salient feature of Wyeth's and Upjohn's labeling for the prescription medications at issue in this appeal is that, before July 2002, that labeling provided no warning about the possibility of a **causal link** between hormone therapy and an increased risk of breast cancer. Wyeth's and Upjohn's FDA–approved labels — in use before the July 2002 announcement of the WHI results — collectively reflected the state of scientific knowledge within the medical community at that time.[2]

Under Pennsylvania law, a claim does not accrue, for statute of limitations purposes, until "the plaintiff could have first maintained the action to a successful conclusion." *Fine* v. *Checcio*, 582 Pa. 253, 266, 870 A.2d 850, 857 (2005); *Buchleitner* v. *Perer*, 794 A.2d 366, 376 (Pa. Super. Ct. 2002); *see also Reitz* v. *County of Bucks*, 125 F.3d 139, 144 (3d Cir. 1997) (applying Pennsylvania law). In turn, maintaining a lawsuit to a successful conclusion requires a plaintiff to be able to prove each of the elements of her claim by a preponderance of the evidence.

These cases involve claims for negligent failure to warn. In Pennsylvania, a negligence claim has four elements: "To establish a cause of action in negligence, the plaintiff must demonstrate that the defendant owed a duty of care to the plaintiff, the defendant breached that duty, the breach resulted in injury to the

[2] Although not at issue in this appeal, plaintiffs herein and the other 1,500–plus plaintiffs in Philadelphia County's hormone therapy litigation intend to prove that Wyeth and Upjohn should have been aware that hormone therapy drugs increase the risk of breast cancer long before the risk was eventually disclosed in July 2002. In response to dozens of red flags or signals, these companies should have conducted comprehensive breast cancer studies that would have revealed what the WHI study did — only decades earlier. These defendants knew that there were unanswered questions about the breast cancer risk and intentionally failed to study that adverse effect. This conduct left patients and doctors in the dark for decades.

plaintiff, and the plaintiff suffered an actual loss or damage." *Martin* v. *Evans*, 551 Pa. 496, 502, 711 A.2d 458, 461 (1998).

Plaintiffs here allege that (a) defendants negligently failed to ascertain, and then warn, plaintiffs' physicians about the true breast cancer risks of E+P; (b) had defendants adequately warned, plaintiffs' physicians would have altered their prescribing habits so that the E+P drugs would not have reached plaintiffs or would have prescribed the combination in the lowest doses for the shortest feasible duration; and thus (c) plaintiffs would have avoided developing breast cancer from their use of these drugs.

In order to prove that defendants' failure to warn caused their injuries (i.e., that plaintiffs would likely have avoided breast cancer had defendants adequately warned), plaintiffs would have to establish scientific causation. That is, plaintiffs would have to establish by a preponderance of the evidence that a scientifically reliable causal connection existed between E+P, at usual doses and duration, and breast cancer. The release of the WHI study's results on July 9, 2002 provided the first piece of that evidence, which has now been proved by more than two dozen epidemiological studies published since 2002.

As plaintiffs have alleged, and as juries here and elsewhere have found, defendants failed to warn of the true breast cancer risk of E+P before WHI. Although defendants were capable of performing, and had a legal duty to perform, a scientifically reliable study to determine this risk, none of these 14 plaintiffs had the means to study the risk. None could perform a scientifically reliable study to

determine whether E+P caused or promoted the development of her own breast cancer.

Thus, there is no basis for concluding — as a matter of law, no less — that plaintiffs, had they undertaken "diligent investigation," would have come to a conclusion different than that of the FDA — the federal agency charged with drug regulation. Plaintiffs would have concluded, as did the FDA when the agency approved the defendants' warnings, that the majority of studies showed no increased risk, and even the clinical trial confirmed the same breast cancer rate for E+P users as the background population. R.1682a.

Tellingly, after publication of the WHI results on July 9, 2002, the FDA substantially changed the warnings on defendants' products. Today, the label expressly warns, in a prominent black box, that E+P increases the risk of invasive breast cancer. R.3244a. The label then proceeds to recommend that physicians who decide to prescribe those medications to treat vasomotor symptoms of menopause should use only the smallest effective dose for the shortest possible amount of time. R.3244a.

