

In the Superior Court of Pennsylvania

Nos. 2620 & 2673 EDA 2007

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.

REPLY BRIEF FOR APPELLANT/
RESPONSE BRIEF FOR CROSS–APPELLEE

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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I. INTRODUCTION

Following a five-week jury trial featuring a total of twenty-four witnesses (sixteen presented by plaintiffs and another eight presented by defendants) and the admission into evidence of approximately 120 exhibits, a jury serving in the Court of Common Pleas of Philadelphia County returned a mixed verdict in this case. The jury found in favor of plaintiff Merle Simon and against defendant Upjohn Company on Mrs. Simon's negligent failure-to-warn claim asserting that Upjohn's prescription medication, Provera, was a cause of her breast cancer. At the same time, however, the jury found against Mrs. Simon's husband on his loss of consortium claim against Upjohn. And the jury also found in favor of Upjohn's co-defendant, Wyeth Pharmaceuticals, Inc., on Mrs. Simon's claim that Wyeth's prescription medication, Premarin, was a cause of her breast cancer.

The jury awarded to Mrs. Simon \$1.5 million in damages on her negligent failure-to-warn claim against Upjohn, and it is noteworthy that Upjohn *does not* challenge the amount of that award as either excessive or unsupported by the evidence in its cross-appeal. It is also noteworthy that Upjohn does not challenge on appeal the sufficiency of the evidence for the jury's finding that Provera was a cause of Mrs. Simon's breast cancer.¹

In its Response Brief for Appellee/Opening Brief for Cross-Appellant, Upjohn raises a total of ten arguments for why the trial court's grant of judgment

¹ See, e.g., "Decrease in Breast Cancer Rates Related to Reduction in Use of Hormone Replacement Therapy," available online at the web site of the National Cancer Institute of the U.S. National Institutes of Health. See <http://www.cancer.gov/newscenter/pressreleases/BreastIncidenceDrop> .

notwithstanding the verdict should be affirmed or, in the alternative, why a new trial should be granted if the trial court's entry of j.n.o.v. in Upjohn's favor is reversed. By contrast, Mrs. Simon's opening brief on appeal raised only two issues. The multiplicity of issues that Upjohn raises on appeal not only demonstrates a revealing lack of confidence in the grounds on which the trial court relied in granting j.n.o.v., but it also gives rise to a presumption that all of Upjohn's appellate issues lack merit. As the Supreme Court of Pennsylvania explained in *Commonwealth v. Ellis*, 534 Pa. 176, 183, 626 A.2d 1137, 1140 (1993):

We concur with the view of an eminent appellate jurist, Judge Ruggero Aldisert, that the number of claims raised in an appeal is usually in inverse proportion to their merit and that a large number of claims raises the presumption that all are invalid.

See also Estate of Lakatos, 656 A.2d 1378, 1380 n.1 (Pa. Super. Ct. 1995) (favorably quoting Judge Aldisert's statement that "when I read an appellant's brief that contains ten or twelve points, a presumption arises that there is no merit to any of them").

Regrettably, the multitude of issues raised in Upjohn's Response Brief for Appellee/Opening Brief for Cross-Appellant is not that brief's most objectionable aspect. Rather, that brief would have this Court improperly apply an "abuse of discretion" standard of review in scrutinizing the trial court's grant of j.n.o.v. in place of the unquestionably applicable "plenary" standard of review. *See Rohm and Haas Co. v. Continental Casualty 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."); *see also Quinby v. Plumsteadville Family*

Practice, Inc., 589 Pa. 183, 205, 907 A.2d 1061, 1074 (2006) (recognizing that the plenary standard of review applies when an appellate court considers a trial court’s grant of j.n.o.v.).

Moreover, Upjohn’s appellate brief ignores the requirement that:

in reviewing a motion for judgment n.o.v., “the 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.”

Quinby, 589 Pa. at 204, 907 A.2d at 1074 (quoting *Moure v. Raeuchle*, 529 Pa. 394, 402, 604 A.2d 1003, 1007 (1992)). Upjohn’s appellate brief also ignores the admonition in both *Quinby* and *Moure* that “a court should only enter a judgment n.o.v. in a clear case and must resolve any doubts in favor of the verdict winner.” *Quinby*, 589 Pa. at 204–05, 907 A.2d at 1074 (citing *Moure, supra*). Upjohn’s appellate brief further impermissibly ignores that “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*, 529 Pa. at 402, 604 A.2d at 1007.

Indeed, not once does Upjohn’s appellate brief acknowledge this Court’s holdings that the entry of j.n.o.v. is a “drastic remedy” or that a trial court “cannot lightly ignore the findings of a duly selected jury.” *Burton–Lister v. Siegel, Sivitz and Lebed Assocs.*, 798 A.2d 231, 236 (Pa. Super. Ct. 2002). As this Court’s ruling in *Burton–Lister* acknowledges but Upjohn’s appellate brief ignores, “a JNOV must be

denied where conflicting evidence has been presented to the jury.” *Id.* That principle alone compels reversal of the trial court’s entry of j.n.o.v. in Upjohn’s favor.

Because Upjohn’s appellate brief ignores the legal requirement that the facts must be stated in a light most favorable to the verdict winner — here, Mrs. Simon — Upjohn’s appellate brief contains numerous factual distortions. In this Reply Brief for Appellants/Response Brief for Cross–Appellee, Mrs. Simon will point out the most egregious of Upjohn’s factual and legal distortions in the context of responding to the specific arguments advanced in Upjohn’s opening brief on appeal. What Mrs. Simon’s Reply Brief for Appellants/Response Brief for Cross–Appellee will make clear is that the trial court committed an error of law in granting j.n.o.v. in Upjohn’s favor and that the trial court’s grant of j.n.o.v. must therefore be reversed. This brief also demonstrates that none of Upjohn’s five grounds for seeking a new trial has merit, and therefore Upjohn’s request in the alternative for a new trial should be rejected.

II. ARGUMENT IN REPLY

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**

Attempting to mislead this Court into applying the incorrect standard of review, Upjohn in its opening brief on appeal asserts that because the opposing parties supposedly agree on the principles of law that govern the trial court’s j.n.o.v.

ruling insofar as it was based on statute of limitations grounds, the “abuse of discretion’ standard applies” to this Court’s review of that ruling. Upjohn’s Opening Appellate Br. at 27.

On the contrary, this Court exercises plenary, non–deferential review of the trial court’s j.n.o.v. ruling insofar as it was based on statute of limitations grounds. To begin with, the plenary standard of review generally applies to appellate review of a trial court’s grant of j.n.o.v. *See Rohm and Haas*, 566 Pa. at 471, 781 A.2d at 1176 (“Our scope of review with respect to whether JNOV is appropriate is plenary, as with any review of questions of law.”); *Quinby v. Plumsteadville Family Practice, Inc.*, 589 Pa. at 205, 907 A.2d at 1074 (same).

Moreover, the trial judge’s Rule 1925(a) opinion in this very case makes clear that the trial court’s j.n.o.v. statute of limitations ruling involved a question of law subject to plenary review. The trial judge explained in her Rule 1925(a) opinion that, “[b]ased on the evidence of record, this trial judge opines that Plaintiff[]’s claim is time barred as the discovery rule exception to the statute of limitations does not apply as *a matter of law*.” Rule 1925(a) Opinion at 15. As the Supreme Court of Pennsylvania recently explained in *Fine v. Checcio*, 582 Pa. 253, 268, 870 A.2d 850, 859 (2005), “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.”

