In the Supreme Court of Pennsylvania

No. 676 EAL 2010

ELIZABETH and JOE COLEMAN, w/h,
Respondents,

v.

WYETH PHARMACEUTICALS, INC.,
Petitioners.

RESPONDENTS' ANSWER IN OPPOSITION TO THE PETITION FOR ALLOWANCE OF APPEAL

On Petition for Allowance of Appeal from the Judgment of the Superior Court of Pennsylvania at No. 2678 EDA 2007, filed August 30, 2010, Reversing the Judgment of the Court of Common Pleas of Philadelphia County, Pennsylvania, Civil Trial Division, June Term, 2004, No. 3179 entered September 24, 2007

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 Respondents Elizabeth and Joe Coleman

In the Supreme Court of Pennsylvania

No. 677 EAL 2010

PATRICIA MEDWID and RICHARD MEDWID,
Respondents,

v.

WYETH PHARMACEUTICALS, INC., et al.,
Petitioner.

RESPONDENTS' ANSWER IN OPPOSITION TO THE PETITION FOR ALLOWANCE OF APPEAL

On Petition for Allowance of Appeal from the Judgment of the Superior Court of Pennsylvania at No. 3026 EDA 2007, filed August 30, 2010, Reversing the Judgment of the Court of Common Pleas of Philadelphia County, Pennsylvania, Civil Trial Division, July Term, 2004, No. 497 entered October 3, 2007

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

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

Counsel for Respondents Patricia and Richard Medwid

In the Supreme Court of Pennsylvania

No. 678 EAL 2010

MARY WEINBERGER,
Respondent,

v.

WYETH PHARMACEUTICALS, INC., et al.,
Petitioners.

RESPONDENT'S ANSWER IN OPPOSITION TO THE PETITION FOR ALLOWANCE OF APPEAL

On Petition for Allowance of Appeal from the Judgment of the Superior Court of Pennsylvania at No. 3089 EDA 2007, filed August 30, 2010, Reversing the Judgment of the Court of Common Pleas of Philadelphia County, Pennsylvania, Civil Trial Division, June Term, 2004, No. 4255 entered October 12, 2007

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

James A. Morris, Jr.
Morris Law Firm
11614 Bee Cave Road
Suite 220
Austin, TX 78738
(512) 263–7739

Counsel for Respondent Mary Weinberger

In the Supreme Court of Pennsylvania

No. 679 EAL 2010

JUDY A. REED and GERALD W. REED, h/w,
Respondents,

v.

WYETH PHARMACEUTICALS, INC., et al.,
Petitioners.

RESPONDENTS' ANSWER IN OPPOSITION TO THE PETITION FOR ALLOWANCE OF APPEAL

On Petition for Allowance of Appeal from the Judgment of the Superior Court of Pennsylvania at No. 3090 EDA 2007, filed August 30, 2010, Reversing the Judgment of the Court of Common Pleas of Philadelphia County, Pennsylvania, Civil Trial Division, June Term, 2004, No. 3605 entered October 18, 2007

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

James A. Morris, Jr.
Morris Law Firm
11614 Bee Cave Road
Suite 220
Austin, TX 78738
(512) 263–7739

Counsel for Respondents Judy A. and Gerald W. Reed

In the Supreme Court of Pennsylvania

No. 680 EAL 2010

KATHLEEN TAW STEPHENSON and MICHAEL R. TAW,
Respondents,

v.

WYETH PHARMACEUTICALS, INC., et al.,
Petitioner.

RESPONDENTS' ANSWER IN OPPOSITION TO THE PETITION FOR ALLOWANCE OF APPEAL

On Petition for Allowance of Appeal from the Judgment of the Superior Court of Pennsylvania at No. 3091 EDA 2007, filed August 30, 2010, Reversing the Judgment of the Court of Common Pleas of Philadelphia County, Pennsylvania, Civil Trial Division, June Term, 2004, No. 3523 entered October 18, 2007

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

James A. Morris, Jr.
Morris Law Firm
11614 Bee Cave Road
Suite 220
Austin, TX 78738
(512) 263–7739

Counsel for Respondents Kathleen Taw Stephenson and Michael W. Taw

In the Supreme Court of Pennsylvania

No. 681 EAL 2010

DIANE MORALES,
Respondent,

v.

WYETH PHARMACEUTICALS, INC., et al.,
Petitioners.

RESPONDENT'S ANSWER IN OPPOSITION TO THE PETITION FOR ALLOWANCE OF APPEAL

On Petition for Allowance of Appeal from the Judgment of the Superior Court of Pennsylvania at No. 3092 EDA 2007, filed August 30, 2010, Reversing the Judgment of the Court of Common Pleas of Philadelphia County, Pennsylvania, Civil Trial Division, July Term, 2004, No. 641 entered October 18, 2007

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

James A. Morris, Jr.
Morris Law Firm
11614 Bee Cave Road
Suite 220
Austin, TX 78738
(512) 263–7739

Counsel for Respondent Diane Morales

In the Supreme Court of Pennsylvania

No. 682 EAL 2010

VICKI LENZI and RONALD J. LENZI,
Respondents,

v.

WYETH PHARMACEUTICALS, INC., et al.,
Petitioners.