To be sure, Judge Tereshko was theoretically correct in observing that the prescriptive period may begin before a plaintiff has conclusive proof that her particular injury was caused by the defendant's negligent conduct. *See* Attachments at 11. But, at a minimum, the prescriptive period could not begin to run until it could be proved that the defendant's negligence was actually capable of causing the plaintiff's injury. A plaintiff's ability to prove that E+P caused breast cancer did not

exist until at least July 9, 2002, when the results of the WHI study became public. *See, e.g.*, R.1706a–07a ("The WHI proved definitively what 30 earlier studies could not: HRT does indeed raise the risk of developing invasive breast cancer.").

Moreover, accepting defendants' argument that the statute of limitations applicable to plaintiffs' claims began to run — and, in certain of these cases, had in fact *expired* — before plaintiffs were capable of proving that E+P caused breast cancer would impermissibly endorse the trial court's perverse "heads I win, tails you lose" result in defendants' favor.

For plaintiffs to establish that defendants' E+P medications caused plaintiffs' breast cancer necessarily requires expert testimony. In Pennsylvania, which continues to apply the *Frye* test, *see Frye* v. *United States*, 293 F. 1013 (D.C. Cir. 1923), to determine the admissibility of expert scientific testimony, the proponent of such testimony must show that "the scientific community [has] reach[ed] some consensus as to reliability" of the expert's approach. *Blum* v. *Merrell Dow Pharmaceuticals, Inc.*, 564 Pa. 3, 6, 764 A.2d 1, 3 (2000); *see also Grady* v. *Frito–Lay, Inc.*, 576 Pa. 546, 557, 839 A.2d 1038, 1044–45 (2003) (noting that the goal of the *Frye* test is to "insure that only reliable expert scientific evidence is admitted at trial").

WHI became the first study that was generally accepted within the scientific community as establishing E+P as a cause of breast cancer because the approach that WHI used was much more scientifically reliable than the preceding studies that had examined the question. R.1706a–07a. Moreover, the results of the studies

that preceded WHI were conflicting and were not understood as demonstrating, in a generally accepted and scientifically reliable manner, that E+P caused breast cancer. *Id.*

Before the results of the WHI study became known on July 9, 2002, even if both a patient and her physician believed E+P had caused the patient's breast cancer, neither would have been able to offer generally accepted scientific proof of causation to establish that E+P caused breast cancer by a preponderance of the evidence. They could not have established more than the FDA had based on its review of the results of the relevant pre–WHI studies. Under Pennsylvania law, a claim does not even begin to accrue until the plaintiff is capable of establishing all facts necessary to prevail on that claim. *See Fine*, 582 Pa. at 266, 870 A.2d at 857; *Buchleitner*, 794 A.2d at 376.[3] The trial court thus erred in holding that plaintiffs' claims were time–barred.

2. Additionally, the trial court erred in holding that no reasonable jury could find that plaintiffs initiated suit within two years of when they knew or should have known that defendants' drugs caused their breast cancer

At a minimum, plaintiffs are entitled to jury consideration of their invocation of the "discovery rule." Under Pennsylvania law, "the statute of limitations begins to run as soon as a right to institute and maintain suit arises." *Crouse* v. *Cyclops*

[3] California law is in accord. *See Fox*, 35 Cal. 4th at 815, 110 P.3d at 925, 27 Cal. Rptr. 3d at 674 ("It would be contrary to public policy to require plaintiffs to file a lawsuit at a time when the evidence available to them failed to indicate a cause of action. * * * Indeed, it would be difficult to describe a cause of action filed by a plaintiff, before that plaintiff reasonably suspects that the cause of action is a meritorious one, as anything other than frivolous.") (internal quotations omitted).

Indus., 560 Pa. 394, 403, 745 A.2d 606, 611 (2000). Yet Pennsylvania law also recognizes the discovery rule, which the Supreme Court has described as "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." *Id.* at 404, 745 A.2d at 611.