Thus, notwithstanding Upjohn’s mistaken argument to the contrary, this Court exercises plenary, non–deferential review of the trial court’s decision to grant

j.n.o.v. in Upjohn's favor based on the supposed expiration of the applicable statute of limitations.

Under Pennsylvania law, "a cause of action accrues when the plaintiff could have first maintained the action to a successful conclusion." *Fine*, 582 Pa. at 266, 870 A.2d at 857; *see also Kapil v. Association of Pa. State College & Univ. Faculties*, 504 Pa. 92, 99, 470 A.2d 482, 485 (1983) (same). When a person is injured and knows that his injury resulted from another party's conduct, the statute of limitations begins to run at the time the injury occurred. However, if a person is unaware of the injury *or* of the fact that the injury was caused by another party's conduct, despite the exercise of reasonable diligence, the so-called "discovery rule" applies and 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 v. Cyclops Indus.*, 560 Pa. 394, 404, 745 A.2d 606, 611 (2000) (emphasis added); *see also Fine*, 582 Pa. at 266–67, 870 A.2d at 858 (same).

Here, it is undisputed that Mrs. Simon became aware of her injury when she was diagnosed with breast cancer on May 21, 2002. However, she claims — and the jury that heard all the evidence at the trial of this case agreed — that she remained reasonably unaware that Upjohn's Provera medication was a cause of her breast cancer until the results of the Women's Health Initiative study became public on July 9, 2002, revealing that long-term use of estrogen and progestin hormone replacement therapy substantially increased breast cancer risk. Plaintiff filed her

complaint initiating this lawsuit on July 1, 2004, two years and forty-one days after she had been diagnosed with breast cancer, but within two years of the release of the WHI study's results. If, as the jury found as a fact, Mrs. Simon was reasonably unaware that Upjohn's Provera was a cause of her breast cancer until the publication of the WHI study's results on July 9, 2002, then Mrs. Simon's lawsuit was timely-filed under the discovery rule because she filed suit on July 1, 2004. *See Fine*, 582 Pa. at 269, 870 A.2d at 860.

Neither the trial court nor Upjohn can point to any evidence establishing that Mrs. Simon *actually knew* that Upjohn's Provera was a cause of her breast cancer when she was diagnosed with breast cancer on May 21, 2002. The jury certainly did not find that as a fact, and in reviewing a grant of j.n.o.v. the facts must be viewed in a light most favorable to Mrs. Simon. Thus, both the trial court and Upjohn are relegated to maintaining that "in the exercise of reasonable diligence" Mrs. Simon was capable of ascertaining that Upjohn's Provera was a cause of her breast cancer as of May 21, 2002.

Ordinarily, as the Supreme Court of Pennsylvania 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. Pennsylvania's highest court explained in *Fine*:

[W]hen a court is presented with the assertion of the discovery rule's application, it must address the ability of the damaged party, exercising reasonable diligence, to ascertain that he has been injured and by what cause. Since this question involves a factual determination as to whether a party was able, in the exercise of reasonable diligence, to know of his injury and its cause, ordinarily, a

jury is to decide it. Where, however, reasonable minds would not differ in finding that a party knew or should have known on the exercise of reasonable diligence of his injury and its cause, the court determines that the discovery rule does not apply as a matter of law.

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

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

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

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

In allowing the “discovery rule” issue to go to the jury, the trial court initially and properly concluded that the facts were not so clear that reasonable minds could not differ concerning when the statute of limitations period should commence.

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 hormone replacement therapy 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).²

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

² Searching far and wide for some inquiry that might have revealed to Mrs. Simon that Provera caused her breast cancer, Upjohn argues that she should have asked Dr. Luckey — the physician treating her for osteoporosis — whether Provera may have caused the breast cancer. Yet Dr. Luckey's own testimony establishes that Dr. Luckey only reviewed the potential breast cancer risk of hormone replacement therapy with patients for whom Dr. Luckey *herself* prescribed HRT. Because Mrs. Simon was receiving HRT from her gynecologists, Dr. Luckey never had that conversation with Mrs. Simon. R.5023a–25a (Luckey Dep. at 37–40).

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) (emphasis added). In other words, in 1996 Wyeth was disclosing to physicians and patients in its FDA-approved 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 the very connection the pharmaceutical companies manufacturing and marketing progestins for combined hormone therapy and the FDA had yet 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.

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 others) 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 (without objection from the FDA), 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 doubted the existence of such a causal relationship were 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, nor is it something that Upjohn is challenging on appeal.

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.

At the very same time that Upjohn was marketing Provera with an FDA-approved label that omitted any breast cancer warning, and at the same time that Wyeth was marketing Prempro (containing estrogen and a synthetic progestin in a single pill) with an FDA-approved label stating that “the effect of added progestins

on the risk of breast cancer is *unknown*,” the trial court’s ruling in this matter holds that a middle-aged housewife from New Jersey, with no medical training in ascertaining the potential causes of breast cancer, reasonably should have determined immediately upon being diagnosed with breast cancer that Upjohn’s Provera had caused that condition. The trial court’s j.n.o.v. ruling on this basis is untenable.

Similarly, the fact that Mrs. Simon’s physicians took her off of estrogen and progestin therapy following her breast cancer diagnosis fails to prove, contrary to Upjohn’s argument, that Mrs. Simon should have recognized that Provera was a cause of her breast cancer. The HRT prescription warning labels in effect at the time Mrs. Simon was using those medications stated that HRT may cause breast cancer to grow more quickly (and, inversely, medications that fight breast cancer seek to suppress even the body’s own estrogen production), but simultaneously those labels stated that it was “unknown” whether progestins (the active ingredient in Provera) cause normal breast cells to turn cancerous. Mrs. Simon sued Upjohn for causing her to have breast cancer, and not for causing a preexisting breast cancer to grow more quickly than it otherwise would.

In the same way that a physician’s warning to a patient suffering epileptic seizures not to drive a car does not establish that driving a car caused the patient to suffer from epileptic seizures (although a car crash involving a head injury very well may have been the cause), nor did Mrs. Simon’s physician’s decision to remove her from HRT upon diagnosis of her breast cancer communicate to her (nor would it

necessarily have communicated to any reasonable person in May 2002) that HRT had caused her breast cancer. Once again, the jury had Upjohn's argument and evidence on this point before it when the jury found as a fact, applying the "discovery rule," that Mrs. Simon's claim against Upjohn was timely-filed.

Last but not least, under Pennsylvania law a claim does not even accrue until "the plaintiff could have first maintained the action to a successful conclusion." *Fine*, 582 Pa. at 266, 870 A.2d at 857. Although, as Mrs. Simon's opening brief on appeal acknowledged, some pre-WHI studies had reported a correlation between combined HRT use and an increasing incidence of breast cancer, there were also studies reaching contrary conclusions. The disputed nature of those findings allowed Upjohn to omit any reference of a breast cancer risk from the Provera label and allowed Wyeth to say in the Prempro label, with the FDA's approval, that a correlation between progestin and breast cancer is "unknown." Thus, before the release of the WHI results occurred on July 9, 2002, a plaintiff such as Mrs. Simon was not capable of maintaining "to a successful conclusion" a lawsuit asserting that Provera caused breast cancer.³ Indeed, Upjohn in its appellate brief has failed to

³ The August 30, 2002 issue of "BenchMarks," published by the National Cancer Institute of the U.S. National Institutes of Health, contained an article headlined "Summary of the Evidence of the Risks and Benefits of Postmenopausal Use of Hormones" establishing the groundbreaking nature of the WHI study's results. The article begins:

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.

point to any plaintiff who — before the release of the WHI study’s results on July 9, 2002 — had prevailed in a lawsuit against Upjohn alleging that Provera caused breast cancer. Because Mrs. Simon could not have maintained her lawsuit against Upjohn to a successful conclusion until the WHI study’s results became public, Mrs. Simon’s claim against Upjohn was not capable of accruing until July 9, 2002, and thus her lawsuit against Upjohn was timely because it was filed within two years of that date.

