NON-PRECEDENTIAL DECISION – SEE SUPERIOR COURT I.O.P 65.37

DONNA KENDALL	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
v.	:	
	:	
WYETH, INC., WYETH PHARMACEUTICALS, INC., WYETH-AYERST PHARMACEUTICALS, INC., WYETH-AYERST INTERNATIONAL, INC., WYETH PHARMACEUTICALS, WYETH LABORATORIES, INC., PFIZER, INC., PHARMACIA & UPJOHN INC. AND UPJOHN CO.	:	
	:	
APPEAL OF: WYETH, INC., WYETH PHARMACEUTICALS, INC., WYETH-AYERST PHARMACEUTICALS, INC., WYETH-AYERST INTERNATIONAL, INC., WYETH PHARMACEUTICALS, WYETH LABORATORIES, INC.,	:	No. 936 EDA 2010
	:	
Appellants	:	

Appeal from the Judgment Entered March 18, 2010,
in the Court of Common Pleas of Philadelphia County
Civil Division at No. 00965 June Term 2004

DONNA KENDALL	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
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WYETH, INC., WYETH PHARMACEUTICALS, INC., WYETH-AYERST PHARMACEUTICALS, INC., WYETH-AYERST INTERNATIONAL, INC., WYETH PHARMACEUTICALS, WYETH LABORATORIES, INC., PFIZER, INC., PHARMACIA & UPJOHN INC. AND UPJOHN CO.	:	

APPEAL OF: PHARMACIA & UPJOHN COMPANY, LLC, Appellant	:	No. 937 EDA 2010

Appeal from the Judgment Entered March 18, 2010,
in the Court of Common Pleas of Philadelphia County
Civil Division at No. 00965 June Term 2004

DONNA KENDALL AND JOHN KENDALL, JR.	:	IN THE SUPERIOR COURT OF PENNSYLVANIA
v.	:	
WYETH, INC., WYETH PHARMACEUTICALS, INC., WYETH-AYERST PHARMACEUTICALS, INC., WYETH-AYERST INTERNATIONAL, INC., WYETH PHARMACEUTICALS, WYETH LABORATORIES, INC., PFIZER, INC., PHARMACIA & UPJOHN INC. AND UPJOHN CO.	:	
APPEAL OF: DONNA KENDALL, Appellant	:	No. 1154 EDA 2010

Appeal from the Judgment Entered March 18, 2010,
in the Court of Common Pleas of Philadelphia County
Civil Division at No. June Term, 2004, No. 0965

BEFORE: FORD ELLIOTT, P.J.E., McEWEN, P.J.E.,* AND PLATT, J.**

* P.J.E. McEwen did not participate in the consideration of this decision.

** Retired Senior Judge assigned to the Superior Court.

MEMORANDUM BY FORD ELLIOTT, P.J.E.: **FILED JANUARY 3, 2012**

Donna Kendall ("Kendall"), Wyeth Pharmaceuticals, Inc. ("Wyeth") and Pharmacia & Upjohn, Inc. ("Upjohn") cross-appeal from the order of March 18, 2010, disposing of post-trial motions and entering judgment. We reinstate the jury's punitive damages award, but affirm in all other respects.

Kendall instituted suit against Wyeth and Upjohn for negligent failure to warn her prescribing physician of the significant risks of breast cancer arising from the ingestion of certain hormone replacement therapy ("HRT") drugs which the defendants manufacture for the prevention of menopausal symptoms. Kendall asserted that these HRT drugs caused or promoted her invasive breast cancer.

Following a jury trial held from October 20, 2009 through November 23, 2009, a verdict was returned in favor of Kendall for compensatory damages in the amount of $6.3 million, with liability apportioned at 60% for Wyeth and 40% for Upjohn. In a separate phase, the jury awarded punitive damages in the amount of $28 million, $16 million against Wyeth and $12 million against Upjohn. Following post-trial motions, the trial court granted Kendall's motion for delay damages in the amount of $1,972,547, for a total award of $8,272,547. The trial court also reduced the amount of punitive damages to $1 million. The defendants' remaining post-trial motions, including for judgment notwithstanding the verdict and/or

a new trial, were denied. These timely appeals followed, and were consolidated ***sua sponte*** on June 9, 2010.[1]

The trial court has summarized the factual background of this matter as follows:

> The HRT drugs in question are Premarin and Prempro, manufactured by Wyeth, and Provera, manufactured by Upjohn. Put quite simply, the hormones estrogen (E) and progesterone [] (P) regulate a woman's menstrual cycle. When one reaches menopause, the production of these hormones is greatly reduced, causing menopausal symptoms such as hot flashes, uterine bleeding, and vaginal atrophy, among others.
>
> Wyeth's drug Premarin, on the market for a number of years, was approved for hot flashes and other menopausal symptoms as an estrogen (colloquially known as "E") replacement. Provera, manufactured by Upjohn, was approved for uterine bleeding as a progesterone (colloquially known as "progestin" or "P") replacement. In the 1970's, more particularly in 1975, studies revealed that there was an increase in endometrial cancer from the use of estrogen alone. It came to be known that this risk of endometrial cancer could be greatly reduced by taking both "E" and "P" products together. Thus, both companies began to market their drugs for this use, Wyeth's Premarin for "E" and Upjohn's Provera for "P." In the 1980s and 1990s, these drugs also were prescribed for cardiovascular disease and osteoporosis, but these uses were never approved by the FDA and are considered "off label uses." In 1994, Wyeth's Prempro (a combination of "E" plus "P") was approved to ameliorate the effects of menopausal symptoms. In 1998, Prempro and Provera were approved to prevent endometrial hyplasia or endometrial cancer.

[1] The parties were not ordered to file concise statements of errors complained of on appeal pursuant to Pa.R.A.P., Rule 1925(b), 42 Pa.C.S.A.

> Plaintiff's physician, Dr. Dale Jones, prescribed Premarin and Provera to Plaintiff from 1992 to 1998 in order to prevent or lessen Plaintiff's menopausal symptoms. In 1998, Dr. Jones prescribed Prempro, which Plaintiff took from 1998 until October or November of 2002 when she was diagnosed with estrogen receptive positive ductal breast cancer. Although there was voluminous testimony over the weeks of this trial, Plaintiff's theory of the case can be simply stated: during the years in which Plaintiff took the drugs, Defendants knew or had reason to know that there existed a substantial risk of breast cancer which resulted from their ingestion, yet Defendants failed to adequately advise the prescribing doctors, Plaintiff's physician included, of these risks. Plaintiff argued that Defendants put caution about the risk aside in favor of profits. The jury, by its verdict, agreed with Plaintiff.

Trial court opinion, 3/18/10 at 2-4.