RESPONDENTS' ANSWER IN OPPOSITION TO THE PETITION FOR ALLOWANCE OF APPEAL

On Petition for Allowance of Appeal from the Judgment of the Superior Court of Pennsylvania at No. 3093 EDA 2007, filed August 30, 2010, Reversing the Judgment of the Court of Common Pleas of Philadelphia County, Pennsylvania, Civil Trial Division, June Term, 2004, No. 3428 entered October 18, 2007

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

James A. Morris, Jr.
Morris Law Firm
11614 Bee Cave Road
Suite 220
Austin, TX 78738
(512) 263–7739

Counsel for Respondents Vicki and Ronald J. Lenzi

In the Supreme Court of Pennsylvania

No. 683 EAL 2010

ZANDA SCHIRN and ROBERT W. SCHIRN, h/w,
Respondents,

v.

WYETH PHARMACEUTICALS, INC., et al.,
Petitioners.

RESPONDENTS' ANSWER IN OPPOSITION TO THE PETITION FOR ALLOWANCE OF APPEAL

On Petition for Allowance of Appeal from the Judgment of the Superior Court of Pennsylvania at No. 3094 EDA 2007, filed August 30, 2010, Reversing the Judgment of the Court of Common Pleas of Philadelphia County, Pennsylvania, Civil Trial Division, June Term, 2004, No. 4226 entered October 18, 2007

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

James A. Morris, Jr.
Morris Law Firm
11614 Bee Cave Road
Suite 220
Austin, TX 78738
(512) 263–7739

Counsel for Respondents Zanda and Robert W. Schirn

In the Supreme Court of Pennsylvania

No. 684 EAL 2010

PEGGY FLEMING–CRAIN,
Respondent,

v.

WYETH PHARMACEUTICALS, INC., et al.,
Petitioners.

RESPONDENT'S ANSWER IN OPPOSITION TO THE PETITION FOR ALLOWANCE OF APPEAL

On Petition for Allowance of Appeal from the Judgment of the Superior Court of Pennsylvania at No. 3095 EDA 2007, filed August 30, 2010, Reversing the Judgment of the Court of Common Pleas of Philadelphia County, Pennsylvania, Civil Trial Division, June Term, 2004, No. 4343 entered October 18, 2007

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

James A. Morris, Jr.
Morris Law Firm
11614 Bee Cave Road
Suite 220
Austin, TX 78738
(512) 263–7739

Counsel for Respondent Peggy Fleming–Crain

In the Supreme Court of Pennsylvania

No. 685 EAL 2010

NANCY and RICHARD HONAKER, h/w,
Respondents,

v.

WYETH PHARMACEUTICALS, INC., et al.,
Petitioners.

RESPONDENTS' ANSWER IN OPPOSITION TO THE PETITION FOR ALLOWANCE OF APPEAL

On Petition for Allowance of Appeal from the Judgment of the Superior Court of Pennsylvania at No. 3096 EDA 2007, filed August 30, 2010, Reversing the Judgment of the Court of Common Pleas of Philadelphia County, Pennsylvania, Civil Trial Division, June Term, 2004, No. 3466 entered October 12, 2007

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

James A. Morris, Jr.
Morris Law Firm
11614 Bee Cave Road
Suite 220
Austin, TX 78738
(512) 263–7739

Counsel for Respondents Nancy and Richard Honaker

In the Supreme Court of Pennsylvania

No. 686 EAL 2010

VIRGINIA HANSEN,
Respondent,

v.

WYETH PHARMACEUTICALS, INC., et al.,
Petitioners.

RESPONDENT'S ANSWER IN OPPOSITION TO THE PETITION FOR ALLOWANCE OF APPEAL

On Petition for Allowance of Appeal from the Judgment of the Superior Court of Pennsylvania at No. 3097 EDA 2007, filed August 30, 2010, Reversing the Judgment of the Court of Common Pleas of Philadelphia County, Pennsylvania, Civil Trial Division, June Term, 2004, No. 3474 entered October 18, 2007

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

James A. Morris, Jr.
Morris Law Firm
11614 Bee Cave Road
Suite 220
Austin, TX 78738
(512) 263–7739

Counsel for Respondent Virginia Hansen

In the Supreme Court of Pennsylvania

No. 687 EAL 2010

HAZEL BLAYLOCK,
Respondent,

v.

WYETH PHARMACEUTICALS, INC., et al.,
Petitioners.

RESPONDENT'S ANSWER IN OPPOSITION TO THE PETITION FOR ALLOWANCE OF APPEAL

On Petition for Allowance of Appeal from the Judgment of the Superior Court of Pennsylvania at No. 3098 EDA 2007, filed August 30, 2010, Reversing the Judgment of the Court of Common Pleas of Philadelphia County, Pennsylvania, Civil Trial Division, June Term, 2004, No. 3721 entered October 12, 2007

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

James A. Morris, Jr.
Morris Law Firm
11614 Bee Cave Road
Suite 220
Austin, TX 78738
(512) 263–7739

Counsel for Respondent Hazel Blaylock

In the Supreme Court of Pennsylvania

No. 688 EAL 2010

GRACIANA MANALO and FELIPE MANALO,
Respondents,

v.

WYETH PHARMACEUTICALS, INC., et al.,
Petitioner.

RESPONDENTS' ANSWER IN OPPOSITION TO THE PETITION FOR ALLOWANCE OF APPEAL

On Petition for Allowance of Appeal from the Judgment of the Superior Court of Pennsylvania at No. 583 EDA 2008, filed August 30, 2010, Reversing the Judgment of the Court of Common Pleas of Philadelphia County, Pennsylvania, Civil Trial Division, June Term, 2004, No. 4503 entered January 4, 2008

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

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

Counsel for Respondents Graciana and Felipe Manalo

In the Supreme Court of Pennsylvania

No. 689 EAL 2010

CAROL J. HESS,
Respondent,

v.

