

# In the Superior Court of Pennsylvania

Nos. 2620 & 2673 EDA 2007

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MERLE SIMON and STEPHEN A. SIMON,

Plaintiffs,

v.

WYETH PHARMACEUTICALS, INC., et al.,

Defendants.

No. 2620 EDA 2007: Appeal of plaintiff Merle Simon;  
No. 2673 EDA 2007: Cross–appeal of defendant Pharmacia & Upjohn Co., LLC.

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## BRIEF FOR APPELLANT

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On Appeal from the Judgment of the Court of Common Pleas of  
Philadelphia County, Pennsylvania, Civil Trial Division,  
June Term 2004, No. 4229

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with the Pa. Rules of Appellate Procedure**

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## I. STATEMENT OF JURISDICTION

On May 15, 2007, following a five-week trial in the Court of Common Pleas of Philadelphia County, a jury returned a verdict in favor of plaintiff Merle Simon and against defendant Upjohn in the amount of \$1.5 million. R.125a (docket entries) Mrs. Simon had sued Upjohn and another defendant on a claim that she had developed invasive lobular breast cancer due to her long-term use of a hormone therapy prescription drug combination, one-half of which was manufactured by Upjohn. R.134a-40a (plaintiffs' complaint).

A jury found that the Provera medication that Upjohn manufactured and marketed was a cause of Mrs. Simon's breast cancer; that Upjohn had failed to adequately warn of Provera's risk of causing breast cancer; and that Mrs. Simon had filed suit against Upjohn within two years of when it was reasonable to recognize that her breast cancer was caused by having consumed Upjohn's product. R.10,390a-92a (jury's verdict).

Following the jury's adverse verdict, Upjohn filed a timely post-trial motion requesting judgment notwithstanding the verdict or a new trial. R.10,393a-435a (Upjohn's post-trial motion). On September 7, 2007, the trial court entered an order granting Upjohn's motion for judgment notwithstanding the verdict. *See Exhibit B* hereto. On October 1, 2007, Mrs. Simon filed a timely appeal from the entry of j.n.o.v. in Upjohn's favor. R.11,990a. This Court possesses appellate jurisdiction pursuant to Pennsylvania Rule of Appellate Procedure 341(a).

## II. STATEMENT OF THE SCOPE AND STANDARDS OF REVIEW

This Court exercises *de novo* review of a trial court’s decision to set aside a jury’s verdict on a motion for judgment notwithstanding the verdict. *See Rohm and Haas Co. v. Continental Cas. Co.*, 566 Pa. 464, 471, 781 A.2d 1172, 1176 (2001) (“Our scope of review with respect to whether JNOV is appropriate is plenary, as with any review of questions of law.”).

In *Birth Center v. St. Paul Cos.*, 567 Pa. 386, 787 A.2d 376 (2001), the Supreme Court of Pennsylvania described the standards for evaluating a motion for judgment notwithstanding the verdict:

In reviewing the propriety of an order granting or denying judgment notwithstanding the verdict, we must determine whether there was sufficient competent evidence to sustain the verdict. *Wenrick v. Schloemann–Siemag Aktiengesellschaft*, 523 Pa. 1, 564 A.2d 1244, 1246 (1989). We view the evidence in the light most favorable to the verdict winner and give him or her the benefit of every reasonable inference arising there from while rejecting all unfavorable testimony and inferences. *Moure v. Raeuchle*, 529 Pa. 394, 604 A.2d 1003, 1007 (1992). Moreover, “[a] judgment n.o.v. should only be entered in a clear case and any doubts must be resolved in favor of the verdict winner.” *Id.*; *see, Atkins v. Urban Redevelopment Authority of Pittsburgh*, 489 Pa. 344, 414 A.2d 100 (1980). Finally, “a judge’s appraisal of evidence is not to be based on how he would have voted had he been a member of the jury . . .” *Moure*, 604 A.2d at 1007 quoting *Brown v. Shirks Motor Express*, 393 Pa. 367, 143 A.2d 374 (1958).

A court may not vacate a jury’s finding unless “the evidence was such that no two reasonable minds could disagree that the outcome should have been rendered in favor of the movant.” *Moure*, 604 A.2d at 1007, quoting *Cummings v. Nazareth Borough*, 427 Pa. 14, 233 A.2d 874 (1967).

*Id.* at 397–98, 787 A.2d at 383.

Similarly, in *Education Resources Institute, Inc. v. Cole*, 827 A.2d 493 (Pa. Super. Ct. 2003), this Court explained:

Preliminarily we note that “[t]he entry of a judgment notwithstanding the verdict . . . is a drastic remedy. A court cannot lightly ignore the findings of a duly selected jury.” *Neal by Neal v. Lu*, 365 Pa. Super. 464, 530 A.2d 103, 110 (1987) (citations omitted).

[T]he evidence must be considered in the light most favorable to the verdict winner, and he must be given the benefit of every reasonable inference of fact arising therefrom, and any conflict in the evidence must be resolved in his favor. Moreover, [a] judgment n.o.v. should only be entered in a clear case and any doubts must be resolved in favor of the verdict winner. Further, a judge’s appraisal of evidence is not to be based on how he would have voted had he been a member of the jury, but on the facts as they come through the sieve of the jury’s deliberations.

*Moure v. Raeuchle*, 529 Pa. 394, 604 A.2d 1003, 1007 (1992) (citations omitted).

*Id.* at 497.

### III. TEXT OF THE ORDER IN QUESTION

On September 7, 2007, the trial court issued the following order:

AND NOW, this 7th day of September, 2007, upon consideration of Defendant Pharmacia & Upjohn Company LLC’s (Defendant Upjohn) *Motion for Post-Trial Relief*, Plaintiffs’ response, Defendant Upjohn’s reply, and the oral argument heard on September 5, 2007, it is hereby **ORDERED** that Defendant Upjohn’s motion is **GRANTED**. Consequently, judgment notwithstanding the verdict is entered in favor of Defendant Upjohn and against Plaintiffs. Defendant Upjohn’s request for a new trial is hereby deemed **MOOT**.

Exhibit B hereto.

#### **IV. STATEMENT OF THE QUESTIONS PRESENTED**

1. Did the trial court err as a matter of law in granting judgment notwithstanding the verdict in Upjohn's favor based on the supposed expiration of the statute of limitations, because Mrs. Simon did not sue Upjohn within two years of having been diagnosed with breast cancer, thereby impermissibly disregarding the jury's finding under the discovery rule, based on an abundance of evidence, that Mrs. Simon had sued Upjohn within two years of when it was reasonable for her to have recognized that consuming Upjohn's product had caused her breast cancer?