We will address Wyeth's issues on appeal first. Wyeth has raised the following claims for this court's review on appeal:

> 1. In this prescription drug case, was Wyeth entitled to JNOV [(judgment ***non obstante veredicto***)] on Plaintiff's punitive damages claim under the rigorous standards required by Illinois law, given (a) the FDA's review and approval of the drugs and of the drugs' labels warning of the risk of breast cancer, (b) the extensive testing and study of the drugs by Wyeth and independent researchers, and (c) the absence any of [sic] evidence that Wyeth misled or withheld information from the FDA?
>
> 2. Was Wyeth entitled to JNOV on Plaintiff's punitive damages claim under federal due process principles where (a) there was a reasonable disagreement in the scientific and medical communities about the risk of breast cancer associated with the medications at

> issue, and (b) Wyeth, which had complied fully with FDA procedures and regulations, reasonably believed that its conduct was lawful and proper?
>
> 3. Did the trial court commit reversible error, warranting a new trial on all issues, by impermissibly admitting extensive, prejudicial evidence of marketing and other conduct that had no connection to the decision by Plaintiff's physician to prescribe HT to her, none of which could properly form a basis for punitive damages under Illinois law and federal due process principles?
>
> 4. Should the testimony of Plaintiff's expert, Dr. Cheryl Blume, have been excluded where Dr. Blume was not qualified to opine as to the adequacy of Wyeth's drugs labeling, and her testimony as to the "reasonableness" of Wyeth's conduct lacked any objective standard and was improperly speculative?

Wyeth's brief at 2-3.

First, Wyeth argues that the trial court erred in denying its motion for JNOV as to punitive damages. The parties agree that as the plaintiff, Kendall, is an Illinois resident, was prescribed HRT drugs in Illinois, and was diagnosed with breast cancer in Illinois, the substantive law of Illinois controls.

> A judgment notwithstanding the verdict is reviewed ***de novo*** and should be granted only when "all of the evidence, when viewed in its aspect most favorable to the opponent, so overwhelmingly favors movant that no contrary verdict based on that evidence could ever stand." ***Pedrick v. Peoria & Eastern R.R. Co.***, 37 Ill.2d 494, 510, 229 N.E.2d 504, 513-14 (1967); ***York v. Rush-Presbyterian-St.Luke's Medical Center***, 222 Ill.2d 147, 178, 305 Ill.Dec.

> 43, 854 N.E.2d 635, 652 (2006). The threshold for a judgment notwithstanding the verdict is high, and a motion for such will only be successful when all of the evidence, together with all reasonable inferences considered in favor of the nonmovant, point to a "total failure or lack of evidence" to prove the nonmovant's case. ***York***, 222 Ill.2d at 178, 305 Ill.Dec. 43, 854 N.E.2d at 652. For that reason, a judgment notwithstanding the verdict is improper if "'reasonable minds might differ as to inferences or conclusions to be drawn from the facts presented.'" ***York***, 222 Ill.2d at 178, 305 Ill.Dec. 43, 854 N.E.2d at 652, ***quoting Pasquale v. Speed Products Engineering***, 166 Ill.2d 337, 351, 211 Ill.Dec. 314, 654 N.E.2d 1365, 1374 (1995).

Bosco v. Janowitz, 388 Ill.App.3d 450, 458-459, 903 N.E.2d 756, 764 (Ill.App. 1 Dist. 2009).

> Punitive damages "are not awarded as compensation, but serve instead to punish the offender and to deter that party and others from committing similar acts of wrongdoing in the future." ***Loitz v. Remington Arms Co.***, 138 Ill.2d 404, 414, 150 Ill.Dec. 510, 563 N.E.2d 397 (1990). Punitive damages may be awarded when the defendant's tortious conduct evinces a high degree of moral culpability, that is, when the tort is "committed with fraud, actual malice, deliberate violence or oppression, or when the defendant acts willfully, or with such gross negligence as to indicate a wanton disregard of the rights of others." ***Kelsay v. Motorola, Inc.***, 74 Ill.2d 172, 186, 23 Ill.Dec. 559, 384 N.E.2d 353 (1978). To determine whether punitive damages are appropriate, "the trier of fact can properly consider the character of the defendant's act, the nature and extent of the harm to the plaintiff that the defendant caused or intended to cause and the wealth of the defendant." Restatement (Second) of Torts § 908(2) (1979). Because punitive damages are penal in nature, they "are not favored in the law, and the courts must take caution to see that punitive damages are not

> improperly or unwisely awarded." ***Kelsay***, 74 Ill.2d at 188, 23 Ill.Dec. 559, 384 N.E.2d 353.

Slovinski v. Elliot, 237 Ill.2d 51, 57-58, 927 N.E.2d 1221, 1224-1225 (Ill. 2010).

Without reciting thousands of pages of testimony, Kendall's evidence on punitive damages boils down to the fact that as early as the 1970s, Wyeth knew of a possible link between its products and breast cancer, but did nothing to warn physicians or pursue definitive studies. To the contrary, Wyeth sought to actively suppress information, instructing its sales representatives not to discuss the matter with physicians, and sponsoring ghostwritten articles denying any causative link between Premarin/Prempro and breast cancer. Wyeth also touted off-label uses including prevention of heart disease, osteoporosis, and dementia for which no beneficial effects were proven. Kendall presented evidence that Wyeth's overarching concern was profit, with the stated goal of having a majority of women in the world taking its products for the rest of their lives, in spite of the known risks. Therefore, there was sufficient evidence that Wyeth acted willfully, or with such gross negligence as to indicate a wanton disregard of the rights of others, such as to support imposition of punitive damages. The trial court did not err in denying Wyeth's motion for JNOV on punitive damages.

Wyeth argues that it complied with FDA mandates including warning labels for its products. However, it is well settled that compliance with industry and governmental safety standards, in and of itself, does not

insulate a defendant from punitive damages. ***Daniel v. Wyeth***, 15 A.3d 909, 932 (Pa.Super. 2011), ***appeal granted in part***, ___ A.3d ___, 2011 WL 6034401 (Pa. Dec. 5, 2011), citing ***Phillips v. Cricket Lighters***, 584 Pa. 179, 191, 883 A.2d 439, 447 (2005). As we stated in ***Daniel***, it was for the jury to decide whether Wyeth performed adequate testing of its product before marketing it for sale, regardless of purported compliance with FDA testing requirements. ***Id.***

In its second issue on appeal, Wyeth contends that the jury's award of punitive damages violated federal due process principles. Again, no relief is due.[2] "The due process clause of the fourteenth amendment prohibits the imposition of grossly excessive or arbitrary punishments on a tortfeasor because such awards serve no legitimate purpose and constitute an arbitrary deprivation of property." ***Blount v. Stroud***, 915 N.E.2d 925, 941 (Ill.App. 1 Dist. 2009), ***appeal denied***, 235 Ill.2d 585, 924 N.E.2d 454 (2010), ***cert. denied***, 131 S.Ct. 503 (2010), citing ***State Farm v. Campbell***, 538 U.S. 408, 417 (2003).

To the extent Wyeth repeats its argument that it was in compliance with FDA regulations, we have already rejected this argument for the reasons discussed above. The record indicates that Wyeth's conduct in this matter was reprehensible and fully merited the imposition of punitive damages. Wyeth was on notice years prior to Kendall's being prescribed

[2] Federal due process is more fully discussed ***infra*** at pgs. 44 ***et seq.***

HRT drugs that they may cause breast cancer, yet purposefully failed to study the matter further and even discouraged others from doing so. Dr. Jones specifically testified that if he had been made aware of the link earlier, he never would have prescribed HRT drugs to Kendall. As was stated in ***Proctor v. Davis***, 682 N.E.2d 1203, 1211-1212 (Ill.App. 1 Dist. 1997):

> If Upjohn did not know what it should have known, it failed in its duty as an expert. It could not fulfill that duty merely by waiting for what it considered sufficient proof of a cause-effect relationship before advising the medical profession with an appropriate alert or warning of the possibility of risk in the use of one of its products.