Based on the evidence reviewed above, and as demonstrated by the jury’s verdict in Mrs. Simon’s favor finding that it was appropriate to apply the “discovery rule,” this is a case in which reasonable minds could and did conclude that that Mrs. Simon could not have known, on the exercise of reasonable diligence, of the cause of her injury immediately upon being diagnosed with breast cancer. As a result, the trial court properly allowed the discovery rule question to be submitted to the jury, but the trial court thereafter erred as a matter of law in granting j.n.o.v. in favor of Upjohn on the statute of limitations issue. This Court should therefore reverse the trial court’s grant of j.n.o.v. in Upjohn’s favor and reinstate the jury’s verdict in favor of Mrs. Simon.

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.

The complete article can be accessed online at:
<http://www.cancer.gov/newscenter/archive/benchmarks-vol2-issue8/page2> .

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

The trial court's grant of j.n.o.v. in favor of Upjohn, in disagreement with the jury's finding that an adequate warning of Provera's breast cancer risk would have caused Mrs. Simon's physicians not to prescribe Provera to her, is likewise deserving of reversal. More than adequate evidence exists to support the jury's finding that, had Upjohn adequately warned of Provera's actual breast cancer risk in combination hormone replacement therapy, Mrs. Simon's physicians would not have prescribed the HRT combination for her use.

It was Kenneth Dollinger, M.D., who decided to prescribe Wyeth's Premarin plus Upjohn's Provera for Mrs. Simon to use beginning in 1992. When Dr. Dollinger retired in 1994, another physician in that same gynecological practice, Joann Somers, M.D., became Mrs. Simon's gynecologist. Mrs. Simon continued on the Premarin and Provera combination until 1996, when Dr. Somers switched Mrs. Simon to Prempro, a newly available Wyeth product that conveniently combined estrogen and progestin in a single pill. Mrs. Simon later used a third gynecologist, who maintained Mrs. Simon on Wyeth's Prempro until Mrs. Simon was diagnosed with breast cancer in May 2002. However, because the jury did not find Wyeth liable, that third physician is irrelevant for the proximate cause issue involving Upjohn only, which is the focus of the second issue that Mrs. Simon is raising on appeal.

In its opening brief on appeal, Upjohn wisely does not ask this Court to approve the trial court's incorrect holding that "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 HRT combination" to *anyone*. Rule 1925(a) Opinion at 26. Rather, as the trial court itself correctly recognized earlier in its Rule 1925(a) Opinion, the proper proximate cause inquiry in a prescription drug failure-to-warn case focuses on the physician's "individualized medical judgment bottomed on a knowledge of both patient and palliative." Rule 1925(a) Opinion at 19 (quoting *Leibowitz v. Ortho Pharmaceutical Corp.*, 307 A.2d 449, 457 (Pa. Super. Ct. 1973) (Hoffman, J., opinion in support of affirmance by equally divided court)).

In *Demmler v. SmithKline Beecham Corp.*, 671 A.2d 1151 (Pa. Super. Ct. 1996), this Court explained:

In the event that a warning is inadequate, proximate cause is not presumed. To create a jury question, the evidence introduced must be of sufficient weight to establish some reasonable likelihood that an adequate warning would have prevented the plaintiff from receiving the drug. Absent proof that a more thorough or more explicit warning would have prevented Mrs. Demmler's use of Parnate, appellants cannot establish that SmithKline's alleged failure to warn was the proximate cause of Mrs. Demmler's injuries.

Id. at 1155 (citations, quotations, and ellipses omitted).

Upjohn, in its opening brief on appeal, attempts to inaccurately portray Mrs. Simon's argument in favor of reversal as consisting of the contention that even though her gynecologists might have continued to prescribe Premarin plus Provera to treat her symptoms of menopause, she would not have consumed those

medications had adequate warnings been available about Provera's propensity to cause breast cancer. After so caricaturing Mrs. Simon's supposed causation argument, Upjohn argues that *dicta* contained in this Court's ruling in *Lineberger v. Wyeth*, 894 A.2d 141 (Pa. Super. Ct. 2006), forecloses Mrs. Simon's supposed argument.

In actuality, however, what Mrs. Simon is arguing is precisely what this Court's precedential ruling in *Demmler* establishes as the law of proximate cause in a prescription drug failure-to-warn case in Pennsylvania and what the *dicta* from *Lineberger* does not foreclose the plaintiff from arguing: namely, that a "reasonable likelihood [exists] that an adequate warning would have prevented the plaintiff from receiving" Provera (and Premarin) from Drs. Dollinger and Somers.

Contrary to Upjohn's arguments on appeal, Mrs. Simon introduced more than sufficient evidence to allow the jury to find, as the jury in fact found, that had Upjohn provided an adequate breast cancer warning for Provera, Mrs. Simon's physicians would not have prescribed Provera to her. Here, 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.

Both Dr. Dollinger and Dr. Somers testified at trial via videotape 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.5013a (Dollinger transcript at 37). If the patient said she did not want those medications, Dr. Dollinger would not have prescribed them to her.

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). And if the patient said she did not want those medications, Dr. Somers would not have prescribed them to her. 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 receive a prescription for those medications, which includes Provera. The jury also heard from Mrs. Simon that, had she received that very 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 receive the medications, and those doctors therefore would not have prescribed the medications 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, which is the very argument apparently rejected in *dicta* in *Lineberger*. 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 once they

communicated the information that they currently share with their patients now that adequate information about Provera's breast cancer risk is known.

Upjohn would have this Court apply the *dicta* in *Lineberger* in a manner that is contrary to the realities of prescription drug marketing in the 21st Century. One need only turn on the television to watch a major commercial network's programming for a brief period to see prescription drugs being marketed directly to consumers, whether for erectile malfunction, baldness, prostate conditions, allergic conditions, acid indigestion, heartburn, and so forth.⁴ Mrs. Simon's treatment with hormone replacement therapy did not address a condition that was life threatening; rather, it was a treatment for conditions that were inconvenient but that women for centuries had endured without resort to hormone therapy medications. For a Court to say that a given patient's receptivity to receiving so-called "lifestyle" drugs, as hormone replacement therapy was considered during the time in question, cannot be evaluated in deciding whether the physician would prescribe the medication to that patient is to deny present day reality.

⁴ For example, the Brief for the New England Journal of Medicine Editors and Authors in Support of Respondent filed in the U.S. Supreme Court in the currently pending case captioned *Wyeth v. Levine*, No. 06-1249 (U.S.), reports that:

Drug companies now spend over \$29 billion annually just to promote their products, including \$11.4 billion on advertising. Nothing demonstrates this better than the case of Vioxx. In 2000, Vioxx was the number one direct-to-consumer advertised drug at \$160 million — larger than the campaigns that year for Pepsi and Budweiser.

Brief for the New England Journal of Medicine Editors and Authors in Support of Respondent at 37 (footnote omitted) (available online at: http://www.abanet.org/publiced/preview/briefs/pdfs/07-08/06-1249_RespondentAmCuNEJournalofMed.pdf).