2. Did the trial court err as a matter of law in granting judgment notwithstanding the verdict in Upjohn's favor on the issue of proximate causation, where the jury found based on an abundance of evidence that Mrs. Simon would not have sustained breast cancer as a result of consuming Upjohn's product had Upjohn provided adequate warnings to Mrs. Simon's physicians of the breast cancer risks inherent in using that product?

## V. STATEMENT OF THE CASE

### A. Relevant Factual History

On May 21, 2002, plaintiff Merle Simon was diagnosed with invasive lobular breast cancer. R.2803a–05a (T.T. 4/24/07 p.m. at 69–71). She thereafter had her left breast surgically removed, and her doctors had her undergo chemotherapy through March 2003. R.2805a–14a (T.T. 4/24/07 p.m. at 71–80). On July 1, 2004, Mrs. Simon and her husband, as co–plaintiff, initiated this lawsuit against defendants alleging that the hormone therapy medication that defendants manufactured and marketed was a cause of Mrs. Simon’s breast cancer. R.10a, 134a–42a (docket entries; plaintiffs’ complaint).

At the conclusion of a trial that lasted five weeks, a jury sitting in the Court of Common Pleas of Philadelphia County ruled that the medication Provera — a synthetic progestin manufactured and marketed by defendant Upjohn — was a cause of Mrs. Simon’s breast cancer; that Upjohn had failed to adequately warn of the breast cancer risk inherent in Provera; that Upjohn’s failure to warn was the cause of Mrs. Simon’s injuries; and that Mrs. Simon had filed suit in a timely manner under the discovery rule because it was not reasonable for her to have suspected that taking Provera was a cause of her cancer until the findings of a widely–publicized government–funded randomized study became public on July 9, 2002, which for the first time in history established a reliable causal link between hormone therapy and increased breast cancer in the women who were taking those medications. R.10,390a–92a (jury’s verdict).

The jury's verdict in favor of Mrs. Simon and against Upjohn awarded to Mrs. Simon \$1.5 million in compensatory damages. R.10,392a (*Id.*). The jury did not award any additional damages in favor of Mrs. Simon's husband. R.10,392a (*Id.*). And the jury returned a verdict against Mrs. Simon and in favor of Upjohn's co-defendant, Wyeth, which had manufactured the prescription medication Premarin, a conjugated estrogen supplement made from the urine of pregnant mares, and Prempro, a combination of Premarin and medroxyprogesterone acetate, a chemical equivalent of Provera. R.10,390a–91a (*Id.*).

Mrs. Simon and her husband reside in West Orange, New Jersey. R.1324a (T.T. 4/12/07 a.m. at 13). Mrs. Simon was born in March 1942 and graduated from college with a degree in teaching. R.2766a–67a (T.T. 4/24/07 p.m. at 32–33). She taught first grade for four years until giving birth to her first child, a girl. R.2778a (T.T. 4/24/07 p.m. at 44). She then was a stay-at-home mother raising two children, both girls. R.2778a (*Id.*). In 1985, after having divorced from her first husband, Mrs. Simon married her current husband. R.2770a–71a (T.T. 4/24/07 p.m. at 36–37).

When Mrs. Simon reached the age of 50 in 1992, she reported to her gynecologist that she was suffering from so-called vasomotor symptoms associated with the onset of menopause, such as hot flashes, mood disturbances, and vaginal dryness. R.2781a (T.T. 4/24/07 p.m. at 47). Her gynecologist at the time, Kenneth Dollinger, M.D., decided to prescribe two hormone therapy medications in 1992. The first — Premarin, manufactured by Wyeth — was a form of estrogen that was believed to alleviate the vasomotor symptoms of hot flashes, mood disturbances, and

vaginal dryness. R.2782a–83a, 5010a (T.T. 4/24/07 p.m. at 48–49; Dollinger transcript at 23). The second — Provera, manufactured by Upjohn — was prescribed to prevent endometrial bleeding and possible endometrial cancer that women who had an intact uterus would experience had they taken an estrogen supplement by itself. R.2782a–83a, 5015a (T.T. 4/24/07 p.m. at 48–49; Dollinger transcript at 75–76). In other words, Provera prevented endometrial hyperplasia (extreme cell proliferation on the endometrial lining of the uterus) in women who had not had a hysterectomy and therefore still had their uterus intact.

According to Mrs. Simon’s testimony at trial, Dr. Dollinger did not advise her of any possible increase in breast cancer risk as the result of taking these medications, which he first prescribed for her in 1992, to alleviate vasomotor symptoms, nor did Dr. Dollinger advise her of any increased breast cancer risk at any time thereafter. R.2787a (T.T. 4/24/07 p.m. at 53). As a result of taking these medications, Mrs. Simon experienced a reduction in the symptoms of menopause. R.2852a (T.T. 4/24/07 p.m. at 118).

In 1994, Dr. Dollinger retired, and Joann Somers, M.D. became Mrs. Simon’s gynecologist. R.2786a (T.T. 4/24/07 p.m. at 52). Dr. Somers maintained Mrs. Simon on Premarin and Provera until 1996, when Dr. Somers switched Mrs. Simon to Prempro, a newly available Wyeth product that combined estrogen and progestin in a single pill. R.2852a–53a (T.T. 4/24/07 p.m. at 118–19). Mrs. Simon continued to take Prempro after switching to a new gynecologist in 1999, Dr. Catherine Sladowski, M.D. R.2789a (T.T. 4/24/07 p.m. at 55). After being diagnosed with

breast cancer in May 2002, Mrs. Simon stopped taking Prempro at the instruction of her physicians, because these hormones were recognized as contributing to the growth of existing cancers of the breast. R.2791a, 2914a, 11,449a (Mrs. Simon's trial and deposition testimony).

None of Mrs. Simon's three gynecologists who prescribed Premarin, Provera, or Prempro ever advised Mrs. Simon that she was increasing her chances of contracting breast cancer as a result of taking those medications. R.2787a, 2789a, 2791a, 2823a (T.T. 4/24/07 p.m. at 53, 55, 57, 89). Indeed, during their depositions taken in conjunction with Mrs. Simon's trial, none of these three doctors expressed the belief, even after Mrs. Simon had been diagnosed with breast cancer and filed this lawsuit, that taking these hormone therapy medications increased a woman's chances of contracting breast cancer. R.5009a-10a, 5067a, 5049a (Dollinger transcript at 19; Somers transcript at 15; Sladowski transcript at 72).

The packaging insert and physician information that Upjohn provided to physicians and patients about Provera contained absolutely no breast cancer warnings 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.

R.5231a (1992 PDR for Provera).