(Citation omitted.)

And, as we stated in ***Daniel***, on nearly identical facts as those presented here:

> In sum, sufficient evidence of record exists to support a jury's finding that from the middle 1970s and forward, Wyeth knew or strongly suspected that hormone replacement therapy increased the risk of breast cancer in post-menopausal women but failed and refused to conduct adequate studies. *** Permitting all available inferences from the evidence in favor of the verdict winner, as our standard of review requires, there was sufficient evidence to permit the jury to conclude that Wyeth's failure to perform adequate tests of the risk of breast cancer was intentional, ***i.e.***, because it did not want confirmation of those risks and the resulting loss of sales and profits. Consequently, sufficient evidence of record exists to support a jury's finding that Wyeth had a subjective understanding that its sale of Prempro was placing women at an increased risk of

> contracting breast cancer, and its failure to test was in conscious disregard of that known risk.

Daniel, 15 A.3d at 932-933.

Next, Wyeth complains that the trial court erred in admitting testimony concerning Wyeth's extensive marketing of its HRT drugs. According to Wyeth, such testimony was irrelevant because Dr. Jones testified he did not rely on such marketing efforts when prescribing HRT to Kendall. Therefore, Wyeth argues, there was no causal connection between its marketing campaign and Kendall's injuries.

Clearly, evidence of Wyeth's marketing of its HRT drugs even in the face of claims they caused breast cancer was admissible and relevant to show reprehensibility of its actions, which went to the issue of punitive damages. There was testimony that Wyeth attempted to "drive the science" by ghostwriting favorable articles and instructed its sales representatives to downplay any breast cancer risk in their discussions with physicians. Wyeth's marketing materials acknowledged a need to "manage the breast cancer issue." While Dr. Jones testified that he did not prescribe HRT drugs to Kendall based on any specific marketing by Wyeth, certainly his belief that HRT drugs had cardiovascular benefits and that the potential benefits outweighed the risks was rooted, at least indirectly, in Wyeth's active promotion of its products.

Finally, Wyeth argues that the testimony of Dr. Cheryl Blume should have been excluded. According to Wyeth, Dr. Blume was unqualified to offer

testimony regarding Wyeth's standard of care and the adequacy of its drug labeling.

> Rule 702 of the Pennsylvania Rules of Evidence provides no particular rules for the qualification of experts. Instead, pursuant to Rule 702 an expert may be qualified to testify so long as he or she has "scientific, technical or other specialized knowledge beyond that possessed by a layperson" that will in some manner assist the jury in understanding the evidence presented. Whether or not an expert witness is qualified to testify is usually a matter left to the sound discretion of the trial court. ***See***, ***e.g.***, ***Jacobs v. Chatwani***, 922 A.2d 950, 956 (Pa.Super.), ***appeal denied***, 595 Pa. 708, 938 A.2d 1053 (2007).

Daniel, 15 A.3d at 925-926. We already held in ***Daniel*** that Dr. Blume was qualified to offer testimony regarding the adequacy of Wyeth's warning labels:

> Sufficient evidence of record existed to permit the trial court to find that Dr. Blume qualified as a satisfactory "medical expert," as that term was used in [***Demmler v. SmithKline Beecham Corp.***, 671 A.2d 1151 (Pa.Super. 1996), ***appeal denied***, 546 Pa. 655, 684 A.2d 557 (1996)]. Her testimony disclosed that she had a Bachelors degree in Biology and a Doctoral degree in Medical Pharmacology and Toxicology. Dr. Blume further testified that in her twenty-year career as an executive with a major pharmaceutical company (Mylan Laboratories), she had been responsible for securing FDA approval of over 100 prescription drugs, and that her responsibilities included revising drug labels in light of post-marketing safety signals. Based upon this testimony, the trial court aptly noted that as a "labeling expert," Dr. Blume was arguably "more qualified than a doctor who deals very marginally with these issues."

Id. at 926 (record citations omitted). For the same reasons, we conclude that Dr. Blume was also qualified to render an expert opinion as to the relevant standard of care and the reasonableness of Wyeth's actions. The trial court did not abuse its discretion in admitting Dr. Blume's testimony.

We now turn to Upjohn's issues on cross-appeal. Upjohn argues 1) that punitive damages were inappropriate; 2) the trial court erred in admitting the expert testimony of Dr. Elizabeth Naftalis, M.D., who testified as to the causation of Kendall's breast cancer; and 3) that the trial court gave the jury erroneous and inadequate instructions on causation and the learned intermediary doctrine. (Upjohn's brief at 2-3.)

First, we address Upjohn's claim that punitive damages were inappropriate in this case. We review for an abuse of discretion. ***Lawlor v. North American Corp. of Illinois***, 949 N.E.2d 155, 174 (Ill.App. 1 District 2011) (citations omitted). "[P]unitive damages may be awarded when torts are committed with fraud, actual malice, deliberate violence or oppression, or when the defendant acts willfully, or with such gross negligence as to indicate a wanton disregard of the rights of others." ***Id.*** (citations and quotation marks omitted). "Punitive damages are not awarded as compensation, but serve instead to punish the offender and to deter that party and others from committing similar acts of wrongdoing in the future." ***Id.*** (citation omitted). "To determine whether punitive damages are appropriate, 'the trier of fact can properly consider the character of the

defendant's act, the nature and extent of the harm to the plaintiff that the defendant caused or intended to cause and the wealth of the defendant.'" ***Id.***, quoting ***Slovinski***, 237 Ill.2d at 58, 927 N.E.2d at 1225.

We can find no abuse of discretion here in allowing punitive damages against Upjohn. Kendall presented evidence that as early as 1961, Upjohn was put on notice that Provera caused mammary cancer in rats. By 1963, Upjohn was on notice that Provera exacerbated breast cancers in humans, but chose not to study this risk. Upjohn actively promoted Provera to be used in combination with exogenous estrogens by post-menopausal women, despite the fact that such use had not been approved by the FDA. The FDA repeatedly denied Upjohn's applications for approval of Provera in combination with exogenous estrogens, citing a lack of sufficient studies and data. Despite this, Upjohn chose not to study Provera in combination with estrogen but continued to promote the use of Provera in combination with estrogens, or "E+P," sending advertisements directly to physicians. Although physicians were free to prescribe E+P, it was an off-label use and Upjohn was forbidden from promoting or advertising for it. Upjohn actively flouted the rules, encouraging long-term use of Provera as "the other half of estrogen replacement therapy."

In 1989 Upjohn became aware of a published medical article reporting a very high increased risk of breast cancer in a small group of women in the study taking HRT drugs. In 1990, Upjohn hired the Degge Group, an

independent research group, to conduct a review of the current state of knowledge on the relationship between HRT drugs and breast cancer. The Degge Group completed its investigation and found that the relationship between exposure to exogenous progestins to breast cancer remained unknown. However, the Degge Group stated that "there are clear opportunities for further fruitful research" and concluded, "we strongly recommend further epidemiological studies that address any possible association of breast cancer with progestin use, particularly in the potential high risk groups discussed above." Again, Upjohn responded by basically "sticking its head in the sand" and failed to conduct any studies to explore a possible link between HRT drugs, including Provera, and breast cancer. Meanwhile, Upjohn continued to promote Provera in violation of FDA guidelines.