Lastly, Upjohn's argument that Mrs. Simon failed to prove that her physicians relied on the Provera label that Upjohn furnished to communicate warnings is utterly without merit. Of course Mrs. Simon's gynecologists could not rely on the Provera label from Upjohn to learn of that medication's breast cancer risk, because that label at the relevant times contained utterly no discussion of the medication's breast cancer risk. Had Upjohn properly warned of Provera's actual breast cancer risk, as disclosed in the results of the WHI study, it cannot be denied that Provera's actual breast cancer risk would have attracted the same sort of widespread attention that the results of the WHI study attracted.

Upjohn likewise cannot deny that each of Mrs. Simon's physicians, all of whom testified during the trial, were familiar with the breast cancer risk of Provera as disclosed in the WHI study results, even though it is doubtful whether any of those physicians ever had a copy of that study's results sitting on their desk. Those physicians would have unquestionably been just as familiar, if not more familiar, with the content of those same breast cancer warnings had they been available in the Physician's Desk Reference book on the pages containing the text of Upjohn's label for Provera.

The jury in this matter had the unique opportunity to observe the testimony of Mrs. Simon's treating physicians and of Mrs. Simon herself to determine the factual question whether, had adequate warnings of Provera's breast cancer risk been promulgated by Upjohn, Mrs. Simon would have still been prescribed that medication by Drs. Dollinger and Somers. Upjohn made all of the same arguments

it is now making on appeal to the jury, and the jury found in Mrs. Simon's favor. The trial court has impermissibly substituted its view of the evidence for the jury's view. Based on all the evidence, the jury found as a fact that Mrs. Simon would not have been prescribed Provera had Upjohn furnished adequate warnings. More than sufficient evidence exists to uphold that finding, and therefore the trial court's grant of j.n.o.v. in Upjohn's favor should be reversed, and the jury's verdict in Mrs. Simon's favor should be reinstated.

C. Federal Law Does Not Preempt Plaintiff's State Law Prescription Drug Failure-to-Warn Claim

As an alternate basis for affirming the trial court's entry of j.n.o.v. in Upjohn's favor, Upjohn argues on appeal that this Court should hold that federal law preempts Mrs. Simon's prescription drug failure-to-warn claim arising under Pennsylvania law.

Upjohn had raised this argument in its motion for j.n.o.v. filed in the trial court, but the trial judge — perhaps revealing her view that Upjohn's preemption argument had absolutely no merit — did not even deign to address the argument in its opinion granting Upjohn's j.n.o.v. motion on two other separate grounds. In any event, no Pennsylvania state court has yet seen merit in an argument that approval by the federal Food and Drug Administration of a particular warning label for a prescription drug precludes a claim under Pennsylvania law that the manufacturer's warning label did not adequately warn of the prescription drug's actual dangers.

For a recent Pennsylvania state trial court decision considering and rejecting a federal preemption defense against a state law prescription drug failure-to-warn case, this Court should see the ruling of the Philadelphia County Court of Common Pleas in *Collins v. SmithKline Beecham Corp.* It issued March 11, 2008 in a case involving a failure-to-warn claim under state law involving the prescription drug Paxil and is online at <http://courts.phila.gov/pdf/opinions/civiltrial/070200762.pdf> .

Upjohn's preemption argument here relies on a type of preemption known as "conflict preemption," which requires Upjohn to show that state law would pose an intolerable conflict with federal law in requiring Upjohn to issue a warning applicable to Provera that accurately disclosed that drug's risks. *See Office of Disciplinary Counsel v. Marcone*, 579 Pa. 1, 17, 855 A.2d 654, 664 (2004) (describing conflict preemption).

The many decisions that reject a preemption defense of the sort that Upjohn is advocating hold that the FDA's review of the data that a prescription drug manufacturer supplies to evaluate the proposed warnings to accompany a drug sets a floor but not a ceiling on the adequacy of the warnings that are needed. *See Levine v. Wyeth*, 944 A.2d 179, 186 (Vt. 2006) (observing that "courts have been nearly unanimous in holding that state failure-to-warn tort claims [involving FDA-approved prescription drugs] do not conflict with federal law" and collecting numerous cases that have so held), *cert. granted*, 128 S. Ct. 1118 (2008); *see also Hill v. Searle Labs.*, 884 F.2d 1064, 1068 (8th Cir. 1989) ("FDA approval is not a shield to liability. FDA regulations are generally minimal standards of conduct

unless Congress intended to preempt common law, which Congress has not done in this area.”) (citations omitted); *Wells v. Ortho Pharmaceutical Corp.*, 788 F.2d 741, 746 (11th Cir. 1986) (“[a]n FDA determination that a warning is not necessary may be sufficient for federal regulatory purposes but still not be sufficient for state tort law purposes”); *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652, 658 (1st Cir. 1981) (acknowledging that FDA approval of a drug label is not conclusive in a common law failure to warn action).

Not only have a variety of judges serving on the Philadelphia County Court of Common Pleas unanimously rejected the federal preemption defense raised by Wyeth and Upjohn in hormone therapy cases, but so has the U.S. District Court for the Eastern District of Arkansas in the federal court Multi-District Litigation cases involving the hormone therapy drugs Premarin, Provera, and Prempro. *See Nelson v. Wyeth*, Phila. Ct. Com. Pl., No. 040101670, Order dated Sept. 7, 2006; *Rowatt v. Wyeth*, Case No. 04-1699 (Nev. 2d Jud. Dist. Washoe Cnty Aug. 31, 2007); *Scroggin v. Wyeth*, Case No. 04-1169 (E.D. Ark. Aug. 29, 2007); *Hill v. Wyeth*, Case No. 05-546 (E.D. Ark. Aug. 29, 2007); *Deutsch v. Wyeth*, Case No. MID-L-0998-06 MT (N.J. Super. June 22, 2007); *Rush v. Wyeth*, Case No. 05-497 (E.D. Ark. Jun. 15, 2006); *Reeves v. Wyeth*, Case No. 05-163 (E.D. Ark. Jun. 15, 2006); *Albertson v. Wyeth*, 63 Pa. D.&C.4th 514 (Phila. Ct. Com. Pl. Jul. 8, 2003).⁵

⁵ For this Court’s convenience, copies of the unreported decisions contained in this series of case citations are attached to this brief.

As Judge Sheppard explained in *Albertson*:

Here, if federal regulation of prescription drugs were deemed exclusive, Pennsylvania's ability to protect its citizens from the dangers of prescription drug use would be severely hampered. Further, it would leave Pennsylvania citizens harmed by prescription drugs without a state tort remedy. This court submits that Congress did not intend such a result. The tort law here is remedial and compensatory in nature, and does not conflict with any aspect of the FDA's regulatory scheme. Thus, preemption of the state remedial measures available to plaintiffs cannot be implied.

63 Pa. D.&C.4th at 530.

Although Upjohn's appellate brief, at page 47, cites with approval the amicus brief of the Solicitor General of the United States in *Wyeth v. Levine*, No. 06-1249 (U.S.), in support of Upjohn's argument that this Court should find Mrs. Simon's claim preempted by federal law, Upjohn fails to note that the Commonwealth of Pennsylvania, acting through its Attorney General, has joined in an amicus brief arguing that the U.S. Supreme Court should hold that federal law *does not preempt* state law prescription drug failure-to-warn claims. In fact, a total of forty-seven states have joined in that amicus brief. The amicus brief is available online at this link: http://www.abanet.org/publiced/preview/briefs/pdfs/07-08/06-1249_RespondentAmCu47States.pdf.