WYETH PHARMACEUTICALS, INC., et al.,
Petitioner.

RESPONDENT'S ANSWER IN OPPOSITION TO THE PETITION FOR ALLOWANCE OF APPEAL

On Petition for Allowance of Appeal from the Judgment of the Superior Court of Pennsylvania at No. 594 EDA 2008, filed August 30, 2010, Reversing the Judgment of the Court of Common Pleas of Philadelphia County, Pennsylvania, Civil Trial Division, June Term, 2004, No. 3973 entered January 10, 2008

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

Brian D. Ketterer
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 Respondent Carol J. Hess

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I. INTRODUCTION

Plaintiffs/respondents in these 14 cases that the Superior Court of Pennsylvania consolidated on appeal respectfully submit this answer in opposition to the Petition for Allowance of Appeal that defendants Wyeth and Upjohn have filed.

The Petition for Allowance of Appeal fails to fairly portray the relevant facts that give rise to the discovery rule issue in these cases and is based on a false premise. The Superior Court's unanimous and carefully reasoned opinion does *not* hold that the discovery rule will toll the running of the statute of limitations in a prescription drug failure to warn lawsuit until a "definitive causal link" or "conclusive connection" is established between the medication and the plaintiff's injury. One searches in vain for any such holding in the Superior Court's opinion, because it simply is nowhere to be found. Rather, the Superior Court's opinion merely holds, in accordance with well–established Pennsylvania law, that even after a claim has accrued, the statute of limitations is tolled until a plaintiff reasonably should have discovered that her injury was caused by the negligent conduct of a third–party.

As the appellate courts of Pennsylvania have held time and again, application of the "discovery rule" and resolution of the question of reasonable diligence are fact issues that a jury must decide unless no reasonable person could disagree over them. In accordance with that large body of precedent, the Superior Court's opinion simply holds that the trial court erred in resolving the discovery

rule issue in these 14 cases as a matter of law against the plaintiffs. Instead, as the Superior Court unanimously ruled, the applicability of the discovery rule in these 14 cases is for the jury to decide. Thus, the Superior Court's opinion does not deny Wyeth or Upjohn the ability to raise a statute of limitations defense before the juries in these cases; rather, the Superior Court merely has held that the trial court erred in holding on summary judgment, as a matter of law, that plaintiffs could not invoke the discovery rule to establish that their actions are timely.

The "confusion" that Wyeth and Upjohn contend exists concerning how the discovery rule should apply in cases such as these is nothing more than a figment of petitioners' imagination. Two separate three–judge panels of the Superior Court of Pennsylvania, in deciding two separate sets of appeals, have unanimously concluded that whether the discovery rule applies under the exact circumstances of these cases presents a jury question — and, in case after case, juries have been resolving that question in favor of the plaintiffs and finding that the lawsuits were timely filed. The Superior Court carefully applied this Court's precedent and its own earlier precedent in reaching its plainly correct decision in these 14 consolidated cases.

The Petition for Allowance of Appeal should also be denied because it inaccurately contends that, under Pennsylvania law, a plaintiff must investigate the cause of her injury even in the absence of any reasonable basis to believe, or ability to determine, that the injury may have been caused by a third–party. To be sure, the "constructive knowledge" aspect of the discovery rule can cause the statute

of limitations to begin to run based on what a plaintiff knew or should have known had she conducted a reasonable investigation. But the purpose of the reasonable investigation requirement is not to force a plaintiff to squander resources on a fool's errand where such a reasonable investigation would not have revealed that the injury was caused by the negligence of a third–party. In other words, a plaintiff's failure to conduct a reasonable investigation is of consequence under Pennsylvania law only where the investigation would have revealed that a third–party's negligence was the cause of the plaintiff's injury. That was not the case here.

As explained below, Wyeth and Upjohn have failed to establish any "special and important reasons" for granting allowance of appeal. *See* Pa. R. App. P. 1114. The Superior Court's ruling in this case does not conflict with any ruling of this Court or of the Superior Court; rather, these consolidated cases simply represent an unremarkable and unquestionably correct application of the discovery rule. Indeed, as explained below, one current member of this Court and one former member of this Court have joined in the Superior Court's decisions holding that whether the discovery rule applies in these hormone replacement therapy breast cancer cases presents a jury question due to the existence of genuine issues of material facts that would allow a reasonable jury to find in favor of either side.

For these reasons and the other reasons explained below, the Petition for Allowance of Appeal should be denied.

II. COUNTER–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.[1] 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).

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[1] Cites herein to "R." followed by a page number refer to the seven–volume Reproduced Record filed in the Superior Court.

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 to Pa. Super. Ct. Brief for Appellants (hereinafter "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 described as unknown. *Id.* The labels 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, as the Superior Court's ruling recognizes, 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.[2] Attachments at 187–99. The WHI was a randomized controlled trial 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).

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[2] *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 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.

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 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 these consolidated cases

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 became 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 immediately upon 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 those cases, the plaintiffs submitted affidavits in response to the summary judgment motions to provide further factual support for their invocation of the discovery rule to make their lawsuits timely.

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.

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. 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 tumor growth.