During the time that Kendall was taking Provera, from 1991 to 1998, the labeling made no mention of any risk of breast cancer in humans. The "warnings" section of the label did mention that it causes mammary nodules in male beagle dogs. In 2002 the Women's Health Initiative ("WHI") study revealed the link between E+P and breast cancer. In 2003 Wyeth changed its labels for Premarin and Prempro to reflect an increased breast cancer risk; however, Upjohn did not change its Provera label until 2007.

Upjohn argues that the jury could not impose punitive damages for failing to discover an unknown risk. However, the record reflects that

Upjohn was willfully ignorant of the increased risk of breast cancer from long-term use of Provera in conjunction with exogenous estrogen. As Kendall argues, there were numerous "red flags," not least of which was the Degge Group's review and explicit recommendation for further study, which Upjohn consciously ignored. Indeed, there was evidence of a possibility of increased risk as early as the 1960s. Yet, inexplicably, Upjohn did not conduct any studies to evaluate a breast cancer risk despite the ability to do so. As Kendall points out, Upjohn conducted other studies including a long-term study to investigate whether Provera protected against osteoporosis (it does not). (Kendall's brief at 28 n.12.) However, Upjohn steadfastly refused to follow up on suggestions for further study of a link between breast cancer in humans and Provera. Even after the WHI study confirmed that E+P greatly increases the risk of breast cancer, Upjohn did not change its labeling until five years later, in 2007. This was sufficient for the jury to find that Upjohn was grossly negligent and acted with wanton disregard for users of its products including Kendall. Upjohn's disingenuous claim that it was unaware of any increased risk does not shield it from liability.

Upjohn also relies on its purported compliance with FDA regulations and labeling guidelines (of course, as discussed ***supra***, Upjohn ignored FDA regulations concerning advertising for off-label use). As Kendall observes, this sounds suspiciously similar to a federal preemption argument which has

been soundly rejected by the United States Supreme Court. ***Wyeth v. Levine***, 555 U.S. 555, 570-571 (2009) ("it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market."). ***See also Daniel***, 15 A.3d at 932 (finding reliance on Wyeth's compliance with FDA testing and labeling requirements to be misplaced; "compliance with industry and governmental safety standards 'does not, standing alone, automatically insulate a defendant from punitive damages'"), quoting ***Phillips***, 584 Pa. at 191, 883 A.2d at 447.

Therefore, Upjohn was responsible for its own labeling regardless of FDA regulations. Similarly, compliance with FDA testing requirements and FDA's eventual approval of E+P does not preclude imposition of punitive damages. "It was for the jury to decide whether Wyeth had performed adequate testing of its product before marketing it for sale." ***Daniel***, 15 A.3d at 932. In ***Daniel***, we cited expert testimony to the effect that "nothing prevents drug companies from conducting additional studies if safety concerns arise either before or after FDA approval." ***Id.*** Similarly, here, there was testimony to the effect that studies of the relationship between HRT drugs, including Provera in combination with exogenous estrogens, were both feasible and strongly recommended. Whether or not

such studies were actually required by the FDA does not insulate Upjohn from punitive damages.

Similar to Wyeth, Upjohn also argues that adequate testing was not feasible and that its marketing efforts were irrelevant to the issue of punitive damages. Upjohn contends that there was no evidence its marketing materials ever reached Kendall's prescribing physician, influenced his decision to prescribe E+P, or was a proximate cause of Kendall's damages.

As Kendall points out, these arguments really go more to the weight of the evidence which is for the jury. (Kendall's reply brief at 14.) At any rate, there was conflicting testimony concerning the feasibility of earlier studies and the jury was free to discount Upjohn's self-serving testimony that such studies were impossible or impractical. In fact, Upjohn's own expert, Dr. Heidi Jolson, conceded that Upjohn had the ability to conduct a breast cancer study but did not. Regarding Upjohn's advertising and marketing efforts, such evidence was clearly relevant to the issue of reprehensibility of Upjohn's conduct, whether or not Kendall's prescribing physician personally relied on such advertising. The evidence showed that Upjohn continued to promote Provera to be used in combination with exogenous estrogens despite the fact that it had not been FDA-approved for such use and despite numerous red flags indicating the need for further research.

Next, Upjohn argues that imposition of punitive damages in this case violates principles of federal due process. Upjohn repeats many of the same

arguments, ***i.e.***, that it complied with FDA labeling requirements, earlier studies prior to the WHI were infeasible, it had no actual knowledge of an increased risk of breast cancer, ***etc.***

"While States possess discretion over the imposition of punitive damages, it is well established that there are procedural and substantive constitutional limitations on these awards. The Due Process Clause of the Fourteenth Amendment prohibits the imposition of grossly excessive or arbitrary punishments on a tortfeasor." ***State Farm v. Campbell***, 538 U.S. 408, 416 (2003) (citations omitted). "The reason is that '[e]lementary notions of fairness enshrined in our constitutional jurisprudence dictate that a person receive fair notice not only of the conduct that will subject him to punishment, but also of the severity of the penalty that a State may impose.'" ***Id.*** at 417, quoting ***BMW v. Gore***, 517 U.S. 559, 574 (1996).

The award of punitive damages in this case was not arbitrary and did not violate federal due process. Upjohn was put on notice of the potential for liability when it continued to market and promote Provera for off-label use despite inadequate testing. Upjohn was warned numerous times of a possible breast cancer link and of the need for further studies and chose to ignore those warnings. Upjohn's claim that the imposition of punitive damages violated its right to due process is without merit.

Next, Upjohn argues that the testimony of Elizabeth Naftalis, M.D., was inadmissible. Dr. Naftalis testified at trial that the HRT drugs were the

cause of Kendall's breast cancer. According to Upjohn, Dr. Naftalis failed to meet the standard set forth in ***Frye v. United States***, 293 F. 1013 (D.C.Cir. 1923) for admission of expert testimony. We disagree.

> As we held [] in ***Trach v. Fellin***, 817 A.2d 1102 (Pa.Super. 2003) [(***en banc***), ***appeal denied***, 577 Pa. 725, 847 A.2d 1288 (2004)] , the ***Frye*** test sets forth an exclusionary rule of evidence that applies only when a party wishes to introduce novel scientific evidence obtained from the conclusions of an expert scientific witness. ***Trach***, 817 A.2d at 1108-1109. Under ***Frye***, a party wishing to introduce such evidence must demonstrate to the trial court that the relevant scientific community has reached general acceptance of the principles and methodology employed by the expert witness before the trial court will allow the expert witness to testify regarding his conclusions. ***Id.***, 817 A.2d at 1108-1109, 1112. However, the conclusions reached by the expert witness from generally accepted principles and methodologies need not also be generally accepted. ***Id.***, 817 A.2d at 1112. Thus, a court's inquiry into whether a particular scientific process is "generally accepted" is an effort to ensure that the result of the scientific process, ***i.e.***, the proffered evidence, stems from "scientific research which has been conducted in a fashion that is generally recognized as being sound, and is not the fanciful creations [sic] of a renegade researcher." ***See id.***, 817 A.2d at 1111 (quoting ***Blum v. Merrell Dow Pharms., Inc.***, 564 Pa. 3, 9-10, 764 A.2d 1, 5 (2000) (Cappy, C.J., dissenting)).