Likewise, the 1996 product information for Prempro (the combined estrogen/progestin pill manufactured by Wyeth) stated:

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.5810a (1996 PDR for Prempro). In sum, both the product information and packaging inserts for Provera manufactured by Upjohn and the product information and packaging inserts for Prempro (the combined product manufactured by Wyeth) failed to disclose to physicians or patients that taking progestins could cause breast cancer.

When Mrs. Simon was diagnosed with breast cancer in 2002, she was instructed to cease consuming Prempro, because the product is not indicated for anyone who actually has breast cancer. R.2791a, 2914a, 11,449a (Mrs. Simon's trial and deposition testimony). Mrs. Simon's physicians, however, did not tell her then or thereafter that the hormone therapy medication she had consumed over the preceding ten years may have been a cause of her breast cancer. R.2819a, 2823a (T.T. 4/24/07 p.m. at 85, 89).

At trial, counsel for plaintiffs introduced evidence showing that Upjohn should have performed an adequate randomized study to determine whether Provera was associated with an increased breast cancer risk based on the inconclusive evidence of such a breast cancer risk that existed in the 1990s when

Upjohn was aware that physicians were using Provera as a so-called “off label” medication combined with Premarin to treat vasomotor symptoms of menopause.

It was not until July 9, 2002, however, that a reliable causal link between Provera and breast cancer was shown to exist. On that date, the results of the “Women’s Health Initiative” study were revealed. R.2819a (T.T. 4/24/07 p.m. at 85). The WHI was a randomized controlled trial sponsored by the National Institutes of Health that was intended to “assess the major health benefits and risks of the most commonly used combined hormone preparation in the United States.” R.6134a (“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 observed:

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.

R.6143a (*Id.* at 330). The authors of the study also 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.” R.6134a (*Id.* at 321).

The results of the WHI received widespread attention from the popular media. As noted above, Mrs. Simon and her husband initiated this lawsuit on July 1, 2004, within two years of when the results of the WHI became public on July 9, 2002, but slightly more than two years after Mrs. Simon was diagnosed with breast cancer on May 21, 2002. The jury at trial was instructed to find whether Mrs. Simon reasonably should have known that the hormone therapy drugs she had

taken had caused her breast cancer before the results of the WHI study became public, and the jury found that the discovery rule applied and that Mrs. Simon's lawsuit was timely. R.10,390a (jury's verdict slip).

## **B. Relevant Procedural History**

Merle Simon filed this lawsuit on July 1, 2004, within two years of July 9, 2002, the date on which the results of the Women's Health Initiative study became public, establishing for the first time ever a scientifically reliable causal link between hormone therapy medication and breast cancer. R.10a (docket entries). Mrs. Simon's breast cancer was diagnosed on May 21, 2002, and thus she initiated this lawsuit within two years and forty-nine days of that diagnosis.

This case was one of several so-called bellwether cases selected for the first round of hormone therapy litigation trials in the Court of Common Pleas of Philadelphia County. Before this case reached a verdict, however, defendants Wyeth and Upjohn filed motions seeking the entry of judgment in their favor, arguing that the lawsuit was time-barred and that plaintiffs failed to show that Mrs. Simon's physicians would not have prescribed the hormone therapy medications for her even if adequate breast cancer warnings had been communicated before the results of the WHI study became public on July 9, 2002. R.143a-50a, 10,214a-21a, 10,226a-36a.

In denying defendants' pre-verdict motions for judgment, the trial court held that this case presented jury questions on both of those issues. R.1071a, 10,281a,

10,282a. The denial of defendants' pre-verdict motions on the statute of limitations issue meant that it was for the jury to decide, based on the relevant evidence, whether under the discovery rule a reasonable person would have recognized that her cancer was caused by hormone therapy medications before the results of the WHI study became public on July 9, 2002. And the denial of defendants' motion for compulsory nonsuit on the issue of proximate cause meant that it was for the jury to decide whether adequate warnings would have prevented Mrs. Simon's doctors from prescribing the hormone therapy medications for her.

The trial of this lawsuit began on April 17, 2007 and lasted for approximately one month. R.1661a-4905a (trial transcripts). At trial, a considerable amount of attention was directed toward issues that are not directly relevant to the two grounds on which the trial court relied in granting judgment notwithstanding the verdict in Upjohn's favor. Specifically, a great deal of testimony and evidence focused on proving (or, from the defendants' perspective, trying to prevent plaintiffs from proving) whether Premarin, Provera, and Prempro caused breast cancer, and also whether the warnings that Wyeth and Upjohn had furnished to Mrs. Simon's physicians when those medications were prescribed for Mrs. Simon adequately warned her physicians of that breast cancer risk.

Neither of these two issues, however, is relevant to the grounds on which the trial court granted j.n.o.v. in Upjohn's favor. The trial court did not grant j.n.o.v. in Upjohn's favor, nor did Upjohn seek the entry of j.n.o.v. in its favor, based on the contention that Provera does not cause breast cancer. Exhibit A hereto; R.10,393a-

435a (Upjohn's post-trial motion). Likewise, the trial court did not grant j.n.o.v. in Upjohn's favor, nor did Upjohn seek the entry of j.n.o.v. in its favor, based on the contention that Upjohn had provided Mrs. Simon's physicians with adequate warnings of the breast cancer risks of using Provera. Exhibit A hereto; R.10,393a-435a (Upjohn's post-trial motion).

On May 15, 2007, after nearly one month's worth of trial, the jury returned a verdict in favor of Mrs. Simon and against Upjohn in the amount of \$1.5 million. R.10,390a-92a (verdict sheet). The jury's verdict also rejected the claim of Mrs. Simon's husband and found that co-defendant Wyeth was not liable for damages to either plaintiff. R.10,390a-92a (verdict sheet). After entry of the jury's verdict, Mrs. Simon filed a timely post-trial motion for delay damages, which the trial court denied by means of an order issued on the same day that the trial court granted Upjohn's motion for judgment notwithstanding the verdict. R.11,981a-89a (plaintiff's post-trial motion); Exhibit C hereto.