In *Fine*, a unanimous Supreme Court of Pennsylvania addressed the role of the trial judge and the jury in applying the discovery rule in language that is directly relevant to the outcome of these 14 appeals:

> [W]hen a court is presented with the assertion of the discovery rule's application, it must address the ability of the damaged party, exercising reasonable diligence, to ascertain that he has been injured and by what cause. Since this question involves a factual determination as to whether a party was able, in the exercise of reasonable diligence, to know of his injury and its cause, *ordinarily, a jury is to decide it*. Where, however, reasonable minds would not differ in finding that a party knew or should have known on the exercise of reasonable diligence of his injury and its cause, the court determines that the discovery rule does not apply as a matter of law.
>
> When the discovery rule applies, the statute of limitations does not commence to run at the instant that the right to institute suit arises, i.e., when the injury occurs. Rather, the statute is tolled, and does not begin to run until the injured party discovers or reasonably should discover that he has been injured and that his injury has been caused by another party's conduct. Whether the statute of limitations has run on a claim is a question of law for the trial court to determine; *but the question as to when a party's injury and its cause were discovered or discoverable is for the jury*.

Fine, 582 Pa. at 267–68, 870 A.2d at 858–59 (emphasis added).

When a person is injured and knows that his injury resulted from another party's conduct, the statute of limitations begins to run at the time the injury

occurred. However, if a person is unaware of the injury *or* of the fact that the injury was caused by another party's conduct, despite the exercise of reasonable diligence, the "discovery rule" applies. The statute of limitations does not begin to run "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*, 560 Pa. at 404, 745 A.2d at 611 (emphasis added); *see also Fine*, 582 Pa. at 266–67, 870 A.2d at 858 (same).

Ordinarily, as Pennsylvania's highest court has recognized, the "exercise of reasonable diligence" test presents a jury question rather than a legal issue that a trial court may decide on its own as a matter of law. *Fine*, 582 Pa. at 267–68, 870 A.2d at 858–59.

Similarly, in *Crouse*, the Supreme Court explained:

> Pursuant to application of the discovery rule, the point at which the complaining party should reasonably be aware that he has suffered an injury is a factual issue "best determined by the collective judgment, wisdom and experience of jurors." Thus, once the running of the statute of limitations is properly tolled, only where the facts are so clear that reasonable minds *cannot differ* may the commencement of the limitations period be determined as a matter of law.

Crouse, 560 Pa. at 404, 745 A.2d at 611 (citations omitted; emphasis in original); *see also Miller* v. *Ginsberg*, 874 A.2d 93, 97–98 (Pa. Super. Ct. 2005) (recognizing that the "discovery rule" ordinarily presents a jury question).

Most recently, in *Wilson* v. *El–Daief*, No. 39 MAP 2008, 2009 WL 400656 (Pa. Feb. 19, 2009), the Supreme Court of Pennsylvania unambiguously reemphasized that where conflicting evidence exists over when a given plaintiff should have

reasonably known that her injury resulted from the negligent conduct of another, whether the discovery rule should apply is a question for the jury to decide. *Id.* at *9–*10.

In articulating the contours of Pennsylvania's discovery rule, the Supreme Court observed in *Fine* that "reasonable diligence is not an absolute standard, but is what is expected from a party who has been given reason to inform himself of the facts upon which his right to recovery is premised." *Fine*, 582 Pa. at 267, 870 A.2d at 858. And, although "there are [very] few facts which reasonable diligence cannot discover*, there must be some reason to awaken inquiry and direct diligence in the channel in which it would be successful*." *Id.* (internal quotations omitted; emphasis added). Perhaps most importantly, *Fine* was clear about the subjectivity of Pennsylvania's standard:

> Put another way, "the question in any given case is not, what did the plaintiff know of the injury done him? But, what might he have known, *by the use of the means of information within his reach*, with the vigilance the law requires of him?" While reasonable diligence is an objective test, "'it 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 in question.*'" Under this test, a party's actions are evaluated to determine whether he exhibited "'those qualities of attention, knowledge, intelligence and judgment which society requires of its members for the protection of their own interest and the interest of others.'"