A separate amicus brief filed in *Wyeth v. Levine* on behalf of ten current and former editors and contributing authors of the *New England Journal of Medicine* also advances a persuasive argument against a holding that federal law preempts failure-to-warn claims relating to prescription drugs. The summary of the argument section of that brief explains:

[T]he FDA is in no position to ensure the safety of prescription drugs. Not only is the FDA seriously hampered in its ability to determine the risks of drugs before they are approved for sale, but it has proven inadequate to the task of addressing hazards that only become apparent after a drug has been widely marketed to an unsuspecting public. Post–approval dangers posed by drugs placed into the market are unfortunately quite common. However, the FDA’s ability to either anticipate these risks or react expeditiously once they have been revealed has been limited by serious information–gathering constraints in both pre– and post–approval settings.

Much of this stems from the fact that the FDA is heavily dependent on the drug makers themselves for the information on which the agency bases its decisions. Not surprisingly, this dependence has its drawbacks. Pharmaceutical companies at times learn about dangers caused by their drugs long before the FDA does, but have failed to disclose this information to the FDA. Thus, as exemplified by the cases of Pondimin/Redux, Vioxx, and Trasyolol, the drug companies have withheld key information from the FDA and ardently negotiated against stricter label warnings — all the while continuing to market their unsafe drugs to an unsuspecting public. In the case of these three drugs alone, literally tens of thousands of American lives have been lost or ruined long after the manufacturers realized that the drugs were not safe.

Brief for the New England Journal of Medicine Editors and Authors in Support of Respondent at 3–4 (available online at: http://www.abanet.org/publiced/preview/briefs/pdfs/07-08/06-1249_RespondentAmCuNEJournalofMed.pdf .

Finally, the U.S. Court of Appeals for the Third Circuit’s recent ruling in *Colacicco v. Apotex, Inc.*, 521 F.3d 253 (3d Cir. 2008) — a decision on which Upjohn relies heavily in arguing that federal law preempts Mrs. Simon’s claim here — fails to provide any support for Upjohn’s preemption argument. In *Colacicco*, the majority on a divided three–judge Third Circuit panel held that federal law preempted the plaintiff’s state law failure–to–warn claim involving the prescription

drug Paxil. Circuit Judge Thomas L. Ambro, in dissent, would have ruled that federal law did not preempt the plaintiff's claim.

Yet the majority's preemption holding in *Colacicco* was very narrowly limited, recognizing as preempted only those state law failure-to-warn claims involving a warning that the FDA itself has expressly considered and rejected. *Id.* at 271. According to the majority opinion, "Thus, we do not decide whether the FDA's mere approval of drug labeling is sufficient to preempt state-law claims alleging that the labeling failed to warn of a given danger * * *." *Id.* Indeed, the majority opinion explains that "[o]ur holding is limited to circumstances in which the FDA has publicly rejected the need for a warning that plaintiffs argue state law requires." *Id.* at 272-73.

In this case, by contrast, Mrs. Simon's failure-to-warn claim pertaining to Provera does not involve a warning that the FDA has previously considered and rejected. On the contrary, after the results of the WHI study became public, the FDA made Wyeth and Provera adopt more accurate warnings that disclosed the actual breast cancer risk inherent in Provera and Prempro. Unfortunately, by that time, Mrs. Simon had already been diagnosed with breast cancer caused by Upjohn's medication.

For all of the foregoing reasons, this Court should reject Upjohn's argument to expand federal preemption of state law prescription drug failure-to-warn claims beyond the boundaries that Pennsylvania state courts, the Third Circuit, and the

federal MDL hormone replacement therapy failure-to-warn jurisdiction have recognized.

III. ARGUMENT IN RESPONSE TO UPJOHN'S CROSS-APPEAL

A. Summary Of The Argument

No doubt recognizing that the trial court's grant of j.n.o.v. in Upjohn's favor is unlikely to survive appellate review, Upjohn in support of its cross-appeal presents this Court with five separate grounds for granting a new trial. None of Upjohn's new trial arguments has merit.

The trial court, in further disregard of the law, failed to discharge its responsibility under Pennsylvania Rule of Civil Procedure 227.1(e) to provide a statement of its reasons for whether it would grant or deny Upjohn's motion for a new trial in the event that this Court reverses the trial court's entry of j.n.o.v. in Upjohn's favor. Upjohn, in its opening brief in support of its cross-appeal, asks this Court to rule in the first instance on Upjohn's new trial arguments.

Plaintiff does not object to having this Court review Upjohn's new trial motion consistent with the "deemed denied due to passage of time" provision of Pennsylvania Rule of Civil Procedure 227.4(1)(b) in order to facilitate a more efficient disposition of the remainder of Upjohn's wholly meritless post-trial motion. Upjohn raised during the course of the trial, in some form or another, all of its current new trial arguments, and the trial court did not immediately see merit in any of those arguments, and thus it requires no great stretch of the imagination to

treat the arguments advanced in Upjohn's new trial motion as having already been denied by the trial court.

Upjohn's efforts to convince this Court to disregard established standards of review are not limited to the j.n.o.v. portion of this appeal. Rather, Upjohn asks this Court to apply the *de novo* standard of review to Upjohn's new trial arguments, overlooking that an "abuse of discretion" standard of review clearly applies. Compare Upjohn's Opening Br. at 1 (advocating a *de novo* standard of review) with *Harman v. Borah*, 562 Pa. 455, 465–66, 756 A.2d 1116, 1121–22 (2000) ("Although all new trial orders are subject to appellate review, it is well-established law that, absent a clear abuse of discretion by the trial court, appellate courts must not interfere with the trial court's authority to grant or deny a new trial.").

All five of Upjohn's arguments for a new trial should be rejected. First, the jury's verdict against Upjohn but in favor of Wyeth is not inconsistent, and therefore the alleged inconsistency of the verdict provides no basis for relief. Second, the trial court's jury instructions and verdict sheet both properly submitted the causation question for the jury's consideration. If the instructions and verdict sheet were harmfully prejudicial to defendants, one wonders how the jury could have found in favor of Upjohn's co-defendant, Wyeth. Third, evidence consisting of Upjohn's advertising to prove that Upjohn knew of and was encouraging the off-label use of Provera in hormone replacement therapy treatment remained relevant and admissible, notwithstanding Upjohn's concession that it had a duty to warn of the risks Provera presented when used in combination with Premarin. Fourth, the

jury found, and the evidence admitted at trial supports the jury's finding, that Mrs. Simon consumed Upjohn's Provera and not some generic substitute. And fifth, the jury's causation and discovery rule findings are not against the manifest weight of the evidence.

For all of these reasons, this Court should reject Upjohn's arguments in the alternative for a new trial and should instead allow the jury's verdict to stand.

B. Applicable Standard Of Review

As the Supreme Court of Pennsylvania has recognized, requests for a new trial are in the first instance assigned to the discretion of the trial judge, subject on appeal only to deferential abuse of discretion review. See *Harman*, 562 Pa. at 465–66, 756 A.2d at 1121–22 (“Although all new trial orders are subject to appellate review, it is well-established law that, absent a clear abuse of discretion by the trial court, appellate courts must not interfere with the trial court's authority to grant or deny a new trial.”). This Court should therefore reject Upjohn's remarkable assertion, on page 1 of its opening brief on appeal, that its new trial motion deserves *de novo* review on appeal.

Upjohn's request for *de novo* review is predicated on Upjohn's assertion that the trial court failed to expressly rule on Upjohn's new trial motion after the trial court granted Upjohn's post-trial motion for judgment notwithstanding the verdict. Although it is undisputed that the trial judge thereby violated her responsibilities under Pennsylvania Rule of Civil Procedure 227.1(e) — one of the trial court's many

legal errors in adjudicating Upjohn’s post-trial motions — the grounds raised in Upjohn’s new trial motion were all raised during the course of the trial, and the trial judge at the time those grounds were originally raised failed to see immediate merit in any of them.