Reading Radio, Inc. v. Fink, 833 A.2d 199, 208 (Pa.Super. 2003), ***appeal denied***, 577 Pa. 723, 847 A.2d 1287 (2004) (emphasis deleted).

> [A]s to the standard of appellate review that applies to the ***Frye*** issue, we have stated that the admission of expert scientific testimony is an evidentiary matter for the trial court's discretion and should not be disturbed on appeal unless the trial court abuses

> its discretion. ***See Commonwealth v. Zook***, [532 Pa. 79, ___,] 615 A.2d [1] at 11 [(1992), ***cert. denied***, 507 U.S. 974 (1993)]. An abuse of discretion may not be found merely because an appellate court might have reached a different conclusion, but requires a result of manifest unreasonableness, or partiality, prejudice, bias, or ill-will, or such lack of support so as to be clearly erroneous. ***Paden v. Baker Concrete Constr., Inc.***, 540 Pa. 409, 658 A.2d 341, 343 (1995).

Grady v. Frito-Lay, Inc., 576 Pa. 546, 559, 839 A.2d 1038, 1046 (2003). "[W]e emphasize that the proponent of expert scientific evidence bears the burden of establishing all of the elements for its admission under Pa.R.E. 702, which includes showing that the ***Frye*** rule is satisfied." ***Id.*** at 558, 839 A.2d at 1045. "[I]n applying the ***Frye*** rule, we have required and continue to require that the proponent of the evidence prove that the methodology an expert used is generally accepted by scientists in the relevant field as a method for arriving at the conclusion the expert will testify to at trial." ***Id.***, citing ***Commonwealth v. Blasioli***, 552 Pa. 149, 153, 713 A.2d 1117, 1119 (1998).

The trial court summarized Dr. Naftalis' testimony as follows:

> In order to determine the validity of Dr. Naftalis' testimony and the methodology which she used to arrive at her conclusions, they must be viewed in light of other evidence of causation presented by the Plaintiff, namely, the epidemiological expert testimony of Doctor Donald Austin and the trial testimony of Doctor Dale Jones. Dr. Austin is a physician as well as an epidemiologist. He is certified in preventive medicine and has a Masters in Microbiology and Public Health. He testified as a medical doctor and epidemiologist that studies

clearly indicated Plaintiff's breast cancer was caused by the ingestion of the HRT drugs. He concluded that the synthetic hormone replacement drugs manufactured by the Defendants not only caused breast cancer in post-menopausal women, but actually promoted its growth.

Dr. Austin then discussed the findings of the Women's Health Initiative study of 2002, which was sponsored by the National Institute[s] of Health (hereinafter referred to as "WHI"). A major result of this study was that the public was made aware of the significant risk of breast cancer from "E" plus "P" ingestion. The WHI study had been instituted a number of years before to determine whether estrogen and progestin replacement medication was beneficial in preventing heart disease and osteoporosis, but the results were inconclusive. The study was terminated after five years because of the discovery that there was an increased risk of breast cancer from consumption of these drugs. It was determined that the overall relative risk (RR) was 1.24 over a base of 1.00, or 24% increased risk. Additionally, Dr. Austin presented sales figures which indicated that after the results of the WHI study became public, sales of HRT drugs declined. Further studies were presented to the jury which indicated that breast cancer rates decreased concomitantly. Dr. Austin concluded that these occurrences were not mere happenstances, but were in fact related to the ingestion of the HRT drugs.

Dr. Austin then cited other studies in support of his opinion that HRT consumption caused breast cancer. He pointed to the English "Million Women's Study," which found a relative risk of 2.0 (100%) after 5 years use, 2.5 (150%) relative risk after 7 years and 3.0 (200%) after 11 years. Another study of 40 women showed the relative risk to be 4.00 (or 300%). The Borquist Ductal Breast Cancer study was also cited, which indicated that "E" plus "P" use increased the relative risk of ductal breast cancer to 2.95 (almost 200%). Based on all these studies, his interpretation of the WHI, and the length

> of time Mrs. Kendall used the drugs, he concluded that her relative risk over the base of 1.00 was 4.35 (or 335%).
>
> Dr. Naftalis based her conclusion on the epidemiological opinions of Dr. Austin and the testimony of Dr. Jones who stated that he prescribed the drugs to Plaintiff for a total of eleven years, but that he would not have prescribed them to Mrs. Kendall for such a lengthy period of time had he known about the risk of breast cancer.[Footnote 3] Based on the testimony of these two physicians, and after weighing Plaintiff's personal health history, Dr. Naftalis deductively reasoned that Plaintiff's breast cancer was caused by the ingestion of the drugs in question manufactured by Defendants.[Footnote 4] Dr. Naftalis asserted that Plaintiff's medical history indicated she would have been at a low risk of developing breast cancer if she had not taken Defendants' HRT drugs. Dr. Naftalis pointed to the fact that Mrs. Kendall had low estrogen levels prior to the use of the drugs, concluding that she would have been below the base Relative Risk of 1.00 for breast cancer had she not consumed these drugs. Dr. Naftalis found that Plaintiff had no family history of breast cancer, nor was she obese, nor did she consume large quantities of alcohol; all of which are considered breast cancer risks. She also pointed out that that [sic] Plaintiff's cancer was estrogen receptor positive in the ductal areas as further evidence that Mrs. Kendall's breast cancer was promoted by the use of estrogen. Dr. Naftalis mentioned two non-risk factors in the Plaintiff's history to support her conclusions. Mrs. Kendall was twelve years old when she had her first menstrual period, which is considered to be a young age. She was eighteen years old when she gave birth to her first child. Studies have shown that these events would have decreased Plaintiff's risk of breast cancer. Consequently, Dr. Naftalis opined that Plaintiff's risk would have been extremely low had she had [sic] not taken the HRT drugs. Since her risk was increased to as much as 300% based on the time period of their use, deductive reasoning

> concluded that ingestion of Defendant's products caused her breast cancer.
>
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>
> [Footnote 3] Defendants in their brief in support of their Post Trial Motions for JNOV and/or a New Trial assert that Plaintiff failed to introduce evidence that Dr. Jones would not have prescribed the HRT medications if Defendants had supplied different warnings. To the contrary, Dr. Jones, in his video taped testimony, clearly stated he would not have prescribed them for such a lengthy time period if he had known what he knows today about the risk of breast cancer. [(citations omitted)].
>
> [Footnote 4] In her report and during cross-examination, Dr. Naftalis referred to the concept of "deductive reasoning" as "differential diagnosis." For the purposes of this case, the meaning of the two phrases is identical.

Trial court opinion, 3/18/10 at 9-11.

There is nothing scientifically novel about using deductive reasoning or differential diagnosis to conclude that Kendall's breast cancer was caused or promoted by the defendants' products. Certainly differential diagnosis is a generally accepted methodology; indeed, Upjohn does not dispute the validity of differential diagnosis generally. (Upjohn's brief at 52.) Here, Dr. Naftalis concluded that Kendall suffered from a lack of endogenous estrogen, as evidenced by her post-menopausal symptoms including vaginal atrophy and hot flashes. Kendall's breast cancer was hormone receptor-positive, meaning that it requires hormones in order to grow. Since Kendall naturally lacked such hormones and was otherwise at low risk for breast cancer, Dr. Naftalis deduced that they must have come from an

exogenous source, ***i.e.***, the HRT drugs she was prescribed by Dr. Jones. As discussed above, numerous studies proved that these drugs substantially increase a woman's risk of breast cancer, up to 300% if taken long-term, as Kendall did.