Id. (internal citations omitted; emphasis added).

Here, to be sure, in moving for summary judgment, the defendants cited to certain studies and articles about them, which preceded announcement of the WHI results and which suggested that a causal connection may exist between combined

hormone therapy drugs and breast cancer.[4] And hormone therapy plaintiffs, including appellants herein, may rely on similar evidence to show that defendants were derelict in failing to earlier conduct — or even commission — a scientifically reliable study to definitively determine whether combined hormone therapy drugs can cause breast cancer.[5] But *Fine* teaches that Pennsylvania's discovery rule is not anchored to what the *defendant* could reasonably know. Nor is it anchored to what the trained medical community could reasonably know. Rather, Pennsylvania's "flexible" standard asks whether each of these hormone therapy plaintiffs was reasonably diligent in searching out the cause of her injury by the use of "the means of information within [her] reach" and in view of "[her] capacity to meet certain situations and the circumstances confronting [her] at the time in question." *Id.* And *Fine* makes clear that this question is for the jury.

The facts of these 14 cases are even more compelling in favor of applying the discovery rule than were the facts of *Fine* and *Wilson*, in which the Supreme Court of Pennsylvania held that a jury could apply the discovery rule to find that plaintiffs' claims were timely. The *Fine* case involved two separate plaintiffs who

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[4] As an aside, defendants' position below that these plaintiffs should earlier have been aware of the risk of breast cancer associated with hormone therapy flies in the face of defendants' routine disavowal in litigation that an association even exists.

[5] Indeed, it was the absence of any such studies that enabled defendants to continue to maintain, up until the WHI results were released in July 2002, that combination hormone therapy presented women with no greater risk of breast cancer than they would have faced without taking such medications, and that "the effect of added progestins on the risk of breast cancer is unknown." R.1682a (1996 PDR for Prempro).

claimed that their dentists had negligently extracted their wisdom teeth, causing permanent facial numbness. 582 Pa. at 260–64, 870 A.2d at 854–56. The plaintiffs sued more than two years after their dental surgeries, but plaintiffs argued that they had sued within two years of when they had reasonably realized that their facial numbness had resulted from the allegedly negligent surgeries. *Id.*

At all relevant times, the plaintiffs in *Fine* had the ability to discover that the negligent extraction of wisdom teeth was scientifically recognized as a cause of facial numbness. They simply failed to recognize that it was the cause of *their* facial numbness. On that record, Pennsylvania's highest court ruled that the plaintiffs' failure to recognize that one scientifically possible cause — the dental surgeons' negligence — was the cause of their facial numbness was not so objectively unreasonable that a jury should be precluded from finding that the lawsuits were timely under the discovery rule. *Id.* at 272–76, 870 A.2d at 861–63.

In *Wilson*, a woman sued her wrist surgeon for having negligently lacerated the radial nerve in her wrist during a surgical procedure. 2009 WL 400656, at *1. The surgery had occurred in August 2000, but the plaintiff did not initiate suit against the surgeon until October 2003. *Id.* The summary judgment record revealed that another doctor who examined the plaintiff following the surgery had concluded, more than two years before the plaintiff filed suit, that her pain may have resulted from laceration of the radial nerve. *Id.* at *3–*4. Thus, it was clear in *Wilson* that the plaintiff could have learned, before the original time to sue had expired, that her surgeon's negligence may have been to blame for her injury simply by

requesting that other doctor's records. Moreover, the plaintiff, during her deposition, had testified that she had first concluded that her injury may have resulted from her surgeon's negligence in September 2001, more than two years before she filed suit. *Id.* at *10.

Despite these facts that were seemingly unfavorable to the plaintiff's invocation of the discovery rule — including plaintiff's own deposition testimony that she realized her doctor was negligent more than two years before filing suit — the Supreme Court of Pennsylvania in *Wilson* nevertheless held that plaintiff's invocation of the discovery rule presented a jury question. *Id.* at 9 & n.12.