After the jury in this lawsuit returned its verdict in favor of Mrs. Simon, and against Upjohn, in the amount of \$1.5 million, Upjohn moved for j.n.o.v. on only three grounds. R.10,394a-95a (Upjohn's post-trial motion). First, Upjohn renewed its argument that Mrs. Simon's lawsuit was time-barred. R.10,395a (Upjohn's post-trial motion). Earlier, the trial court had rejected Upjohn's motion for summary judgment, motion for a nonsuit, and motion for a directed verdict based on this very ground. R.1071a, 10,282a, 4589a-619a (trial court's orders; transcript of directed verdict argument). Second, Upjohn renewed its argument that Mrs. Simon's

physicians would have prescribed Provera for her even if Upjohn had adequately warned of the medication's breast cancer risk. R.10,394a (Upjohn's post-trial motion). Earlier, the trial court had rejected Upjohn's summary judgment motion, nonsuit motion, and directed verdict motion based on this same ground. R.10,281a, 4589a-619a (trial court's order; transcript of directed verdict argument). And, lastly, Upjohn sought j.n.o.v. on the ground that Mrs. Simon's common law failure-to-warn tort claim was preempted by federal law. R.10,394a (Upjohn's post-trial motion). Earlier, the trial court had rejected Upjohn's summary judgment, nonsuit, and directed verdict motions raising this ground, and the trial court did not rely on this ground in granting j.n.o.v. in Upjohn's favor. R.1070a, 10,279a, 4606a, 4619a (trial court's orders; transcript of directed verdict argument).

Upjohn's post-trial motion, in addition to requesting the entry of judgment notwithstanding the verdict, also sought a new trial on numerous other grounds. R.10,395a-96a (Upjohn's post-trial motion). The trial court, in violation of Pennsylvania Rule of Civil Procedure 227.1(e), failed to address and announce how it would rule on the arguments advanced in Upjohn's motion, in the alternative, for a new trial. Exhibit B hereto (trial court's order on post-trial motions).

On September 7, 2007, the trial court issued an order granting Upjohn's motion for j.n.o.v. Exhibit B hereto (*Id.*) Mrs. Simon filed a timely notice of appeal from that ruling on October 1, 2007. R.11,990a (plaintiff's notice of appeal). On October 5, 2007, Upjohn filed a cross-appeal from the trial court's failure to rule on

Upjohn's request, in the alternative, for a new trial in violation of Pennsylvania Rule of Civil Procedure 227.1(e). R.11,995a (Upjohn's notice of appeal).

On December 26, 2007, the trial court issued an opinion pursuant to Pennsylvania Rule of Appellate Procedure 1925(a) setting forth the reasons for the trial court's entry of j.n.o.v. in Upjohn's favor. Exhibit A hereto (trial court's Rule 1925(a) opinion). The opinion explains that the trial court entered j.n.o.v. in favor of Upjohn on two grounds: statute of limitations and proximate cause.

With regard to the statute of limitations, the trial court ruled that Mrs. Simon reasonably should have known that Provera was a cause of her breast cancer as of the date that she was diagnosed with breast cancer on May 21, 2002, and thus the applicable two-year statute of limitations had expired on any claim against Upjohn before Mrs. Simon filed this lawsuit on July 1, 2004. Rule 1925(a) opinion at 15. The trial court's ruling set aside the jury's specific finding that Mrs. Simon's lawsuit was timely under the discovery rule because it was indeed reasonable for her not to realize that Provera was a cause of her breast cancer until news of the results of the WHI study emerged on or after July 9, 2002. In granting j.n.o.v. in Upjohn's favor on the issue of the statute of limitations, the trial court also reached a result in conflict with the trial court's earlier denial of Upjohn's motion for summary judgment on this ground, as well as the trial court's earlier denials of Upjohn's motions for a nonsuit and a directed verdict on this ground.

The second and final ground on which the trial court relied in entering j.n.o.v. in favor of Upjohn involved the issue of proximate cause. Rule 1925(a) opinion at

17–27. Although the jury’s verdict demonstrates that the jury found that Mrs. Simon would not have contracted breast cancer from using Provera had Upjohn provided adequate warnings of that medication’s breast cancer risk, the trial court chose to disregard that finding in granting j.n.o.v. in Upjohn’s favor on the proximate cause issue. Specifically, the district court’s Rule 1925(a) opinion explains that, in the district court’s view, Mrs. Simon’s physicians would still have prescribed Provera even if Upjohn had adequately warned of the medication’s risk of causing breast cancer. Rule 1925(a) opinion at 26.

The testimony that the jury heard at trial from Mrs. Simon’s prescribing gynecologists came in the form of videotaped deposition testimony shown to the jury, and thus the evidence relating to proximate cause introduced at trial was no different from the evidence relating to proximate cause that existed in the record on Upjohn’s nonsuit motion. R.5008a–16a, 5039a–62a, 5063a–67a (transcripts of Mrs. Simon’s gynecologists’ testimony). Nevertheless, the trial court’s grant of j.n.o.v. on this basis reached a result contrary to the trial court’s denials of Upjohn’s request for a nonsuit and a directed verdict on the issue of proximate cause.

Because this case involves an appeal and a cross–appeal, the parties are entitled to submit a total of two appellate briefs each. In this step one Brief for Appellant, Mrs. Simon focuses on arguing for both the reversal of the trial court’s entry of j.n.o.v. in favor of Upjohn and the reinstatement of the jury’s \$1.5 million verdict in Mrs. Simon’s favor. Next, in its step two Brief for Appellee/Cross–Appellant, Upjohn presumably will oppose Mrs. Simon’s appeal and will advance

arguments in support of Upjohn's cross-appeal. Then, in her step three Reply Brief for Appellant/Cross-Appellee, Mrs. Simon will submit her reply in support of her appeal and will respond to Upjohn's cross-appeal. Finally, in its step four Reply Brief for Cross-Appellee, Upjohn will submit a reply limited to the issues raised in Upjohn's cross-appeal.

## **VI. SUMMARY OF THE ARGUMENT**

Following a trial that lasted a little over one month, a jury sitting in the Court of Common Pleas of Philadelphia County found that the prescription medication Provera, manufactured by defendant Upjohn, was a cause of plaintiff Merle Simon's breast cancer; that Upjohn had failed to adequately warn of the breast cancer risk inherent in Provera; that an adequate warning would have prevented Mrs. Simon's physicians from prescribing Provera to her; and that Mrs. Simon filed suit against Upjohn within two years of when it was reasonable for her to have recognized that Provera was a cause of her breast cancer.

After having properly denied Upjohn's motions for summary judgment, nonsuit, and a directed verdict raising these very same grounds, the trial court erroneously reversed course and granted judgment notwithstanding the verdict in Upjohn's favor on two grounds: (1) that Mrs. Simon's lawsuit was untimely, because she should have realized that Provera had caused her breast cancer at the moment her breast cancer was diagnosed; and (2) that proximate cause was lacking, because

Mrs. Simon's gynecologists later continued to prescribe Provera for certain other of their patients even after the medication's actual breast cancer risks became known.