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.[3]

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[3] Defendants' own pre–WHI labels conclusively demonstrate that the instruction not to continue to ingest hormone therapy medications after receiving a breast cancer diagnosis does not establish that defendants' hormone therapy medications caused breast cancer. R.1682a–83a. There is thus no inconsistency between plaintiffs' fact sheets and their sworn explanations of those fact sheets. Those explanations are in essence identical to the position that defendants themselves took in their pre–WHI labels — that it is unknown whether hormone therapy medications cause breast cancer, but hormone therapy medications should not be ingested by women who have been diagnosed with breast cancer.

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.

Medwid

Plaintiff 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.

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.

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 13 consolidated 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.

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.

Relevant appellate proceedings before the Superior Court of Pennsylvania

On December 31, 2009, a unanimous three–judge panel of the Superior Court of Pennsylvania issued its ruling in *Simon* v. *Wyeth Pharm., Inc.*, 989 A.2d 356 (Pa. Super. Ct. 2009). In the *Simon* case, as in these 14 consolidated appeals, the plaintiff filed suit claiming that Wyeth and Upjohn's E+P caused her breast cancer. Mrs. Simon's suit was filed more than two years after she had been diagnosed with

breast cancer but less than two years after the results of the WHI study had become public.

Mrs. Simon's case went to trial in the Philadelphia Court of Common Pleas, where a jury returned a damages verdict in her favor. Among other things, the jury found that Mrs. Simon's lawsuit was timely filed under the discovery rule. On defendant Upjohn's post–trial motion for judgment notwithstanding the verdict, however, the trial judge granted j.n.o.v. in Upjohn's favor ruling, among other things, that Mrs. Simon's lawsuit was time–barred as a matter of law based on Judge Tereshko's earlier opinion in the *Coleman* case holding that the statute of limitations began to run immediately on receiving a diagnosis of breast cancer even before the WHI study's results had become public.

The Superior Court's ruling in *Simon* reversed the trial court's entry of j.n.o.v. in Upjohn's favor. In *Simon*, a unanimous three–judge panel of the Superior Court ruled that the question of the discovery rule's applicability was properly submitted to the jury and that the evidence presented allowed a rational jury to find that the discovery rule applied and that Mrs. Simon's lawsuit was timely filed. *See Simon*, 989 A.2d at 367–68. In deciding these 14 consolidated appeals, the Superior Court explained that its earlier ruling in *Simon* was controlling.[4]

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[4] Wyeth and Upjohn incorrectly contend, in their Petition for Allowance of Appeal filed in these 14 consolidated cases, that Upjohn was unable to seek review in this Court of the *Simon* case because that case settled. That contention is simply not credible. The *Simon* case did not settle until August 2010, by which time the ordinary periods for seeking further review of the *Simon* ruling, which the Superior Court issued on December 31, 2009, had long since expired. In the *Simon* case, Upjohn deliberately opted to pursue relief on its motion for a new trial, which the

In these 14 consolidated appeals, the Superior Court — in accordance with its earlier unanimous ruling in *Simon* — held that plaintiffs' invocation of the discovery rule to make their suits timely could not be resolved in favor of the defendants as a matter of law on summary judgment. Rather, the Superior Court ruled that numerous genuine issues of material fact existed — concerning both plaintiffs' invocation of the discovery rule in general and the question of plaintiffs' reasonable diligence to discover whether their breast cancers had been caused by the tortious conduct of a third–party — necessitating that juries resolve the discovery rule's applicability in each of these 14 cases.

In violation of Pennsylvania Rule of Appellate Procedure 1115(d), which requires the petitioner to present with "accuracy * * * whatever is essential to a ready and adequate understanding of the points requiring consideration," Wyeth and Upjohn's Petition for Allowance of Appeal incorrectly contends that the Superior Court has ruled that the discovery rule will toll the running of the statute of limitations in a prescription drug failure to warn lawsuit until a "definitive causal link" or "conclusive connection" is established between the medication and the plaintiff's injury. Had the Superior Court in fact so ruled, the Superior Court

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trial court had originally failed to address in violation of Pa. R. Civ. P. 227.1(e), instead of pursuing allowance of appeal in this Court from the Superior Court's reversal of the trial court's entry of j.n.o.v. in Upjohn's favor. Upjohn's failure to seek allowance of appeal from the Superior Court's statute of limitations ruling in *Simon* indicates that Upjohn realized that the discovery rule issue presented in *Simon* (and, by extension, in these 14 consolidated cases) does not satisfy the stringent criteria for review on allowance of appeal.

would have necessarily decided that plaintiffs' lawsuits were timely filed as a matter of law, which the Superior Court expressly refused to do.

Rather, in these 14 cases, juries can resolve the discovery rule issue in favor of either party; all that the Superior Court has done is correctly and unremarkably hold that defendants are not entitled to have the discovery rule issue presented in these 14 cases resolved in their favor as a matter of law on summary judgment based on the records as they now exist in these cases. That fact–bound ruling is in accordance with this Court's governing precedents and does not satisfy the criteria for allowance of appeal.