In *Wilson*, as in *Fine*, it was ascertainable as a matter of accepted scientific knowledge that the injuries that the plaintiffs sustained could have resulted from their surgeons' negligence. In these consolidated 14 appeals, by contrast, plaintiffs could not present sufficient scientific evidence that E+P caused their breast cancer until July 9, 2002, fewer than two years before they filed suit. Thus here, unlike in *Wilson* and *Fine*, there was no "channel" in which plaintiffs' inquiry "would be successful" because, until the publication of the WHI study's results on July 9, 2002, it had not been scientifically proved that combined hormone therapy caused breast cancer.

As this Court explained in *Stein* v. *Richardson*, 448 A.2d 558 (Pa. Super. Ct. 1982) (en banc):

> the principle emerges that three independent phases of knowledge must be known or knowable to plaintiff before the limitation period commences: (1) knowledge of the injury; (2) knowledge of the operative

> cause of the injury; and (3) knowledge of the causative relationship between the injury and the operative conduct.

Id. at 563 (internal quotations omitted).

Here, as explained above, plaintiffs could not establish by a preponderance of the evidence the "causation relationship between the injury and the operative conduct" before release of the WHI results on July 9, 2002. Thus, the third element necessary to start the running of the statute of limitations on plaintiffs' claims was missing until at least July 9, 2002. The second element was also missing because a reasonable jury would not be forced to conclude that plaintiffs had "knowledge of the operative cause of the injury" until after that same date.

In the *Hess* case, for example, Ms. Hess did not disclose on the fact sheet filed with her complaint that any physician had told her that her breast cancer was related to hormone therapy medication. R.3431a. Ms. Hess testified that she did not learn that her breast cancer may be related to Wyeth's hormone therapy medication until after July 9, 2002, when the publicity surrounding the WHI study's results first came to her attention. R.3389a. There is no evidence contradicting her sworn testimony.

In the other 12 cases decided at their outset and in the absence of any discovery, the plaintiffs had answered "fact sheet" interrogatories stating that they had been advised that their breast cancer "is related" or "may be related" to defendants' hormone therapy medications. Judge Tereshko, in granting defendants' motions for summary judgment in those twelve cases, improperly ruled that plaintiffs' fact sheet answers established as a matter of law that they knew their

breast cancer had been caused by defendants' hormone therapy medications. *See*, *e.g.*, Attachments at 46–47.

A plaintiff's statement on her fact sheet that she had a discussion with a medical professional about whether her breast cancer "was related" or "may be related" to defendants' hormone therapy medication does not necessarily mean that the plaintiff was informed that the defendants' medications *caused* her breast cancer. Such a conclusion requires an impermissible inference in favor of defendants, rather than the non-moving plaintiffs — and an untenable inference at that.

In the various affidavits explaining these "fact sheet" answers, plaintiffs confirmed that they were referring only to the fact that their doctors had told them to discontinue taking hormone therapy drugs after their breast cancer diagnosis. *See*, *e.g.*, R.1337a, 1666a, 3013a–14a. Thus, the "related to" in question was that hormone therapy medications were contraindicated for women diagnosed as having breast cancer. The relationship to which these fact sheet answers referred *was not* that defendants' hormone therapy medications had caused these plaintiffs to have breast cancer. "A 'contraindication' does not attempt to establish or report a cause and effect relationship." *In re Richardson-Merrell, Inc. "Benedictin" Prods. Liab. Litig.*, 624 F. Supp. 1212, 1231 (S.D. Ohio 1985) (*citing* SCHMIDT'S ATTORNEY'S DICTIONARY OF MEDICINE (J. Schmidt, ed. 1985); STEDMAN'S MEDICAL DICTIONARY (W. Dornette 5th ed. 1982)).

In the words of Justice Antonin Scalia, "as many a curbstone philosopher has observed, everything is related to everything else." *California Div. of Labor Standards Enforcement* v. *Dillingham Const., N.A., Inc.*, 519 U.S. 316, 335 (1997) (Scalia, J., concurring). In the context of these consolidated appeals, the statement in a plaintiff's "fact sheet" that she was told that defendants' hormone therapy medications were or may be "related to" the plaintiff's breast cancer does not equate to a statement that the plaintiff was told that defendants' hormone therapy medications *had caused* the plaintiff's breast cancer.