Neither of the grounds on which the trial court relied in granting Upjohn's motion for judgment notwithstanding the verdict can withstand appellate review. On the issue of the statute of limitations and application of the discovery rule, this is not a case in which a court can hold as a matter of law that Mrs. Simon should have known that Provera caused her breast cancer when she was diagnosed with that condition. The evidence before the jury demonstrated that Mrs. Simon's physicians who prescribed Provera to her never warned her of the medication's breast cancer risk; Upjohn's product information to physicians and packaging inserts for patients never warned of any breast cancer risk to humans; the doctors who diagnosed Mrs. Simon's breast cancer did not tell her it was caused by Provera; and, most importantly, no scientifically reliable randomized controlled study had ever disclosed Provera's breast cancer risk until July 9, 2002, a date *less than* two years before Mrs. Simon filed suit against Upjohn.

The evidence in this case created a jury issue concerning whether the discovery rule should apply and whether a reasonable person in Mrs. Simon's position would have recognized that Provera caused her breast cancer before the results of the Women's Health Initiative study became public on July 9, 2002. The jury found, based on an abundance of evidence, that Mrs. Simon reasonably did not recognize that Provera caused her breast cancer until the WHI results were announced, and thus her lawsuit filed on July 1, 2004 was timely under the

discovery rule. The trial court's entry of j.n.o.v. fails to view the evidence in the light most favorable to Mrs. Simon, impermissibly substitutes the trial judge's view of the evidence for the jury's view of the evidence, and therefore must be reversed.

The trial court's grant of j.n.o.v. on the issue of proximate cause is likewise incapable of withstanding appellate review. The question is not whether Mrs. Simon's gynecologists continued to prescribe Provera for *other patients* after the medication's actual breast cancer risk became known, but rather whether those gynecologists would have prescribed Provera for Mrs. Simon had the medication's actual breast cancer risk been known when she received the medication. On that issue, the jury had more than sufficient evidence from which to find, as it did, that Mrs. Simon's gynecologists would not have prescribed Provera to Mrs. Simon had the drug's actual breast cancer risks been known when she began taking the medication.

Establishing proximate cause in a prescription drug failure-to-warn case governed by Pennsylvania law is often not an easy task, but in this case Mrs. Simon introduced sufficient evidence to raise a question of fact for the jury to decide, as the trial court correctly realized in letting the issue go to the jury. The trial court's entry of j.n.o.v. in Upjohn's favor on the question of proximate cause impermissibly disregards critically important testimony from Mrs. Simon's prescribing physicians about how the results of the Women's Health Initiative study altered those gynecologists' approach to deciding whether to prescribe combined hormone therapy treatment that includes Provera. And the trial court's legally incorrect assertion

that a plaintiff, to establish proximate cause, must prove that his or her physician no longer prescribes the medication in question to *any patient* raises an essentially insurmountable hurdle that no reported Pennsylvania appellate decision has ever established or recognized as proper.

Rather, under Pennsylvania law, all that a plaintiff must demonstrate to a jury's satisfaction by a preponderance of the evidence is that an adequate warning would have prevented the doctor from prescribing the medication in question to *the plaintiff*. The evidence that Mrs. Simon introduced in this case allowed the jury to find that adequate warnings would have caused Mrs. Simon's physicians not to prescribe combined hormone therapy for her, and thus the trial court erred in entering j.n.o.v. in Upjohn's favor on the question of proximate cause.

For all of these reasons, as examined in greater detail below, this Court should reverse the trial court's entry of judgment notwithstanding the verdict in Upjohn's favor and order the trial court to reinstate the jury's verdict in favor of Mrs. Simon.

## **VII. ARGUMENT**

### **A. Abundant Evidence Exists In Support Of The Jury's Finding That Mrs. Simon's Claim Was Timely Under The Discovery Rule, And Thus The Trial Court Erred In Entering J.N.O.V. In Upjohn's Favor Based On The Supposed Expiration Of The Statute Of Limitations**

At the close of the evidence in this case, the trial court instructed the jury to determine based on the evidence whether a reasonable person in Mrs. Simon's

situation would have realized that the hormone therapy medications manufactured and marketed by defendants were a cause of her breast cancer at the time the cancer was diagnosed. R.4871a–73a (T.T. 5/15/07 at 66–68). The jury, in its verdict, found in favor of Mrs. Simon, concluding that not until the results of the Women’s Health Initiative study were publicized some forty–nine days after Mrs. Simon’s cancer diagnosis was it reasonable for Mrs. Simon to have realized that defendants’ medications were a cause of her breast cancer. R.10,390a (jury verdict slip).

An abundance of evidence supports the jury’s finding in this regard, and therefore it was error for the trial court to have granted judgment notwithstanding the verdict in Upjohn’s favor based on the supposed expiration of the statute of limitations applicable to Mrs. Simon’s failure–to–warn claim.

As the Supreme Court of Pennsylvania has ruled, a trial court’s mere disagreement with the facts found by the jury does not provide a valid basis for granting judgment notwithstanding the verdict:

While a judge may disagree with a verdict, he or she may not grant a motion for J.N.O.V. simply because he or she would have come to a different conclusion. Indeed, the verdict must stand unless there is no legal basis for it. Without agreeing or disagreeing with Judge Koudelis or Judge Clouse, we view the evidence in the light most favorable to Birth Center, the verdict winner, and give it the benefit of every reasonable inference arising therefrom while rejecting all unfavorable testimony and inferences. From that perspective, we are unable to conclude that no reasonable jury could have found that St. Paul acted in bad faith. Therefore, although, like Judge Koudelis, we may not have reached the same verdict as the jury, there was sufficient evidence to sustain the verdict and a reasonable basis for the jurors to have found, from the evidence, that St. Paul acted in bad faith.

*Birth Center v. St. Paul Cos.*, 567 Pa. 386, 397–99, 787 A.2d 376, 383–84 (2001).

Under Pennsylvania law, “the statute of limitations begins to run as soon as a right to institute and maintain suit arises.” *Crouse v. Cyclops Indus.*, 560 Pa. 394, 403, 745 A.2d 606, 611 (2000). Yet Pennsylvania law also recognizes the discovery rule, which the Supreme Court of Pennsylvania 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.

More recently, in *Fine v. Checcio*, 582 Pa. 253, 870 A.2d 850 (2005), 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 this very appeal:

Therefore, when 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.

*Id.* at 267–68, 870 A.2d at 858–59.

Here, there is no dispute that Mrs. Simon’s injury became known to her on May 21, 2002, when she was diagnosed with breast cancer. The question the jury was instructed to decide, under the evidence admitted at trial, was whether a reasonable person in Mrs. Simon’s position would have realized before the publicity surrounding the release of the results of the Woman’s Health Initiative study on July 9, 2002 — establishing for the very first time a reliable causal link between combined hormone therapy medication and breast cancer — that defendants’ hormone therapy medications were a cause of her breast cancer.