III. THE PETITION FOR ALLOWANCE OF APPEAL SHOULD BE DENIED

A. The Superior Court Correctly Applied Well–Established Pennsylvania Law In Holding That Applicability Of The "Discovery Rule" To Toll The Running Of The Statute of Limitations Should Ordinarily Be Determined By A Jury

Because allowance of appeal will be granted only when "special and important reasons" exist, *see* Pa. R. App. P. 1114, allowance of appeal is reserved for cases in which the Superior Court has issued a decision that either has departed from established law or is in conflict with an earlier ruling of this Court or of the Commonwealth Court. These 14 consolidated cases, however, do not satisfy any of the criteria for allowance of appeal.

Wyeth and Upjohn, in their Petition for Allowance of Appeal, incorrectly assert that the Superior Court has held that the discovery rule will toll the running

of the statute of limitations in a prescription drug failure–to–warn lawsuit until science has established a "definitive causal link" or "conclusive connection" between the medication and the plaintiff's injury. In actuality, the Superior Court's opinion in this case contains no such holding. The Superior Court's opinion in this case does not, and does not purport to, alter or expand applicability of the "discovery rule" beyond its already established boundaries.

That the Petition for Allowance of Appeal resorts to misrepresenting the Superior Court's actual holding as its central premise is sufficient grounds in and of itself for denying allowance of appeal. *See* Pa. R. App. P. 1115(d) (describing "accuracy" as an "[e]ssential requisite" of a petition for allowance of appeal).

Judge Mary Jane Bowes — in her 57–page opinion for a unanimous Superior Court panel in these 14 consolidated appeals — exhibits her characteristic thorough grasp of the record on appeal and careful application of well–established law to the facts of these cases. The Superior Court's decision repeatedly cites and faithfully applies this Court's governing discovery rule precedents in *Crouse* v. *Cyclops Indus.*, 560 Pa. 394, 745 A.2d 606 (2000), *Fine* v. *Checcio*, 582 Pa. 253, 870 A.2d 850 (2005), and *Wilson* v. *El–Daief*, 600 Pa. 161, 964 A.2d 354 (2009).

The Superior Court's opinion in this case correctly holds under well–established law that 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*, 560 Pa. at 403, 745 A.2d at 611. Yet Pennsylvania law also recognizes the discovery rule,

which this 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*, this Court's unanimous opinion addressed the role of the trial judge and the jury in applying the discovery rule:

> [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*. * * *
>
> 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, 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 this 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.

Along those lines, in *Crouse*, this 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).

In *Wilson* v. *El–Daief*, 600 Pa. 161, 964 A.2d 354 (2009), this Court 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 174–75, 964 A.2d at 361–62.

Articulating the contours of Pennsylvania's discovery rule, this 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). Importantly, *Fine* was clear about the subjective aspects 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).

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 the plaintiff 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 consolidated appeals are even more compelling in favor of applying the discovery rule than were the facts of *Fine* and *Wilson*, in which this Court held that a jury could apply the discovery rule to find that plaintiffs' claims

were timely. The *Fine* case involved two separate plaintiffs who 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 they 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, this 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. 600 Pa. at 165, 964 A.2d at 356. 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 168, 964 A.2d at 358. 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 167, 964 A.2d at 357.

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 — this Court in *Wilson* nevertheless held that plaintiff's invocation of the discovery rule presented a jury question. *Id.* at 181 & n.12, 964 A.2d at 365–66 & n.12. Defendants' out–of–context quote from *Wilson* for the proposition that Pennsylvania applies the discovery rule more strictly than many other States in fact represents nothing more than this Court's recognition that in many other States the statute of limitations issue in *Wilson* would have been resolved as a matter of law in favor of the plaintiff, whereas in Pennsylvania it presented a jury question capable of being resolved in favor of either party. *Id.* at 181 n.12, 964 A.2d at 366 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 this appeal, by contrast, plaintiffs could not present sufficient scientific evidence that defendants' combination hormone replacement therapy caused their breast cancers 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 Women's Health Initiative study's results on July 9, 2002, reliable scientific evidence did not exist to establish that combined hormone therapy caused breast cancer. *See Simon*, 989 A.2d at 367 ("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.").

While defendants rely on what they now call "numerous" pre–WHI studies and news stories — which supposedly communicated a message in conflict with defendants' own FDA–approved pre–WHI labeling — those materials do not ***compel*** a finding in defendants' favor. That is the standard defendants must meet to sustain a summary judgment that takes the discovery rule issue from the jury. There is no evidence in this record that the plaintiffs even saw the handful of medical journal articles on which defendants now rely or, if they had, could reasonably assess the significance of those articles, which defendants themselves minimized, dismissed, or omitted in their pre–2002 labeling.

Likewise, there is no evidence that any of the plaintiffs saw any of the handful of articles or television news segments — defendants rely on just 14 such publications over the five year period between 1995 and 2000. U.S. media churn out hundreds if not thousands of newspaper articles and television news segments each day, making the isolated publications on which defendants rely a mere drop in an ocean of information. Each State has at least one major newspaper, and if each of those newspapers printed just 10 articles a day, that would add up to at least 500

articles per day nationwide. Larger States — such as California, Florida, New York, Pennsylvania, and Texas — are of course home to many more than just one major newspaper.

While large corporations such as defendants can afford services that track press coverage relating to them, there is little if any likelihood that any of this coverage actually reached any of these 14 plaintiffs. Defendants have certainly not proven beyond genuine issue that the plaintiffs received the articles and reports on which defendants rely. Rather, defendants have produced absolutely no evidence that any of these plaintiffs were aware of any of the news coverage or handful of medical journal articles that defendants cite.