To appreciate this distinction, one need look no further than Wyeth's own pre–WHI labels. Those labels denied any causal link between hormone therapy and breast cancer, instead merely cautioning that women who already have breast cancer should not ingest hormone therapy drugs. R.1682a–83a. There is nothing inconsistent with the explanations provided in plaintiffs' affidavits because those explanations are in essence identical to the position that defendants themselves took in their pre–WHI labels.

The questions that the fact sheets asked, which the defendants helped draft, could have been written to ask when the plaintiff learned that defendants' hormone therapy medications had caused the plaintiff's breast cancer. The fact sheets, however, do not ask that question. The "related to" question actually posed on the fact sheets was clearly intended as a starting point for discovery, and not as the ending point that could support the entry of summary judgment in defendants' favor on statute of limitations grounds.

In the *Coleman* case, as the result of relentlessly clever questioning, the attorney taking Mrs. Coleman's deposition was finally able to trick Mrs. Coleman into saying "Yes. I guess" regarding causation. Mrs. Coleman's actual testimony, in context, is as follows:

> 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 that 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.

Q. Okay.

A. I'm not sure. The time line, you are going to have to excuse me.

R.94a–95a.

Later, Mrs. Coleman sought to correct and clarify her response to the final question quoted above:

> Q: Is there anything about your answer you want to change?
>
> A: 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.
>
> Q: All right. So, is your testimony now that when the doctor told you that your cancer was estrogen receptor positive, is your testimony, now, after this break, that you don't think that meant it was related to hormones?
>
> A: At the time, I — we did not discuss it, and I — I never gave it a thought as to that.

R.188a.

In granting summary judgment in *Coleman*, Judge Tereshko once again impermissibly construed the evidence in a light most favorable to the defendants. In so doing, Judge Tereshko improperly ignored that Mrs. Coleman promptly clarified that she had misspoken. Moreover, it is exceedingly unlikely that a physician who told Mrs. Coleman in October 2000, when her breast cancer was diagnosed, that the breast cancer was "estrogen receptor positive" was in fact attempting to communicate that hormone replacement therapy caused the breast cancer, given that there was no established causal link between E+P and breast cancer until after July of 2002.

For all of these reasons, in *Coleman*, as in the other 13 consolidated appeals, whether to apply the discovery rule to find plaintiffs' lawsuit timely presented a jury question:

> [W]here the issue involves a factual determination regarding what is a reasonable period of time for a plaintiff to discover his injury and its cause, the determination is for the jury. *Cf. Smith v. Bell Telephone Co.*, 397 Pa. 134, 142, 153 A.2d 477, 481 (1959). Only where the facts are undisputed and lead unerringly to the conclusion that the length of time it took the plaintiff to discover the injury or its cause was unreasonable may the question be decided as a matter of law on summary judgment.

Burnside v. *Abbott Labs.*, 505 A.2d 973, 988 (Pa. Super. Ct. 1985).

The Supreme Court of Pennsylvania's recent decision in *Wilson* makes clear that a patient cannot be expected to know more about the cause of her injury than her own treating physicians. *See Wilson*, 2009 WL 400656, at *9. Both of the gynecologists who had prescribed E+P to Mrs. Coleman testified under oath at their depositions that they did not realize that combined hormone replacement therapy could cause breast cancer until the results of the WHI study became public in July 2002. R.161a–64a, 221a, 238a.

Moreover, in *Wilson*, as in Mrs. Coleman's case, the defendant attempted to capitalize on a particular exchange from the plaintiff's deposition testimony to establish that the plaintiff knew more than two years before filing suit that the defendant's negligence was the cause of her injuries. *See Wilson*, 2009 WL 400656, at *10. In *Wilson*, the Supreme Court of Pennsylvania held, based on the entire record, that a factual question was presented for the jury on whether to apply the discovery rule, notwithstanding plaintiff's arguably unhelpful deposition testimony

that she realized the defendant's negligence was the cause of her injury more than two years before filing suit. *Id.* at *9 & n.12. The same result — presenting the discovery rule question to a jury — must follow in Mrs. Coleman's case under the Pa. Supreme Court's decision in *Wilson*.