Plaintiff joins with Upjohn in asking this Court to decide the merits of Upjohn’s new trial arguments, because that presents the most efficient way to dispose of Upjohn’s post-trial motions in their entirety. However, because the trial court has already failed to see merit in any of these arguments when Upjohn first raised them during trial, and consistent with the “deemed denied due to passage of time” provision applicable to post-trial motions contained in Pennsylvania Rule of Civil Procedure 227.4(1)(b), this Court should apply the traditional “abuse of discretion” standard of review in evaluating Upjohn’s appeal from the trial court’s failure to grant Upjohn’s new trial motion.

C. The Jury’s Findings Against Upjohn But In Favor Of Wyeth Are Not Inconsistent And Thus Do Not Furnish A Basis For Granting A New Trial

In the first of its five grounds for seeking a new trial on appeal, Upjohn argues that the jury’s verdict finding Upjohn liable while simultaneously finding co-defendant Wyeth not liable is inconsistent, and therefore Upjohn is entitled to a new trial. Of course, if it is logically possible to understand the jury’s verdict as consistent (or as not inconsistent), then this Court must reject this ground for a new trial. *See McDermott v. Biddle*, 544 Pa. 21, 25, 674 A.2d 665, 667 (1996) (“We begin

with the presumption that jury verdicts are consistent, that is, consistency will be presumed unless there is no reasonable theory to support the jury's verdict.”).

Although admittedly plaintiff was disappointed that the jury did not find both defendants liable for her injuries, a logical explanation for viewing both aspects of the jury's verdict as consistent is readily available, as plaintiff explains below. In any event, plaintiff would prefer to retain her verdict against Upjohn only, even if that means that plaintiff will not have another chance at a trial to prove to a jury's satisfaction that both Upjohn and Wyeth are liable for her injuries. This Court should recognize, however, that this ground raised by Upjohn for a new trial, if granted, would necessitate a new trial at which plaintiff has another chance to prove that *both* Wyeth *and* Upjohn are liable for her injuries.

But that would only be necessary if the jury's verdict were actually inexplicably inconsistent, which is surely not the case here. The facts before the jury show that from 1992 through 1996, Mrs. Simon consumed Upjohn's Provera and Wyeth's Premarin. The labeling for Upjohn's Provera, it is undisputed, contained no breast cancer warning whatsoever. The labeling for Wyeth's Premarin did contain at least some discussion of cancer risk. Moreover, the jury had before it evidence that women who had undergone hysterectomies and thus could receive estrogen (which is what Premarin consisted of) without progestin (which is what Provera consisted of) and not face any risk of endometrial hyperplasia had not exhibited any notable incidence of increased breast cancer. R.5798a (1992 PDR for Premarin) (stating that “[t]he majority of studies have shown no association with the usual

doses used for estrogen replacement therapy and breast cancer.”). Translated into English, the jury had before it evidence that taking Premarin alone had not been shown to increase women’s breast cancer risk.

Thus, focusing on the period from 1992 to 1996, the jury very well could have concluded that Upjohn’s Provera was a cause of Mrs. Simon’s breast cancer, while Wyeth’s Premarin was not. If the jury found that Premarin did not cause Mrs. Simon’s breast cancer, then it follows that Wyeth’s breast cancer warning for Premarin was not inadequate.

From 1996 until Mrs. Simon was diagnosed with breast cancer in 2001, she consumed Wyeth’s Prempro, which consisted of a combination of estrogen and progestin in a single pill. Yet the jury very well may have concluded that Wyeth should not be liable because its warning label for Prempro contained at least some mention of studies that had found a breast cancer risk from progestin. R.5810a (1996 PDR for Prempro). Even more likely, however, the jury could have based its verdict in Wyeth’s favor on expert testimony that the jury heard about the long amount of time that it takes for breast cancer to develop. R.2532a, 3837a (T.T. 4/23/07 p.m. at p.60 (testimony of Dr. Roland Schwarting); T.T. 5/7/07 a.m. at p.25 (testimony of Dr. Lewis A. Chodosh that “breast cancers are complex and they take many years to develop”)). In other words, if the jury concluded from the testimony it heard that it would take more than six years for a substance such as progestin to cause breast cancer, then the jury’s verdict finding Upjohn liable (since Mrs. Simon consumed Upjohn’s progestin at the earliest time, from 1992 through 1996) but

Wyeth not liable (since Mrs. Simon consumed Wyeth's progestin at a later time, from 1996 through 2001) for breast cancer discovered in 2002 is entirely logical and free of conflict.

Not only can the jury's verdict be logically understood as conflict-free, but Upjohn's allegation of a conflict is predicated on a misrepresentation of the trial court's jury instructions that Upjohn repeats not once but at least four times throughout its opening brief. On page 58, in the midst of its argument that the jury's verdict contains a conflict mandating a new trial, Upjohn writes:

The Court instructed the jury that an adequate warning "must disclose the known or knowable harmful consequences of the product," including specifically the "risk of breast cancer *when ingesting these drugs in combination*."¹⁴³

¹⁴³ R.4838A, 4841A (Jury Instructions T.T. 5/15/07 a.m. at 33, 36) (emphasis added).

Based on this out-of-context combination of two snippets from the trial court's jury instructions, Upjohn argues that the jury charge required both Upjohn and Wyeth to warn not only of the risks of their own medication, but also of the risks of the other company's medication. In addition to appearing on page 58 of Upjohn's opening brief on appeal, the same exact combination of quotation snippets, with the same citation to pages 33 and 36 of the trial court's jury charge transcript, also appears on pages 14 and 20-21 of Upjohn's opening brief on appeal.

Of course, the cited authority for Upjohn's above-quoted sentence is revealing, because it discloses that the two quotes that Upjohn has spliced together into a single sentence of argument come from two separate portions of the trial

court's jury charge found *three pages apart* in the trial transcript. Even more shocking, however, is the fact that Upjohn has spliced together these two snippets of the jury's charge entirely out of context, so that Upjohn can argue that they stand for a proposition that neither statement, in its original context, actually supports.

The first portion of Upjohn's jury charge snippet combination comes from page 36 of the jury charge transcript. In context, what the trial judge told the jury was as follows:

A manufacturer of a product must warn of the benefits and risks not generally known or recognized for which it knows or reasonably should have knowledge.

To provide an adequate warning, the manufacturer **must disclose the known or knowable harmful consequences of the product** so that a reasonable, prudent physician can prescribe the product.

A manufacturer has a duty to warn of all risks of any foreseeable use of its product, including the risks created when the product is used with another product.

R.4841a (T.T. 5/15/07 at 36) (emphasis added to highlight Upjohn's preferred snippet). Viewed in context, what the trial court was properly instructing the jury in the above passage is that a prescription drug manufacturer has the obligation to warn of the risks of its product, including the risk that its product presents when used together with another product. The above-quoted passage does not require a drug manufacturer to warn of the dangers of some other prescription drug product manufactured by *another* manufacturer.

The second-half of Upjohn's out-of-context combination of jury charge snippets comes from page 33 of the transcript. In context, the trial court there was instructing the jury as follows:

I will proceed now to explain these issues. In this case, the plaintiffs have the burden of proving the following claims: Were the defendants negligently — I'm sorry. Let me start again. Wyeth and/or UpJohn negligently failed to provide adequate warnings of the risks and benefits of their hormone therapy drugs; that is, did they fail to use due care in labeling of their hormone replacement therapy drugs to prevent the **risk of breast cancer when ingesting these drugs in combination?**

R.4837a-38a (T.T. 5/15/07 at 32-33) (emphasis added to highlight Upjohn's preferred snippet). Once again, when viewed in context, all that the trial judge was instructing the jury was that each manufacturer had the responsibility to warn of the breast cancer risk of that manufacturer's own product, either when taken alone or in combination with another manufacturer's product.