The real evidence in this case — affidavits concerning the discussions plaintiffs had with their physicians at the time of diagnosis and when they became aware that defendants' drugs had caused their breast cancer, and not unadorned news clippings of dubious relevance — shows the contrary.

For example, Mrs. Manalo's physician told her that there was no way to confirm what actually caused her breast cancer, and she 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 WHI study had established a causal link between breast cancer and Wyeth's hormone therapy medications. R.3013a–14a. Similarly, Ms. Hess submitted to the trial court the affidavit of Dr. Douglas Yingling, who was her general surgeon and the physician who managed her cancer surgery. In his affidavit, Dr. Yingling testified that he does not

specifically recall any conversation he had with Mrs. Hess at the time of her cancer diagnosis. Yet, he continues: "Had she asked me in April of 2002 whether her hormone therapy caused her cancer, I would have told her that I did not know." R.3645a.

Ms. Blaylock testified that "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." R.2924a. Mrs. Medwid testified that she was not told at the time of her diagnosis that her breast cancer was caused by hormone therapy medications and that she did not learn that "Prempro could have been a cause of my breast cancer" until after July 9, 2002. R.1337a–38a. The evidence concerning the other plaintiffs shows the same.

In addition, the information defendants expressly designed to reach the plaintiffs and their doctors — defendants' packaging inserts and product labels — told a far different story than the one defendants now attempt to embellish with bits and pieces of publications over a five–year period. During that same five–year period, defendants continued to tell plaintiffs, and the world, that:

- 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 hormone 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. And Upjohn's pre–July 2002 Provera labeling contained no human breast cancer warning at all, instead referring only to dogs and then immediately discounting that information as having no bearing on human breast cancer risk. Attachments at 186. Defendants' pre–WHI labeling provided no warning about the possibility of a **causal link** between hormone therapy and an increased risk of breast cancer and did everything it could to suggest there was no such link.

In sum, defendants' pre–WHI labels did not tell plaintiffs, their doctors, or anyone else that using these medications at typical dosages for typical durations increased the risk of breast cancer. Rather, defendants suggested just the opposite. Given those facts, reasonable jurors applying the discovery rule could find that plaintiffs used reasonable diligence to discover that defendants caused plaintiffs' cancer and file suit.

In the *Simon* opinion and the Superior Court's opinion in these 14 consolidated appeals, a total of five judges serving on the Superior Court have examined whether plaintiffs' invocation of the discovery rule in these combination hormone replacement therapy prescription drug failure–to–warn cases presented a jury question, and all five of those judges have unanimously concluded that indeed a jury question is presented. Former Justice Fitzgerald joined in the ruling in this case, and current Justice Orie Melvin joined in the *Simon* ruling at a time when she

was a Justice–elect still serving on the Superior Court. In addition, as the Superior Court's opinion in these 14 consolidated appeals observes, juries in other cases are resolving the identical discovery rule question in favor of other plaintiffs, and those findings are thereafter being upheld on appeal.[5] If these cases were appropriate for the entry of summary judgment in favor of defendants on the discovery rule issue, other juries and appellate courts would be resolving the discovery rule question in favor of defendants, which is the opposite of what is actually happening.

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 *Simon* v. *Wyeth*, a case that was 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*, the Superior Court thereafter reversed in a ruling that Upjohn failed to ask this Court to review. *See Simon*, 989 A.2d at 367–68.

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[5] Indeed, before Judge Tereshko was appointed to lead the mass torts program in Philadelphia — a post that he has since been 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 after the release of the WHI study's results on July 9, 2002. R.1595a–98a.

Moreover, the Superior Court's reversal of Judge Tereshko's legally incorrect entry of summary judgment in these fourteen consolidated cases on statute of limitations grounds is 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. More recently, as the Superior Court's ruling on these 14 cases recognizes, the U.S. Court of Appeals for the Eighth Circuit affirmed the jury's resolution of the discovery rule issue in plaintiff's favor in the *Scroggin* case. *See Scroggin v. Wyeth (In re Prempro Products Liability Litig.)*, 586 F.3d 547, 563–65 (8th Cir. 2009) (holding that whether plaintiff's claim against Wyeth and Upjohn accrued when she was diagnosed with breast cancer or some point after the subsequent publication of the WHI study linking the use of hormone replacement therapy to breast cancer was an issue for the jury).

Similarly, the Superior Court of New Jersey rejected precisely the position the defendants are advocating 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 U.S. Court of Appeals for the Eighth Circuit, which exercises appellate jurisdiction over the federal MDL court in Arkansas assigned to preside over hormone replacement therapy breast cancer litigation in the federal court system, and the state courts in New Jersey and Nevada, the Superior Court correctly ruled under Pennsylvania law that defendants' summary judgment motions based on statute of limitations grounds should have been denied. The Superior Court's decision reversing the entry of

summary judgment in these 14 appeals has returned Pennsylvania courts to the judicial mainstream in hormone therapy cases.

Because the Superior Court's opinion in this case has faithfully applied longstanding Pennsylvania law in holding that the plaintiffs' invocations of the discovery rule present questions of fact for the jury to decide, defendants' Petition for Allowance of Appeal should be denied.

B. Defendants Misapprehend Pennsylvania Law In Arguing That A Plaintiff Must Investigate The Cause Of Her Injury Even In The Absence Of Any Reasonable Basis For Concluding That The Injury Resulted From A Third–Party's Wrongful Conduct

The second ground on which defendants seek allowance of appeal lacks merit both as a matter of law and as a matter of fact on the record of these cases.