3. Submission of the statute of limitations question in these cases to juries under the discovery rule will return Pennsylvania to the judicial mainstream in hormone therapy breast cancer actions

In *Wilson*, the Supreme Court of Pennsylvania recognized that, where the facts governing if and whether to apply the discovery rule are in dispute — as they unquestionably are in these 14 cases — a defendant seeking to preclude a plaintiff's claim as untimely must convince *the jury* that the plaintiff's claim is time–barred in order to win on statute of limitations grounds. *See Wilson*, 2009 WL 400656, at *9 n.12.

Before Judge Tereshko was appointed to lead the mass torts program in Philadelphia — a post that he was recently reassigned from — the judge previously in charge of that program had denied all motions for summary judgment on statute of limitations grounds in cases governed by a two–year statute of limitations where the plaintiff had filed suit within two years of the release of the WHI study's results on July 9, 2002. R.1595a–98a.

Juries, when allowed to decide whether the discovery rule should apply in these cases, have held that the statute of limitations did not begin to run until publication of the WHI study's results. In the case of *Simon* v. *Wyeth*, tried to a verdict before a jury in the Philadelphia Court of Common Pleas, the jury found

that the plaintiff's lawsuit was timely under the discovery rule, even though she filed suit more than two years after having been diagnosed with breast cancer, because she had filed suit within two years of July 9, 2002. Although the trial judge later granted j.n.o.v. in Upjohn's favor on statute of limitations grounds based on Judge Tereshko's summary judgment ruling in *Coleman*, that entry of j.n.o.v. is now the subject of a separate appeal pending before this Court. At oral argument in the *Simon* appeal on February 24, 2009, a three–judge panel of this Court expressed considerable skepticism about the correctness of the trial court's entry of j.n.o.v. based on statute of limitations grounds.

Moreover, this Court's reversal of Judge Tereshko's legally incorrect entry of summary judgment in these fourteen consolidated cases on statute of limitations grounds would be consistent with how courts in other jurisdictions have been ruling on this very same issue in hormone therapy cases.

In the federal multi–district litigation pending before U.S. District Judge Wm. R. Wilson, Jr. in the Eastern District of Arkansas, Judge Wilson has refused to grant summary judgment on statute of limitations grounds in cases where the plaintiff has sued within the applicable statute of limitations commencing when the results of the WHI study became public on July 9, 2002. *See*, *e.g.*, *Scroggin* v. *Wyeth*, 2007 WL 3228125, at *1 (E.D. Ark. Nov. 1, 2007); R.1600a–13a. Rather, the MDL judge has left those issues for a jury's resolution.

Indeed, the federal court jury in the *Scroggin* MDL case returned a verdict in plaintiff's favor, and against Wyeth and Upjohn, for compensatory and punitive

damages, finding plaintiff's lawsuit timely under the discovery rule. More recently, Judge Wilson rejected defendants' post–judgment challenges to the jury's award of compensatory damages, and defendants' appeal is now pending before the U.S. Court of Appeals for the Eighth Circuit. Furthermore, the juries in two other MDL hormone therapy cases, while finding for Wyeth on other grounds, nonetheless rejected the statute of limitations defense.

Similarly, the Superior Court of New Jersey rejected precisely the position the defendants have advocated here:

> Defendants are asking the plaintiff to conclude that ingestion of the defendant's HRT [hormone replacement therapy] drugs was causative and not a mere exacerbation of her breast cancer before the WHI Study results were released to the public and the medical community at large. That is simply unrealistic and not feasible given the circumstances. It is nonsensical to require a layperson to know what learned medical professionals did not even know about HRT. It is therefore entirely unreasonable to require a patient without any medical training to make the logical connection between her ingestion of HRT drugs and her breast cancer and possess a reasonable belief that she could sue Wyeth for her injuries before the WHI findings were released to the public. This court is convinced that the warnings the plaintiff read effectively chilled her inquiry as to the causative nature of her cancer.