In fact, had the trial court instead have charged the jury that the manufacturer of one prescription drug had the obligation to warn of the breast cancer risk of *another manufacturer's* prescription drug because the first manufacturer knew that the two drugs would be used in combination, you can be sure that both Upjohn and Wyeth would have vehemently objected to any such jury charge, and rightfully so.

Here, the jury charge viewed in context reveals that the trial court did not instruct the jury that Wyeth had a duty to warn about the dangers of Upjohn's Provera or that Upjohn had a duty to warn about the dangers of Wyeth's Premarin or Prempro, and thus this Court should reject Upjohn's inconsistent verdict

argument as predicated on a false premise. It is a false premise that Upjohn apparently finds endearing, because Upjohn’s brief repeats it at least four times (*see* Upjohn’s Opening Br. at 14, 20–21, 29, 58), but fortunately the repetition of a falsehood does not make it truthful. Rather, it only further undermines the credibility of Upjohn’s entire appellate presentation.

For these reasons, this Court should reject the first ground that Upjohn proffers for a new trial.

D. The Trial Court’s Jury Instructions And Jury Verdict Sheet Properly Charged The Jury On Proximate Cause

Upjohn’s second argument in support of its request for a new trial challenges the adequacy of the trial court’s jury charge and verdict sheet pertaining to the question of proximate cause. At the outset, Upjohn’s argument is severely undermined by the jury’s verdict in favor of Upjohn’s co–defendant, Wyeth. If the trial court’s proximate cause instructions and jury verdict sheet were egregiously flawed on the subject of proximate cause, one wonders how the jury managed to find that Wyeth was not legally responsible for causing plaintiff’s breast cancer.

At the outset of its challenge to the trial court’s jury instructions, Upjohn asserts that the trial court should have instructed the jury that:

the plaintiff must prove “that an adequate warning would have prevented the plaintiff from receiving the drug,” and that Mrs. Simon had the burden of proving that “a different warning would have changed [her physicians’] decision[s] to prescribe” her Provera.

Upjohn's Opening Br. at 60 (brackets in original). Unfortunately, the two separate things that Upjohn is arguing that a plaintiff must prove, in the above-quoted passage from Upjohn's opening brief on appeal, are in fact one and the same.

What Upjohn's argument boils down to is that instead of delivering verbatim Upjohn's proffered jury instructions, the trial court charged the jury as follows:

The plaintiff must prove, therefore, that the defendants failed to adequately warn physicians about the risks of high-dose combination hormone replacement therapy prescribed for a long duration of time, and that this failure to adequately warn resulted in either or all of the prescribing physicians to prescribe combination hormone replacement therapy in a dose and for a duration of time that more likely than not was a factual cause of Mrs. Simon's breast cancer.

Have you understood the manufacturer's responsibility as to its warning, the adequate warning that it must provide?

Let the record reflect the jury has.

R.4842a (T.T. 5/15/07 at 37).

The above-quoted instruction required Mrs. Simon to prove that, had her physicians received an adequate breast cancer warning from Upjohn, those physicians would not have prescribed Provera for Mrs. Simon or they would have prescribed hormone therapy treatment for a much shorter period of time, thereby avoiding the increased breast cancer risk inherent in prolonged usage.

Moreover, the above-quoted passage is merely a summary of a far more extensive causation charge that begins on page 32 of the trial transcript. R.4837a-42a (T.T. 5/15/07 at 32-37). Both the above-quoted summary and the entire causation charge, viewed as a whole (which Upjohn's brief improperly fails to do), adequately submit the proximate cause issue to the jury. *See Commonwealth v.*

Gibson, 951 A.2d 1110, 1142 (Pa. 2008) (“Jury instructions are to be evaluated as a whole”); *McManamon v. Washko*, 906 A.2d 1259, 1271 (Pa. Super. Ct. 2006) (“In reviewing a trial court’s charge to the jury, we must not take the challenged words or passage out of context of the whole of the charge, but must look to the charge in its entirety.”) (internal quotations omitted).

Upjohn further criticizes the jury verdict sheet, alleging that the verdict sheet improperly “combined two separate causation questions into one.” More specifically, Upjohn argues that the trial court should have separately asked the jury “whether hormone therapy caused Mrs. Simon’s breast cancer” and “whether Mrs. Simon’s physicians would have prescribed Provera even if they had been given information that plaintiffs contend was adequate.” Upjohn’s Opening Br. at 62.

Unfortunately for Upjohn, the jury verdict sheet actually used in this case posed precisely these questions. Question two on the verdict sheet asked:

Did Wyeth and/or UpJohn negligently fail to provide adequate warning regarding the risk of breast cancer to Mrs. Simon's prescribing physicians during the time that she took Premarin, Provera and Prempro?

R.4880a (T.T. 5/15/07 at 75). And question three on the verdict sheet asked:

Were the inadequate warnings regarding Premarin, which is a Wyeth product, Prempro, which is a Wyeth product and/or Provera, which is an UpJohn product, a factual cause of Mrs. Simon's injuries?

R.4881a (T.T. 5/15/07 at 76).

These two questions on the jury verdict sheet adequately required the jury to decide all the necessary proximate causation issues. To be sure, question three required the jury to decide both that Provera caused Mrs. Simon’s breast cancer and

that an adequate warning about Provera's breast cancer risk from Upjohn to Mrs. Simon's physicians would have caused those physicians not to prescribe Provera. But there is nothing inherently objectionable about having a single verdict question reflect multiple findings. *See, e.g., Fritz v. Wright*, 589 Pa. 219, 233, 907 A.2d 1083, 1091 (2006) (noting that trial courts have the discretion to require the jury to return a general verdict consisting of nothing more than either a finding for the plaintiff accompanied by a specification of damages or a finding for the defendant).

Indeed, if in civil cases a jury was required to separately record its findings on every single predicate fact necessary to return a verdict for the plaintiff, then presumably the same rule should apply in criminal cases before a jury can return a finding of guilty in favor of the prosecution. But this requirement of separately recorded findings does not apply even in criminal cases, and therefore Upjohn's argument that it should apply in civil cases is revealed to be utterly without merit.

For these reasons, this Court should reject Upjohn's new trial argument based on the jury instructions and verdict sheet.

E. The Trial Court Did Not Abuse Its Discretion By Admitting Into Evidence Advertisements Establishing That Upjohn Knew Of And Encouraged The Off-Label Use Of Provera With Premarin In Hormone Replacement Therapy

In its third ground for a new trial, Upjohn argues that the trial court erred in admitting into evidence advertisements that Upjohn created showing that Upjohn knew of and was encouraging the off-label use of Provera in combination with Wyeth's Premarin in hormone replacement therapy treatment. Upjohn argues that

this evidence was irrelevant, because there was no evidence that either the plaintiff or her treating physicians ever saw the ads, and because “Upjohn had already stipulated to the legal duty” to warn against the risks of Provera when Provera was being used in combination with Premarin. Upjohn’s Opening Br. at 65. This Court should reject Upjohn’s arguments because the trial court did not abuse its discretion in admitting this evidence, and even if the trial court did abuse its discretion, the evidence was at most irrelevant and not harmful to Upjohn on the issues that the jury had to resolve in reaching its verdict.