In 13 of these 14 cases, defendants moved for summary judgment on statute of limitations grounds based solely on plaintiffs' complaints and associated fact sheets, in the absence of any discovery whatsoever. As the Superior Court recognized, it is thus far from undisputed that these plaintiffs failed to conduct any investigation into their claims before the results of the WHI study became public, and the record simply does not support defendants' assertion in that regard.

In the *Coleman* case, which is the one case among these 14 lawsuits in which extensive discovery occurred, the record shows that Ms. Coleman sought to learn the cause of her breast cancer but reasonably failed to discover that combination hormone replacement therapy medications were to blame.

As the Superior Court's opinion explains:

> 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*.

Coleman v. *Wyeth Pharm., Inc.*, 6 A.3d 502, 516 (Pa. Super. Ct. 2010) (slip op. p. 25).

Summarizing its discussion of the reasonable diligence inquiry in connection with the *Coleman* appeal, the Superior Court wrote:

> 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.

Id. at 520 (slip op. p. 34).

Defendants' argument is also without merit as a matter of law. Under Pennsylvania law, the discovery rule ceases to toll the running of the statute of limitations when the plaintiff either knows or should have known of her injury and its cause. The "should have known" formulation is sometimes referred to as "constructive knowledge," imputing to the plaintiff knowledge of the cause of her injury that a reasonable investigation would have disclosed, regardless of whether the plaintiff herself actually conducted any investigation whatsoever.

Defendants' argument appears to be that a plaintiff must conduct a reasonable investigation into the cause of her injury in order to invoke the discovery rule, even if the investigation would not have revealed the cause of the plaintiff's injury. In essence, defendants' argument would require the plaintiff to engage in a fool's errand — mandating the expenditure of valuable resources in the search for something incapable of being found — as a condition precedent for invoking the discovery rule in any case. That is simply not what Pennsylvania law requires.

As the Superior Court's opinion correctly explains:

> 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.

Coleman, 6 A.3d at 520 (slip op. pp. 35–36). The Superior Court's resolution of the reasonable diligence inquiry consists of a fact–bound decision limited to these cases and not some sweeping decision of general applicability.

In a last ditch effort to attempt to salvage some relief, Wyeth and Upjohn argue that this Court's forthcoming decision in *Gleason* v. *Borough of Moosic*, No. 7

MAP 2010 (argued October 20, 2010), may affect the reasonable diligence analysis in discovery rule cases. Defendants' argument ignores that these 14 cases have nothing in common with *Gleason*. In *Gleason*, the plaintiffs immediately knew or should have known that defendants' sewer construction project caused plaintiffs' basement to flood. And plaintiffs knew or should have known that the flooding resulted in mold accumulation and that such mold may have caused plaintiffs' health ailments. By contrast, in these 14 consolidated appeals, as the Superior Court's decision holds, it was reasonable for plaintiffs not to have realized that defendants' combination hormone replacement therapy medications caused plaintiffs' breast cancers until publication of the results of the WHI study in July 2002.

Moreover, in *Gleason* the Superior Court ruled, applying existing law, that plaintiffs' tort claims were time–barred. This Court in *Gleason* granted the *plaintiffs'* petition for allowance of appeal, which asked this Court to overturn the Superior Court's affirmance of the entry of summary judgment against plaintiffs on statute of limitations grounds and instead hold that the due diligence inquiry in that case presented a jury issue. Because the facts in *Gleason* are so very different from the facts of this case, even if this Court were to affirm in *Gleason*, it would have no impact on the outcome of these 14 hormone replacement therapy breast cancer cases. Then–Superior Court Judge Orie Melvin served both on the Superior Court panel that decided *Gleason* and on the Superior Court panel that decided *Simon* v. *Wyeth*, and Judge Orie Melvin joined in both decisions, further

demonstrating that the Superior Court's ruling in *Gleason* does not conflict with the Superior Court's rulings in *Simon* and *Coleman*.

Wyeth and Upjohn's suggestion that this Court should return these appeals to the Superior Court to await the outcome of this Court's ruling in *Gleason* incorrectly assumes that the *Gleason* decision could somehow control the far different, fact–bound reasonable diligence inquiry in these cases. That suggested procedure should also be rejected because it is without precedent in either the decisions of this Court or the Pennsylvania Rules of Appellate Procedure. What this Court should instead do is simply deny allowance of appeal in these case. In the unlikely event that this Court's ruling in *Gleason* has any impact on these cases, Wyeth and Upjohn will be able to invoke the *Gleason* decision on remand in the trial court. Each of these 14 cases is far from final resolution. The *Coleman* case has yet to reach trial, and the other 13 cases have yet to enter the discovery phase. There is no reason to further delay the orderly resolution of these personal injury cases brought by women approaching an advanced age who claim that their breast cancer was caused by defendants' medications.

For these reasons, the second ground raised in defendants' Petition for Allowance of Appeal lacks merit, and the petition should be denied.

* * * * *

Defendants' rote recitation of the rationales underlying statutes of limitations provides no reason to find the claims ***in these cases*** time–barred. Defendants do not, and cannot, contend that requiring them to defend against the

claims of these 14 plaintiffs inflicts any actual prejudice on them. In fact, they are currently defending numerous lawsuits that contain claims indistinguishable from the claims in this case, both in the Philadelphia Court of Common Pleas and in federal and state courts throughout the United States. As noted above, courts elsewhere have uniformly rejected defendants' statute of limitations defense on essentially the same record as the record in these cases. Although statutes of limitations unquestionably serve important purposes, defendants have failed to show, and indeed cannot show, that any of those purposes are implicated here.