The evidence before the jury on the issue of when Mrs. Simon reasonably should have discovered the cause of her injury consisted of the following. Mrs. Simon herself testified that none of the three gynecologists who prescribed this medication for her from 1992 through 2002 had told her that the medication could cause breast cancer. R.2787a, 2789a, 2791a, 2823a (T.T. 4/24/07 p.m. at 53, 55, 57, 89). Videotaped deposition testimony presented to the jury from those same three physicians did not contradict Mrs. Simon’s testimony in that regard. R.5009a–10a, 5067a, 5049a (Dollinger transcript at 19; Somers transcript at 15; Sladowski transcript at 72). Moreover, when Mrs. Simon was diagnosed with breast cancer in May 2002, she was not told by any physician that defendants’ hormone therapy medications was or could be a cause of her breast cancer. R.2819a, 2823a (T.T. 4/24/07 p.m. at 85, 89).

The product information that Upjohn provided to physicians and their patients concerning Provera did not disclose that Provera did or could cause breast cancer in humans. All that the product information disclosed was that Provera had caused mammary tumors and cancers in beagle dogs, but Upjohn expressly disavowed the relevance of that information as to humans:

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.

R.5231a (1992 PDR for Provera).

The product information that Wyeth issued to physicians in 1996 in connection with the introduction of the Prempro medication — combining Premarin and a synthetic progestin in a single pill — likewise included a beagle dog warning with respect to progestin, but that warning was made even less relevant as to humans by Wyeth’s inclusion of the following statement: “Therefore, the MPA-induced [meaning progestin-induced] increase of mammary tumors in dogs probably has no significance to humans.” R.5811a (1996 PDR for Prempro).

Most importantly, however, Wyeth’s product information pertaining to Prempro twice states that “the effect of added progestins on the risk of breast cancer is unknown.” R.5810a, 5811a (1996 PDR for Prempro). In other words, in 1996 Wyeth was disclosing to physicians and patients in the product information for Prempro that the inclusion of progestins in combined hormone therapy had an

“unknown” effect on the risk of breast cancer. Yet the trial court in this case has held, as a matter of law — disregarding the jury’s express findings to the contrary — that a middle-aged housewife from New Jersey with no medical training should have realized what the pharmaceutical companies manufacturing and marketing progestins for combined hormone therapy had refused to acknowledge: that progestins caused breast cancer. As the jury properly found based on the evidence of record, it was not reasonable to expect Mrs. Simon to realize that Provera was a cause of her breast cancer until the results of the WHI study became public on July 9, 2002, for the first time establishing a reliable causal connection between combined hormone therapy and breast cancer.

The Prempro product information stated, with regard to the estrogen component of Prempro:

Some studies have reported a moderately increased risk of breast cancer 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.

R.5810a (1996 PDR for Prempro). Even the above-quoted language, which applies solely to the Premarin (estrogen) aspect of hormone therapy, did not apply directly to Mrs. Simon, because she was not taking “higher doses” of estrogen, nor had she taken the medication for longer than ten years. R.2962a (T.T. 4/25/07 p.m. at 23–24, 27–28).

To be sure, the jury did hear evidence during the course of the trial about certain studies, which preceded announcement of the Women’s Health Initiative’s

results, indicating that a causal connection may exist between combined hormone therapy medication and breast cancer. R.3339a (T.T. 5/1/07 a.m. at 106). The plaintiffs introduced this evidence to prove to the jury that the defendants had been derelict in failing to conduct (or to cause to be conducted by another) a reliable randomized study to determine whether an actual causal link existed between these combined hormone therapy medications and breast cancer. It was the absence of any such studies that enabled Upjohn and Wyeth to continue to maintain, up until the results of the Women's Health Initiative were released in July 2002, that "the effect of added progestins on the risk of breast cancer is unknown." R.5810a (1996 PDR for Prempro).

Moreover, the jury also heard that even after the announcement of the results of the Women's Health Initiative, some gynecologists and other physicians and scientists disagreed over whether progestins such as Provera cause breast cancer. Among the medical professionals who doubt the existence of such a causal relationship are all three of Mrs. Simon's prescribing gynecologists. R.5009a-10a, 5067a, 5049a (Dollinger transcript at 19; Somers transcript at 15; Sladowski transcript at 72). Of course, gynecologists do not focus their practice of medicine on ascertaining the cause of cancers, and the jury's finding that Upjohn's Provera was a cause of Mrs. Simon's breast cancer is not something that Upjohn challenged in its j.n.o.v. motion, nor is it a finding that the trial court set aside in granting j.n.o.v. in Upjohn's favor.

It was not until July 9, 2002 that a reliable causal link between Provera and breast cancer was shown to exist. On that date, the results of the “Women’s Health Initiative” study were revealed. The WHI was a randomized controlled trial conducted by the National Institutes of Health that was intended to “assess the major health benefits and risks of the most commonly used combined hormone preparation in the United States.” R.6134a (“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 observed:

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.

R.6143a (*Id.* at 330). The authors of the study also 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.” R.6134a (*Id.* at 321).

The results of the WHI received widespread attention from the popular media. As noted above, Mrs. Simon and her husband initiated this lawsuit on July 1, 2004, within two years of when the results of the WHI became public on July 9, 2002. The jury at trial was instructed to find whether Mrs. Simon reasonably should have known that the hormone therapy drugs she had taken were the cause of her breast cancer before the results of the WHI study became public, and the jury found that the discovery rule applied and that Mrs. Simon’s lawsuit was timely.

The trial court erred in entering judgment notwithstanding the verdict in Upjohn’s favor on issue of statute of limitations. From the time that Mrs. Simon

began taking Provera in 1992 through to the time that the results of the WHI were made public in July 2002, the product information that Upjohn and Wyeth used for their medications containing synthetic progestins (Provera and Prempro) disavowed any causal link between progestins and breast cancer. At best, before July 2002 there were some studies published in medical journals not readily available to housewives such as Mrs. Simon suggesting that there might be a causal link, other studies published in similarly obscure medical journals suggesting that there was not any causal link, and Upjohn and Wyeth's failure to undertake any reliable randomized study to establish once and for all whether such a causal link existed or not.

Given that the two gynecologists who prescribed Upjohn's Provera for Mrs. Simon to use were unwilling to acknowledge in their videotaped deposition testimony shown to the jury at trial that even the WHI study established a causal link between Provera and breast cancer, it defies logic for the trial court to have held that upon being diagnosed with breast cancer in May 2002 Mrs. Simon was immediately on notice that Provera was a cause of her breast cancer.