In *Old Chief v. United States*, 519 U.S. 172, 186–87 (1997), the Supreme Court of the United States recognized “the familiar, standard rule” that a party is “entitled to prove its case by evidence of its own choice, or, more exactly, that [the opposing party] may not stipulate or admit his way out of the full evidentiary force of the case as [the plaintiff] chooses to present it.” Upjohn’s argument herein that its stipulation to a duty to warn of the risks of Provera when used in combination hormone replacement therapy should prevent plaintiff from proving her case using actual evidence runs afoul of the “familiar, standard rule” recognized in *Old Chief*.

As Upjohn’s opening brief on appeal recognizes, physicians have the ability to prescribe FDA-approved drugs for so-called “off-label” uses, meaning uses for which the FDA has not approved the drug or evaluated its safety and efficacy. In some instances, such off-label uses may become widespread and well-known, while in other instances such off-label uses may be all but unknown to the drug’s manufacturer. In this case, Upjohn’s offer to stipulate to a duty to warn of Provera’s

risks when used in combination with Premarin was not an adequate substitute for plaintiff's evidence showing not merely that Upjohn knew that Provera was being used with Premarin, but rather that Upjohn was in fact directly and enthusiastically encouraging such off-label use. The jury could have permissibly found that Upjohn's duty to warn of Provera's risks in combination hormone replacement therapy was enhanced by the fact that Upjohn was encouraging that particular off-label use. Upjohn's proffered stipulation was not an adequate substitute for the evidence that the trial court properly allowed.

Thus, Upjohn is incorrect when it argues that this evidence was inadmissible merely because neither Mrs. Simon nor her physicians saw the advertisements. The advertisements' effect on Mrs. Simon or her physicians was not the purpose for which this evidence was introduced. Although Upjohn was willing to concede its duty to warn of off-label risks (which, by the way, further eviscerates Upjohn's FDA preemption defense, a defense that does not ordinarily encompass off-label risks), the trial court properly recognized that Upjohn's concession could not be used to defeat the evidentiary force of plaintiff's showing that Upjohn was not just suffering this particular off-label use against the company's will but was rather actively promoting and encouraging it.

Stated simply, if a drug company decides to market and profit from the sale of a drug, and if it decides to promote supposed benefits in marketing materials, it assumes the obligation to test and warn. Had Upjohn conducted the appropriate studies, the information known to the medical community today about the risk of

breast cancer from combination hormone therapy would have been known long before Mrs. Simon was offered that treatment.

Upjohn is thus absolutely incorrect in arguing that this evidence “had nothing to do with Mrs. Simon’s case.” Upjohn’s Opening Br. at 66. The evidence was properly admitted to establish Upjohn’s duty to warn, and Mrs. Simon had the burden of establishing that duty before the jury could find Upjohn liable. There is no indication that the jury relied on this evidence for any other purpose — as it was not relevant to the jury’s other inquiries — and therefore Upjohn cannot demonstrate any prejudice flowing from the trial court’s proper admission of this evidence to establish a duty to warn.

Accordingly, Upjohn is not entitled to a new trial on this basis.

F. The Jury Found That Mrs. Simon Took Provera Rather Than A Generic Substitute, And Sufficient Evidence Exists In Support Of That Finding

Upjohn’s second to last ground for a new trial asserts that the trial court did not require the jury to determine whether Mrs. Simon took Upjohn’s Provera or some generic equivalent of that drug. Although Upjohn is correct that the jury verdict sheet did not require a specific finding on that point, the jury did receive evidence in the form of testimony and exhibits regarding the name-brand versus generic issue, and the jury’s verdict finding Upjohn liable demonstrates that the jury found as a fact that Mrs. Simon took Provera rather than a generic substitute. Moreover, sufficient evidence of record exists in support of that finding.

In its opening brief on appeal, at pages 68–69, Upjohn quotes testimony from both former Upjohn executive Peter Philander and from Mrs. Simon herself about whether she would have received Upjohn’s Provera or a generic substitute. Yet Upjohn’s brief omits that Mrs. Simon’s medical records make clear that the progesterone she took was Provera. R.11,902a (Exhibit 27 to plaintiff’s brief in opposition to Upjohn’s post-trial motion). The records from Mrs. Simon’s osteoporosis doctor, Dr. Luckey, also show that Mrs. Simon was consuming the brands Provera and Premarin. R.11,904a (Exhibit 28 to plaintiff’s brief in opposition to Upjohn’s post-trial motion). Moreover, plaintiffs possessed evidence showing that Provera was far and away the number one prescribed progestin in New Jersey and that there was little generic competition for that medication in that state. R.11,530a (plaintiff’s brief in opposition to Upjohn’s post-trial motion at 38). In opposition to Mrs. Simon’s evidence that she consumed Upjohn’s Provera, Upjohn offered nothing more than conjecture.

Although the jury was not given a specific verdict interrogatory to answer reflecting the jury’s finding that Mrs. Simon consumed Provera instead of a generic substitute, had the jury in fact found that she had not taken Provera, common sense would have dictated a verdict in Upjohn’s favor. In other words, before the jury could find in favor of Mrs. Simon and against Upjohn, the jury had to conclude, based on the evidence before it, that she took Provera and not a generic substitute. Indeed, the jury charge that the trial court provided to the jury included the following passage:

Just sort of to restate it again, the plaintiffs must prove to you that the defendants' drugs caused the plaintiff's damages. This is referred to as a factual cause. The question is, Did Wyeth and/or Upjohn's hormone pills — were they a factual cause in bringing about Mrs. Simon's injuries?

R.4850a (T.T. 5/15/07 at 45). This jury instruction specifically requires the jury to find that it was *defendants'* drugs and *Upjohn's* hormone pills that Mrs. Simon consumed before the jury could find Upjohn liable. Thus, the jury's verdict in favor of Mrs. Simon and against Upjohn necessarily demonstrates that the jury found that Mrs. Simon consumed Provera rather than any generic substitute. And, as explained above, more than sufficient evidence supports that finding.

Accordingly, this Court should reject Upjohn's fourth ground for a new trial.

G. The Jury's Findings On Causation And The Discovery Rule Are Not Against The Manifest Weight Of The Evidence

As the fifth and final ground for a new trial, Upjohn advances a perfunctory, one-paragraph argument that this Court should rule that the jury's findings on causation and the discovery rule were against the weight of the evidence.

In *Choma v. Iyer*, 871 A.2d 238, 243 (Pa. Super. Ct. 2005), this Court explained that “[a] new trial will not be granted on the basis of a weight of the evidence claim unless the evidence supporting the verdict is so inherently improbable or at variance with admitted or proven facts or with ordinary experience as to render the verdict shocking to the court's sense of justice.” This Court further explained that “[a] new trial should not be granted where the evidence is conflicting

and the jury could have found for either party, or where the trial judge would have reached a different conclusion on the same facts.” *Id.*

As explained above and in Mrs. Simon’s opening brief on appeal, a wealth of evidence exists in support of the jury’s finding that Upjohn’s failure to warn caused Mrs. Simon to receive Provera and that Mrs. Simon initiated suit within two years of having reasonably discovered the cause of her injuries. Accordingly, no basis exists for ordering a new trial due to insufficiency of the evidence, and this Court should therefore reject the fifth and final ground for a new trial advanced by Upjohn on appeal.

IV. 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, reject Upjohn's cross-appeal seeking a new trial, order the trial court to reinstate the jury's verdict in favor of Mrs. Simon, and instruct the trial court to address on the merits Mrs. Simon's timely motion for delay damages.

Respectfully submitted,

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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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