In ***Donaldson v. Central Illinois Public Service Co.***, 199 Ill.2d 63, 262 Ill.Dec. 854, 767 N.E.2d 314 (2002), relied on by this court sitting ***en banc*** in ***Trach***, the plaintiffs were four parents of children who developed neuroblastoma, allegedly as a result of exposure to coal tar during clean-up of a former coal gasification plant site. ***Trach***, 817 A.2d at 1115. Neuroblastoma is a very rare form of cancer that attacks the peripheral nervous system, usually occurring in young children and infants at a rate of nine out of one million. ***Id.*** While coal tar is acknowledged as one of the most powerful carcinogens known to exist, the scientific community was limited in its ability to specifically link exposure to coal tar with development of neuroblastoma due to the small number of neuroblastoma cases. ***Id.*** In addition, ethical considerations prevented exposing humans to coal tar for research purposes; and controlled settings to study the effects of exposure were made difficult by the fact that potential environmental factors were often not detected until the onset of illness. ***Id.***

As a result of these evidentiary problems, the plaintiffs' experts extrapolated from similar studies and theories to conclude that coal tar exposure caused the children's neuroblastomas. ***Id.*** The Illinois Supreme

Court held that the trial court did not err in admitting the testimony of the plaintiffs' experts, holding that "when an expert relies upon scientific literature discussing similar, but not identical, cause and effect relationships, the fact that the expert must extrapolate affects the weight of the testimony rather than its admissibility." ***Id.*** at 1116, citing ***Donaldson***, 199 Ill.2d at 85, Ill.Dec. 854, 767 N.E.2d at 328.

Similarly, here, the defendants were free to point out to the jury that determining causation in any single patient is difficult if not impossible. However, such an argument goes to the weight to be afforded Dr. Naftalis' testimony, not its admissibility. As the trial court states, it is akin to an increased risk of harm theory in a medical malpractice failure to timely diagnose case, where an expert testifies that the diagnostic delay increased the risk of the patient's harm. (Trial court opinion, 3/18/10 at 13.) Similarly, in a mesothelioma case, it is not always possible to rule out other causative factors such as smoking, environmental pollutants, ***etc.***; however, an expert is still permitted to testify that within a reasonable degree of medical certainty, asbestos exposure from the defendants' products caused the plaintiff's harm.

Although it analyzed Dr. Naftalis' testimony under the federal standard as expressed in Federal Rule of Evidence 702 and ***Daubert v. Merrell Dow Pharmaceuticals***, 509 U.S. 579 (1993), we note that the Eighth Circuit Court of Appeals found her testimony to be admissible in ***Scroggin v.***

Wyeth, 586 F.3d 547 (8th Cir. 2009), ***cert. denied***, 130 S.Ct. 3467 (2010). As in this case, Dr. Naftalis testified in ***Scroggin*** that the tumors in Scroggin's breasts, which were hormone-receptor-positive, were caused by her ingestion of HRT drugs. Scroggin's breast cancer was hormone dependent and there was evidence that Scroggin's own body was unable to produce sufficient hormones and therefore could not be the cause. ***Id.*** at 566. Similar to Kendall, the plaintiff in ***Scroggin*** experienced menopausal symptoms such as vaginal atrophy which are caused by estrogen deficiency and were relieved by administration of HRT drugs. ***Id.*** As in ***Scroggin***, in the instant case, many of Upjohn's arguments really go to the weight to be accorded Dr. Naftalis' testimony:

> We find unpersuasive the contention that Dr. Naftalis' testimony should not have been admitted because Scroggin has some breast cancer risk factors and a family history of breast cancer. Dr. Naftalis sufficiently established that hormones were necessary to the development of Scroggin's tumors and conducted her differential diagnosis from this starting point. Although not necessary to the formation of her opinion, Dr. Naftalis addressed the known causes of breast cancer and possible risk factors. Wyeth and Upjohn argue that this review was insufficient, but Dr. Naftalis's 'explanations as to conclusions not ruled out went to weight and not admissibility.'

Id., quoting ***Lauzon v. Senco Prods., Inc.***, 270 F.3d 681, 694 (8th Cir. 2001).

> . . . Dr. Naftalis was able to testify that Scroggin's breast cancer would not have developed without hormone replacement therapy because Scroggin's

> body was not producing sufficient amounts of hormones to allow hormone-receptor-positive tumors to develop. Thus, Dr. Naftalis ruled out the other possible cause of Scroggin's breast cancer, and her expert testimony was properly admitted. Wyeth and Upjohn had the opportunity to expose the testimony's weaknesses through vigorous cross-examination and the presentation of contrary evidence.

Id. at 567 (footnote omitted) (citation omitted).

Of course, here, the evidence as to causation was even stronger than in ***Scroggin*** because Kendall had no family history of breast cancer and had no breast cancer risk factors. In fact, Dr. Naftalis testified that Kendall had a relative risk below the baseline of 1.0. Although the court in ***Scroggin*** was using the federal standard for admissibility of expert testimony, the reasoning is sound and we determine that Dr. Naftalis' testimony was likewise admissible under the ***Frye*** standard. The trial court did not abuse its discretion in permitting Dr. Naftalis to testify as to causation.

Next, Upjohn claims that the trial court erred in its instructions to the jury. Specifically, Upjohn points to the court's instructions on the learned intermediary doctrine and causation.

> Our standard of review regarding jury instructions is limited to determining whether the trial court committed a clear abuse of discretion or error of law which controlled the outcome of the case.
>
> > Error in a charge is sufficient ground for a new trial if the charge as a whole is inadequate or not clear or has a tendency to mislead or confuse rather than clarify a material issue. A charge

> will be found adequate unless the issues are not made clear to the jury or the jury was palpably misled by what the trial judge said or unless there is an omission in the charge which amounts to a fundamental error. In reviewing a trial court's charge to the jury we must look to the charge in its entirety.

Underwood ex rel. Underwood v. Wind, 954 A.2d 1199, 1204 (Pa.Super. 2008), quoting ***Gorman v. Costello***, 929 A.2d 1208, 1212 (Pa.Super. 2007), in turn citing ***Quinby v. Plumsteadville Family Practice, Inc.***, 589 Pa. 183, 197, 907 A.2d 1061, 1069-1070 (2006).

"A trial court has wide discretion in phrasing jury instructions, and absent an abuse of discretion or an inaccurate statement of law, there is no reversible error." ***Harman ex rel. Harman v. Borah***, 562 Pa. 455, 475, 756 A.2d 1116, 1127 (2000) (citation omitted).

> [T]he suggested standard jury instructions are not binding, even where a party requests a trial judge specifically to use them. "These instructions are guides only and the trial judge is free to deviate from them or ignore them entirely. What is important is whether the charge as a whole provides a sufficient and correct legal basis to guide a jury in its deliberations."

City of Philadelphia v. Duda by Duda, 595 A.2d 206, 211-212 (Pa.Cmwlth. 1991), ***appeal denied***, 532 Pa. 658, 615 A.2d 1314 (1992), quoting ***Mackowick v. Westinghouse Electric Corp.***, 541 A.2d 749, 752 (Pa.Super. 1988) (***en banc***), ***affirmed***, 525 Pa. 52, 575 A.2d 100 (1990).