Moreover, the trial court's conclusion that Mrs. Simon should have realized that Provera was a cause of her breast cancer because her physicians told her to stop taking Prempro when she was diagnosed with breast cancer (*see* Rule 1925(a) opinion at 16) is based on confused logic and provides no basis for affirmance. The Prempro product information that Wyeth published, at the same time that it denies any causal link between progestins and breast cancer, does explain that Prempro is

contraindicated for any women who have breast cancer. R.5810a (1996 PDR for Prempro). This is because hormones such as estrogen are known to promote the further growth of existing breast cancer, which is why various breast cancer treatments involve chemotherapy drugs intended to stop the woman from producing even her normal amount of estrogen. R.2814a (T.T. 4/24/07 p.m. at 80).

Just as the fact that a patient may be instructed to stop taking blood thinning medication in advance of surgery does not mean that the blood thinning medication caused the condition requiring surgery, being told to stop taking hormone therapy on being diagnosed with cancer does not prove that the medication was the cause of the cancer. And, as the jury heard Mrs. Simon testify (without any rebuttal from defendants), Mrs. Simon's doctors who diagnosed her breast cancer did not inform her that the hormone therapy medication she had been taking was the cause of her cancer (R.2819a (T.T. 4/24/07 p.m. at 85)), nor did she have any reason to suspect that her cancer was caused by that medication until the results of the WHI study became public.

In order for Mrs. Simon to prevail on appeal, and for this Court to reverse the trial court's entry of j.n.o.v. in Upjohn's favor on the statute of limitations issue, Mrs. Simon does not need to convince this Court that she was entitled to prevail on the discovery rule issue as a matter of law. Rather, Mrs. Simon believes that the trial court acted properly — when denying Upjohn's motion for summary judgment and motions for a nonsuit and a directed verdict — in holding that application of the discovery rule presented a factual issue for the jury to resolve. The trial court's

rulings in that regard were precisely correct under the Pa. Supreme Court's holdings in *Fine v. Checcio* and *Crouse v. Cyclops Indus., supra*.

There was more than sufficient evidence for the jury to decide, as it did, that Mrs. Simon reasonably did not realize that Provera was the cause of her breast cancer until the results of the WHI study became public in July 2002, some forty–nine days after Mrs. Simon had been diagnosed with breast cancer on May 21, 2002. For Upjohn to suggest that Mrs. Simon should have spent the first forty–nine days after having been diagnosed with a terrifyingly dangerous, life–threatening condition combing through obscure medical texts in an attempt to discover who or what was legally responsible for having caused her to contract breast cancer is simultaneously cruel and comical. But even if that were the duty that she should have discharged, the jury's verdict on the discovery rule issue establishes that the information contained in those obscure medical texts was equivocal and far from definitive in establishing any causal link between Provera and breast cancer.

In its Rule 1925(a) opinion issued in this case, the trial court cites as support for its entry of j.n.o.v. against Mrs. Simon on the statute of limitations issue the opinion in support of summary judgment that Philadelphia Common Pleas Court Judge Allan L. Tereshko issued in favor of defendant Wyeth in the case captioned *Coleman v. Wyeth Pharmaceuticals Inc.*, June Term, 2004, No. 3179 (C.C.P. Sept. 24, 2007). The *Coleman* case, which is separately pending on appeal before this Court at No. 2678 EDA 2007, is distinguishable from this case on numerous substantive and procedural grounds.

Substantively, according to the trial court's opinion in the *Coleman* case, the plaintiff in *Coleman* testified at her deposition that when she was diagnosed with breast cancer, the doctor who made the diagnosis told Mrs. Coleman that Wyeth's Prempro had caused her breast cancer. See *Coleman* 1925(a) opinion at page 11. And procedurally, because *Coleman* was decided on summary judgment, the issue of the discovery rule's application in *Coleman* had not been submitted to a jury for its resolution, whereas in Mrs. Simon's case it was.

Unlike the plaintiff in *Coleman*, Mrs. Simon testified in this case that no doctor had ever advised her, before the results of the WHI study became public on July 9, 2002, that taking combined hormone therapy medication caused her cancer. R.2819a (T.T. 4/24/07 p.m. at 85). And in this case, unlike in *Coleman*, a jury properly heard and evaluated the evidence relevant to the discovery rule's application and permissibly found that the discovery rule applied and that Mrs. Simon's lawsuit was therefore timely.

For all of the foregoing reasons, in Mrs. Simon's case the trial court acted properly in submitting the question of the discovery rule's application to the jury under established Pennsylvania Supreme Court rulings. Because an abundance of evidence supports the jury's verdict that the discovery rule applies and that Mrs. Simon's suit was timely filed, this Court should reverse the trial court's entry of judgment notwithstanding the verdict in Upjohn's favor and reinstate the jury's verdict in favor of Mrs. Simon.

**B. The Trial Court Erred In Granting J.N.O.V. In Upjohn's Favor On The Ground That Upjohn's Failure To Warn Was Not A Proximate Cause Of Mrs. Simon's Injuries**

Pennsylvania law recognizes that because prescription medications such as Provera are only available to patients at the instruction of a licensed physician, the duty to warn of risks inherent in prescription medications runs from the manufacturer to the physician. *See Brecher v. Cutler*, 578 A.2d 481, 484–85 (Pa. Super. Ct. 1990).

In order for a plaintiff in a failure-to-warn lawsuit to establish the element of proximate cause, the plaintiff must therefore establish that if the prescription drug's manufacturer had provided adequate warnings to the prescribing physician, the physician would not have prescribed the medication to the plaintiff. *See Lineberger v. Wyeth*, 894 A.2d 141, 149–50 (Pa. Super. Ct. 2006); *Demmler v. SmithKline Beecham Corp.*, 671 A.2d 1151, 1155 (Pa. Super. Ct. 1996).

Thus, for example, where a prescribing physician has testified that he or she never relies on warnings that the prescription drug's manufacturer provides, the Superior Court has held that the plaintiff failed establish the element of proximate cause because a different warning would not have come to the physician's attention. *See Demmler*, 671 A.2d at 1155–56. Similarly, if the prescribing physician testifies that he or she would still have prescribed the drug in question to the plaintiff even if the manufacturer had provided an adequate warning, the element of proximate cause is not satisfied. *See Lineberger*, 894 A.2d at 150–51. Thus, it is not sufficient for the plaintiff to testify that the plaintiff, if an adequate warning had been given,

would not have consumed the medication in question if the prescribing physician would still have prescribed the medication even if an adequate warning had been given.

In this case, the jury properly found based on the evidence of record that Mrs. Simon's gynecologists who had prescribed Provera would not have prescribed that medication for Mrs. Simon's use had Upjohn provided those physicians with adequate warnings. Because Mrs. Simon took Provera from 1992 through 1996 (when she began taking the Prempro combined pill manufactured by Wyeth), the two gynecologists whose testimony is pertinent to the issue of proximate cause with respect to Upjohn are Drs. Dollinger and Somers.