R.1623a–24a (*Deutsch* v. *Wyeth*, HRT Mass Tort Case, MID–L–998–06 MT (N.J. Super. Ct. Law Div.) (June 14, 2007), at 9–10).

A Nevada trial court has likewise rejected defendants' invocation of the statute of limitations on a similar record:

> The Court is unable to conclude that Ms. Scofield possessed the requisite information to commence the running of the statute. Indeed, reasonable diligence would have revealed a confusing tangle of ambiguous and contradictory knowledge in the scientific community regarding the role of HT in relation to breast cancer.

R.1629a (*McCreary* v. *Wyeth*, No. CV04–1699 (2d Dist. Ct. Nev.) (Apr. 5, 2007), at 3).

In common with the law being applied by the federal MDL court in Arkansas and the state courts in New Jersey and Nevada, under Pennsylvania law defendants' summary judgment motions based on statute of limitations grounds should have been denied. A ruling that reverses the entry of summary judgment in these 14 appeals will return Pennsylvania courts to the judicial mainstream in hormone therapy cases.

As explained above, the plaintiffs' claims for negligent failure to warn did not accrue, at the earliest, until the WHI study's results became known on July 9, 2002. And a reasonable jury could conclude, based on the evidence in these 14 cases, that the plaintiffs instituted suit within two years of when a reasonable person would realize that defendants' hormone therapy medications had caused plaintiffs' breast cancer.

Accordingly, this Court should reverse Judge Tereshko's entry of summary judgment in favor of defendants on statute of limitations grounds and remand these cases to permit plaintiffs to proceed with their claims.

VIII. CONCLUSION

For the reasons set forth above, this Court should reverse the trial court's entry of summary judgment in defendants' favor on statute of limitations grounds and allow plaintiffs' claims to proceed in the trial court.

Respectfully submitted,

Dated: March 5, 2009

Howard J. Bashman
2300 Computer Avenue
Suite G–22
Willow Grove, PA 19090
(215) 830–1458

Fredric S. Eisenberg
Eisenberg, Rothweiler, Winkler,
Eisenberg & Jeck, P.C.
1634 Spruce Street
Philadelphia, PA 19103
(215) 546–6636
Counsel for Coleman

Stephen A. Corr
Mellon, Webster & Shelly
87 N. Broad Street
Doylestown, PA 18901
(215) 348–7700
Counsel for Medwid

James A. Morris
Brian D. Ketterer
Brent Coon & Associates
1500 JFK Boulevard
Suite 1301
Philadelphia, PA 19102
(215) 564–9245
Counsel for Weinberger; Reed; Taw; Morales; Lenzi; Schirn; Fleming–Crain; Honaker; Hansen; and Blaylock

Tobias Millrood
Pogust Braslow & Millrood, LLC
8 Tower Bridge, Suite 1520
161 Washington Street
Conshohocken, PA 19428
(610) 941–4204
Counsel for Manalo

John J. Cord, Jr.
Robert K. Jenner
Janet, Jenner & Suggs, L.L.C.
1829 Reisterstown Road, Suite 320
Baltimore, MD 21208
(410) 653–3200
Counsel for Hess

CERTIFICATE OF SERVICE

I hereby certify that I am this day serving two true and correct copies of the foregoing document upon the persons and in the manner indicated below which service satisfies the requirements of Pa. R. App. P. 121:

Service by First Class U.S. Mail addressed as follows:

Emily J. Lawrence, Esquire
Morgan, Lewis & Bockius, LLP
1701 Market Street
Philadelphia, PA 19103
(215) 963–5241
Counsel for Pharmacia & Upjohn Company, LLC

Andrew J. Trevelise, Esquire
Reed Smith, LLP
2500 One Liberty Place
1650 Market Street
Philadelphia, PA 19103
(215) 851–8250
Counsel for Wyeth Pharmaceuticals, Inc.

Dated: March 5, 2009

Howard J. Bashman
2300 Computer Avenue
Suite G–22
Willow Grove, PA 19090
(215) 830–1458