> The learned intermediary doctrine provides that manufacturers of prescription drugs have a duty to

> warn prescribing physicians of the drugs' known dangerous propensities, and the physicians, in turn, using their medical judgment, have a duty to convey the warnings to their patients. ***Kirk v. Michael Reese Hospital & Medical Center***, 117 Ill.2d 507, 517, 111 Ill.Dec. 944, 513 N.E.2d 387 (1987); ***Fakhouri v. Taylor***, 248 Ill.App.3d 328, 330, 187 Ill.Dec. 927, 618 N.E.2d 518 (1993). As a result, the doctrine prevents imposing a duty upon drug manufacturers to warn patients directly. ***Kirk***, 117 Ill.2d at 519, 111 Ill.Dec. 944, 513 N.E.2d 387; ***Fakhouri***, 248 Ill.App.3d at 330, 187 Ill.Dec. 927, 618 N.E.2d 518.

DiGiovanni v. Albertson's, Inc., 405 Ill.App.3d 932, 935, 940 N.E.2d 73, 75 (Ill.App. 1 Dist. 2010), ***appeal denied***, 949 N.E.2d 1097, 351 Ill.Dec. 2 (Ill. 2011).

Initially, in its opening charge to the jury, the trial court instructed that drug manufacturers have a duty to warn the general public as well as prescribing physicians. Later, following objection by the defendants, the trial court clarified its initial instruction as follows:

> Ladies and gentlemen, when I gave opening instructions to you, I want to clarify -- I think I should probably clarify something. When we're talking about the drug companies, the defendants in this case, and their obligation to provide sufficient warnings or sufficient labeling, that duty extends just to the medical prescribers, not to the general public. However -- and I'm not suggesting this in this case, but if the defendants should breach this duty and not do it, and the prescribers then prescribe something that has a risk that the prescriber doesn't know or have reason to know to the general public, then the drug company's obligation, of course, extends to the general public that might take a drug that's -- that poses a risk to that particular individual. And if that

> individual gets a risk [sic], then their duty extends to that person, as well.

Trial court opinion, 3/18/10 at 18, quoting notes of testimony, morning session, 10/22/09 at 101-102. In its closing instructions to the jury, the trial court stated:

> . . . you have to look at whether or not there was a negligent failure to warn in this case. It's what was communicated to Dr. Jones. In other words, a drug company owes a duty to the prescribers, that is, the medical personnel, basically, doctors, owes a duty to convey to them the reasonable risks involved in taking the drug based on what they knew or should have known under the circumstances of the case. But anyway, that's the duty. The duty goes to the doctor. However, if the drug company is negligent in their failure to warn, and their labeling is insufficient, and as a result of that, the doctor then unknown -- not knowing about the risks, prescribes the risk [sic] to the general public, in this case, Mrs. Kendall, and she suffers from the risk they failed to advise, then the drug companies [owe] a duty to her.

Id. at 19, quoting notes of testimony, morning session, 11/20/09 at 12-13.

Examining the court's instructions in their entirety, we find that they adequately conveyed the concept of the learned intermediary doctrine to the jury. The trial court explained to the jury that the defendants' duty to warn was to Dr. Jones. The defendants admit that they owe a legal duty to the ultimate consumers of its products including Kendall. (***Id.*** at 20.) Otherwise, a consumer could never maintain a cause of action against a pharmaceutical company for injuries sustained as a result of taking its products. The trial court was simply attempting to convey to the jury that

although a drug manufacturer's duty runs to the prescribing physician, if that physician prescribes a particular drug to his or her patient as a result of the manufacturer's failure to adequately warn of the risks involved in taking the drug, then the patient can maintain a lawsuit against the manufacturer for alleged injuries. (***Id.*** at 19-20.) As the trial court remarks, if no duty extended to Kendall, then she would have no case. (***Id.*** at 19.)

Furthermore, we agree with Kendall that any perceived error in the trial court's instructions on the learned intermediary doctrine did not control the outcome of the case where Dr. Jones testified that had he been made aware of the risks, he never would have prescribed E+P to Kendall for such an extended period of time. (Kendall's reply brief at 43-45.) In fact, Dr. Jones altered his prescribing habits vis-à-vis E+P after the publication of the WHI study. (***Id.***) There was plenty of evidence in the record to support the allegation that Wyeth and Upjohn breached their duty to warn prescribing physicians, including Dr. Jones, of the dangers of E+P, particularly with prolonged use. Therefore, it is difficult to conceive how the defendants were prejudiced by the allegedly erroneous instruction to the effect that their duty to warn also extended to the general public including Kendall. They would only be shielded from liability based on the learned intermediary doctrine if they had issued adequate warnings to doctors of the risks of taking their products.

Upjohn also complains about the trial court's charge on causation, which was as follows:

> Was the defendants' negligence a substantial factor in bringing about plaintiff's breast cancer? Now, a lot has been said or written about causation. I've gone to a lot of judicial conferences. And a load of judges are in the room, and each one has a different way of terming it. Sometimes instead of substantial factor, proximate cause is used, or factual cause, or but for. I'm using the term "substantial factor." If you want to think of it as factual cause, proximate cause, but for, you can. But whatever you term it, it's a legal cause. In order for Mrs. Kendall to recover in this case, the defendant's negligent conduct must have been a substantial factor, factual cause, proximate cause, but for in bringing about her breast cancer. This is what the law recognizes as a legal cause. A substantial factor, factual cause, proximate cause, but for is an actual, real factor, although the result may be unusual or unexpected. But it is not an imaginary or fanciful factor or only an insignificant connection with Mrs. Kendall's breast cancer. But keep in mind you can have more than one cause, which is a legal cause for bringing about a given end. In other words, you can have more than one cause which is a substantial factor, factual cause, proximate cause, or but for in bringing about a given end.

Trial court opinion, 3/18/10 at 20-21, quoting notes of testimony, morning session, 11/20/09 at 16-18.

According to Upjohn, Illinois uses the "but for" test, ***i.e.***, that Kendall's invasive breast cancer would not have occurred but for the defendants' negligent conduct. Upjohn complains that the trial court's use of various terms interchangeably, including the substantial contributing factor test, was erroneous.

First, we disagree that Illinois uses only the "but for" test for causation.

> Proximate cause consists of two distinct elements: actual cause and legal cause. Actual cause, or cause in fact, is determined by simply analyzing the facts. A defendant's conduct may be deemed the actual cause of a plaintiff's injury if, "but for" the defendant's conduct, the injury would not have occurred. Actual cause can also be established where the defendant's conduct is a material element and substantial factor in bringing about the plaintiff's injuries.

McCoy v. McCoy, 227 Ill.App.3d 244, 248, 591 N.E.2d 124, 127 (Ill.App. 4 Dist. 1992), citing ***Turner v. Roesner***, 193 Ill.App.3d 482, 490, 140 Ill.Dec. 415, 420, 549 N.E.2d 1287, 1292 (1990). ***See also Lee v. Chicago Transit Authority***, 152 Ill.2d 432, 455, 605 N.E.2d 493, 502 (Ill. 1992) ("Cause in fact can only be established when there is a reasonable certainty that a defendant's acts caused the injury or damage. Under the substantial factor test, the defendant's conduct is a factual cause of the plaintiff's injury if the conduct was a material element and a substantial factor in bringing about the injury."), citing ***McCoy***, ***supra***; W. Keeton, Prosser & Keeton on Torts § 41, at 267 (5th ed. 1984).