To be sure, both Dr. Dollinger and Dr. Somers testified that they have continued to prescribe Provera to certain other patients of theirs who take Premarin if those patients have intact uteruses. To avoid the risk of endometrial (uterine) cancer and endometrial hyperplasia (extreme cell proliferation on the endometrial lining of the uterus) in women who have not had a hysterectomy and therefore still had their uteruses intact, both Dr. Dollinger and Dr. Somers have continued to prescribe Provera to women with intact uteruses who are taking Premarin. R.5012a-13a, 5064a-65a (Dollinger transcript at 37; Somers transcript at 10).

Nevertheless, both Dr. Dollinger and Dr. Somers testified (and this testimony came into evidence at trial when those doctors' videotaped deposition excerpts were played for the jury) that in the aftermath of the WHI study, their prescribing habits in offering patients combined hormone therapy has greatly changed.

Dr. Dollinger testified as follows:

Q. Knowing what you know today about hormone therapy and the information that you've gained from reviewing the WHI, if you know that information in 1992 when Merle Simon came to you with symptoms of menopause, hot flashes and night sweats, would you have prescribed her Premarin and Progestin at that time?

A. I would then have a long discussion with her about how bad her symptoms were. I would tell her about the study. I would try to interpret the study for her. \* \* \* I would still have to warn somebody about the study, which, by the way, is what I do now.

R.5012a–13a (Dollinger transcript at 36–37). Dr. Dollinger then went on to testify that after communicating to his patient that the WHI study had established a causal linkage between combined hormone therapy medication and breast cancer, he would allow his patient to decide for herself whether she wanted him to prescribe the medication for her. R.5012a–13a (Dollinger transcript at 37).

Similarly, Dr. Somers testified as follows:

Q. And did your dialogue with your patients change at all after the Women's Health Initiative?

A. It had to, because of the media blitz concerning the breast cancer risk, the purported increase in breast cancer risk with prolonged usage of hormone replacement, and that changed the discussion to a large degree, in terms of the details of that. We had to go over the Women's Health Initiative results and speak to the patients and describe to them and inform them of the study and how it was done, and the conclusions that they arrived at, and so there was a lot of education that needed to be done concerning the Women's Health Initiative.

R.5065a (Somers transcript at 10–11). Dr. Somers likewise testified that, after communicating to her patient that the WHI study had established a causal linkage between combined hormone therapy medication and breast cancer, she would allow

her patient to decide for herself whether she wanted to receive the combined hormone therapy medication. R.5065a (Somers transcript at 10–11). The trial court was thus mistaken in asserting, in its Rule 1925(a) opinion, that “Plaintiffs did not introduce any evidence from Dr. Somers relevant to establishing proximate causation.” Rule 1925(a) opinion at page 26.

The facts in evidence in this case established to the satisfaction of the jury that, in the aftermath of the WHI study, both Dr. Dollinger and Dr. Somers would leave it up to their individual patients to decide, in light of the breast cancer risk now known to be inherent in combined hormone therapy treatment, whether to take those medications, which includes Provera. The jury also heard from Mrs. Simon that had she received that information from Drs. Dollinger and Somers when they were deciding whether to prescribe the combined hormone therapy medications to her to treat her symptoms of menopause, Mrs. Simon would have told those doctors that she did not want to take the medications, and those doctors therefore would not have prescribed it for her. R.2824a (T.T. 4/24/07 p.m. at 90).

The foregoing evidence made the question of proximate cause an issue for the jury to decide, as the trial court properly recognized in submitting the question to the jury for resolution. Here, based on the evidence, the jury permissibly found that Mrs. Simon’s treating physicians would not have prescribed Provera (or, by extension, Premarin) for her had adequate warnings been available, as became the case once the Women’s Health Initiative study’s results were made public.

Mrs. Simon is not arguing that she would not have taken Provera even if her physicians had prescribed it to her. Rather, all she contends (and what the evidence viewed in a light most favorable to her establishes as reflected in the jury's verdict) is that her physicians would not have prescribed Provera to her had adequate warnings been available. What would have happened if adequate warnings had been available presents the quintessential jury question, because it requires inferences to be drawn from the testimony and other evidence. The jury believed the testimony of Mrs. Simon's former prescribing gynecologists when they testified that they would have allowed Mrs. Simon to decide, based on the cancer risk that the WHI study established, whether to receive prescriptions for these medications. And the jury believed the testimony of Mrs. Simon when she testified, based on the cancer risk that the WHI study established, that she would not have had her gynecologists prescribe the combined hormone therapy medications to her.

Moreover, the trial court erred in holding that — merely because Mrs. Simon's former gynecologists continue to prescribe combined hormone therapy for *other patients* — Mrs. Simon has failed to prove the existence of proximate cause on *her claim* against Upjohn. According to the trial court's Rule 1925(a) opinion, at page 26, "in order to prove proximate causation, Plaintiffs were required to establish that Plaintiff-wife's treating physicians would not, under any circumstances, prescribe the dangerous drug HRT combination" for any patient. But the trial court cites no support for that remarkable proposition, and indeed no precedent exists establishing any such requirement under Pennsylvania law.

Each patient has his or her unique condition, and therefore a drug that a physician might find too dangerous to prescribe for one patient's use may not be too dangerous to prescribe for another patient whose condition or symptoms are more extreme. The fact that a doctor is prescribing a medication for one patient does not establish, as a matter of law, that the doctor would also continue to prescribe it for another (or, in the trial court's view, for every other) patient. Based on the testimony that the jury heard during the trial of this case, the jury could reasonably have decided (as it did) that Mrs. Simon would not have been prescribed Upjohn's Provera (or Wyeth's Premarin) had adequate warnings been available to Mrs. Simon's physicians in 1992 through 1996. The evidence, viewed in a light most favorable to Mrs. Simon as the verdict winner, is more than sufficient to support the jury's finding, and therefore the trial court erred in entering j.n.o.v. in Upjohn's favor on the issue of proximate cause.

Accordingly, this Court should reverse the trial court's entry of judgment notwithstanding the verdict in Upjohn's favor on the issue of proximate cause and should instruct the trial court to reinstate the jury's verdict in Mrs. Simon's favor.

## VIII. CONCLUSION

For the reasons set forth above, this Court should reverse the trial court's entry of judgment notwithstanding the verdict in Upjohn's favor, direct the trial court to reinstate the jury's verdict in favor of Mrs. Simon, and direct the trial court to address on the merits Mrs. Simon's timely motion for delay damages.

Respectfully submitted,

Dated: December 5, 2008

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## 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:

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