By contrast, the harmful "real world" consequences of the holding that defendants ask this Court to reach cannot be ignored. Defendants ask this Court to hold that every woman who is diagnosed with breast cancer must immediately begin investigating whether some third–party is or may be responsible for causing the cancer, even though breast cancer may be caused by a variety of factors for which no third–party may be responsible. In each of these 14 consolidated cases, a jury could reasonably find that these plaintiffs had no obligation to investigate whether their breast cancer was caused by any third–party until the results of the WHI study had become public. Moreover, a jury could also similarly find that a reasonable pre–WHI investigation would not have disclosed anything different from what defendants' own product labels had disclosed, which would not have notified these women that defendants' products caused or may have caused their breast cancer.

Pennsylvania law concerning limitations recognizes the importance of providing injured plaintiffs with a reasonable opportunity to obtain legal recourse from tortfeasors who have negligently or recklessly injured them. Accordingly, Pennsylvania courts have tempered the unfair results that rigid application of statutes of limitations can produce by recognizing the "discovery rule" and holding that the statute of limitations does not even begin to run until the plaintiff knows or reasonably should have known that she has been injured ***and*** that her injury resulted from the wrongful conduct of another.

These cases, like most that come before this Court, are not resolved by abstract policy arguments, but by the specific facts and circumstances of the cases themselves. Indeed, it is for that reason that Pennsylvania case law assigns resolution of discovery rule issues concerning statutes of limitations to juries to decide as a factual matter, rather than to trial judges to decide on summary judgment. *See Wilson*, 600 Pa. at 181 & n.12, 964 A.2d at 365–66 & n.12; *Fine*, 582 Pa. 267–68, 870 A.2d at 858. Here, the facts of these cases would permit a reasonable jury to resolve those issues in the plaintiffs' favor. Each woman has stated under oath — some multiple times — that she did not discover that defendants had caused her breast cancer until after July 9, 2002, when the WHI study's results on breast cancer were published, and the balance of the record is replete with factual issues concerning the reasonableness of that non–realization.

The Superior Court's ruling in these 14 consolidated cases is both unremarkable and unquestionably correct. The "uncertainty" over how the

discovery rule should apply in cases such as this simply does not exist. Two separate three–judge panels of the Superior Court have reached the identical result on the very issue presented in these cases, and defendants have failed to point to any ruling that is actually in conflict with the outcome of these cases.[6]

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[6] Wyeth and Upjohn's contention that the Superior Court's ruling on these 14 consolidated appeals conflicts with this Court's decision in *Wilson* ignores this Court's *actual holdings* in *Wilson* that: (1) the Superior Court erred in affirming the trial court's grant of summary judgment in favor of the defendant on the discovery rule issue; and (2) the discovery rule's applicability in *Wilson* must be submitted to and decided by the jury. *See Wilson*, 600 Pa. at 181, 964 A.2d at 365 ("we conclude that, in the present circumstances, the ordinary rule should apply that factual issues pertaining to the plaintiff's notice and diligence are for the jury").

Moreover, defendants' contention that the Superior Court's ruling on these 14 consolidated appeals conflicts with four rulings that the Superior Court issued between 1991 and 1995 — at least ten years before this Court's far more recent discovery rule decisions in *Fine* and *Wilson* — is equally without merit. The Superior Court's rulings in *Ingento* v. *AC&S, Inc.*, 633 A.2d 1172 (Pa. Super. Ct. 1993), and *Love* v. *Raymark Indus., Inc.*, 633 A.2d 1185 (Pa. Super. Ct. 1993), both involved lung cancer diagnoses received by plaintiffs with extensive workplace exposures to asbestos — a substance that had long before been established as a cause of lung cancer. In *Bigansky* v. *Thomas Jefferson Univ. Hosp.*, 658 A.2d 423 (Pa. Super. Ct. 1995), the plaintiff suffered immediate pain following surgery to implant a medical device, and the plaintiff immediately suspected that the surgery had been improperly performed. Moreover, the Superior Court in *Bigansky* remarked with respect to its statute of limitations holding that "this case is unique as to its particular facts." *Id.* at 431. Finally, in *Carns* v. *Yingling*, 594 A.2d 337 (Pa. Super. Ct. 1991), the Superior Court actually ruled that the discovery rule *did* apply and that the statute of limitations did not begin to run until the plaintiff "was aware of his injury and that it had been caused by another's conduct." *Id.* at 340. The Superior Court's ruling in *Carns* is thus entirely in accord with the Superior Court's ruling on these 14 consolidated appeals.

IV. CONCLUSION

For the reasons set forth above, the Petition for Allowance of Appeal should be denied.

Respectfully submitted,

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

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, Jr.
Morris Law Firm
11614 Bee Cave Road
Suite 220
Austin, TX 78738
(512) 263–7739
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

Brian D. Ketterer
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:

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

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

Robert C. Heim, Esquire
Judy L. Leone, Esquire
Donald C. Le Gower, Esquire
Dechert LLP
2929 Arch Street
Philadelphia, PA 19104
(215) 994–4000
Counsel for defendants Wyeth and Upjohn

Dated: December 23, 2010

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