Therefore, the trial court's instruction that the jury could find cause in fact if the defendants' negligent conduct was a substantial contributing factor in bringing about the plaintiff's harm was an accurate statement of Illinois law. Regarding Upjohn's argument that the instruction was confusing, as Kendall points out, Upjohn did not raise this specific objection at trial;

therefore, it is waived. (Kendall's reply brief at 47; ***Stumpf v. Nye***, 950 A.2d 1032, 1041 (Pa.Super. 2008), ***appeal denied***, 599 Pa. 711, 962 A.2d 1198 (2008) ("our courts have made clear that an appellant must make a timely and specific objection to a jury instruction to preserve for review a claim that the jury charge was legally or factually flawed.") (citations omitted) (quotation marks omitted).

Upjohn also claims that the trial court erred in failing to instruct the jury on "warning causation," ***i.e.***, that Dr. Jones would not have prescribed the HRT drugs if adequate warnings had been provided, or that adequate warnings would have caused Dr. Jones to discontinue HRT before Kendall's injuries occurred. (Upjohn's brief at 63, 66.) However, it appears that under Illinois law, a heeding presumption exists that doctors will perform non-negligently when presented with an adequate warning. ***Giles v. Wyeth, Inc.***, 500 F.Supp.2d 1063, 1066 (S.D.Ill. 2007). The learned intermediary doctrine will not apply where the doctor was insufficiently warned. ***Id.*** "What the doctor might or might not have done had he been adequately warned is not an element plaintiff must prove as a part of her case." ***Id.***, quoting ***Mahr v. G.D. Searle & Co.***, 72 Ill.App.3d 540, 28 Ill.Dec. 624, 390 N.E.2d 1214, 1233 (1979). Furthermore, as Kendall states, Dr. Jones testified unequivocally that he would not have prescribed HRT drugs in the manner and duration that he did had he been warned of the increased risk of breast cancer. (Kendall's reply brief at 53.) Warning

causation was never an issue. Therefore, Upjohn cannot demonstrate how it was prejudiced by the lack of such an instruction.

Finally, we turn to Kendall's issue on appeal, that the trial court erred in remitting the jury's punitive damages award from $28 million to just $1 million, compared with compensatory damages in excess of $6 million. We determine that the jury's punitive damages award did not offend due process and the trial court's remittitur was an abuse of discretion and unsupported by the record. Therefore, we will reinstate the original punitive damages award.

"[T]his court reviews a ruling on a motion for a remittitur for an abuse of discretion. The underlying question is whether the trial court was correct in ordering the remittitur." ***Leyshon v. Diehl Controls North America, Inc.***, 946 N.E.2d 864, 876 (Ill.App. 1 Dist. 2010), ***appeal denied***, 351 Ill.Dec. 3, 949 N.E.2d 1098 (2011), citing ***Slovinski v. Elliot***, 237 Ill.2d 51, 61, 340 Ill.Dec. 210, 927 N.E.2d 1221 (2010) (additional citation omitted).

> The amount of punitive damages will not be reversed unless it must have been the result of passion, partiality or corruption. As the jury's determination of the amount of punitive damages is predominately a factual issue, the court will not reverse the award unless it is against the manifest weight of the evidence.

Id., citing ***Blount v. Stroud***, 395 Ill.App.3d 8, 22, 333 Ill.Dec. 854, 915 N.E.2d 925 (2009).

First, we examine the punitive damages award under the Illinois common law standard.

> The relevant circumstances to consider in reviewing a jury award of punitive damages include, but are not limited to, the nature and enormity of the wrong, the financial status of the defendant and the defendant's potential liability. ***Blount***, 395 Ill.App.3d at 22, 333 Ill.Dec. 854, 915 N.E.2d 925. Each case is assessed in light of the specific facts and circumstances involved, and the underlying purpose of a punitive damage award must be satisfied. ***Blount***, 395 Ill.App.3d at 22, 333 Ill.Dec. 854, 915 N.E.2d 925. As the supreme court recently reiterated: "Punitive damages 'are not awarded as compensation, but serve instead to punish the offender and to deter that party and others from committing similar acts of wrongdoing in the future.'" ***Slovinski***, 237 Ill.2d at 57–58, 340 Ill.Dec. 210, 927 N.E.2d 1221, ***quoting Loitz v. Remington Arms Co.***, 138 Ill.2d 404, 414, 150 Ill.Dec. 510, 563 N.E.2d 397 (1990). The court cautioned that, as punitive damages are not favored in the law and are penal in nature, courts must make sure they are not awarded improperly or unwisely. ***Slovinski***, 237 Ill.2d at 58, 340 Ill.Dec. 210, 927 N.E.2d 1221.

Leyshon, 946 N.E.2d at 877. Under Illinois common law, there is no requirement that the amount of punitive damages imposed on a defendant bear any particular proportion to the size of the plaintiff's compensatory recovery. ***Id.***, citing ***Blount***, 395 Ill.App.3d at 23, 333 Ill.Dec. 854, 915 N.E.2d 925.

Instantly, the jury's punitive award of $28 million, while large, correlated with the enormity of the defendants' wrong, their clear liability, and the devastating impact on the plaintiff. As Kendall sets forth in her brief

on appeal, the jury's award corresponds to 28 "red flags," 16 for Wyeth and 12 for Upjohn, which should have put the defendants on notice that their products were potentially unsafe. Wyeth and Upjohn chose to ignore each of these "red flags" which Kendall pointed out to the jury.

Kendall presented evidence that as early as 1976, Wyeth's own internal documents revealed that it was aware of a possible link between use of exogenous estrogen and breast cancer. In 1989, at Wyeth's annual Estrogen Deprivation Conference, Dr. Malcolm Pike, a world renowned breast cancer researcher, stated his position that E+P could double a woman's risk of breast cancer. Wyeth responded by contemplating barring Dr. Pike from any future events sponsored by Wyeth-Ayerst. Kendall argues in her brief that the evidence she presented demonstrated that Wyeth elected not to perform any breast cancer studies, fearing that such studies might prove "costly" and the results potentially "embarrassing." (Kendall's brief at 13.) Wyeth's concerns regarding costs lose credibility in the face of its excitement at the prospect of Premarin becoming a "billion dollar drug." (***Id.*** at 14.)

Similarly, in 1990, the FDA's advisory committee on fertility and maternal health was asked to consider whether combination E+P raised the risk of breast cancer in menopausal women; it ultimately concluded that there was insufficient data to definitively answer the question. Wyeth, of course, did not take it upon itself to conduct any studies but instead

celebrated the fact that the committee meeting had turned out to be a "non-event."

As described above, Wyeth also engaged in the legal, though ethically troubling, practice of "ghostwriting," whereby Wyeth paid physicians to lend their names to medical and scientific papers touting the benefits of E+P while downplaying any risks. Wyeth stated its goal was to "drive science" and eventually have the "vast majority of women in the world" taking Prempro "for the rest of their lives." (***Id.*** at 16.) In 1998, Jamie Durocher, Wyeth's group product director in women's healthcare, stated that Wyeth had to "manage the breast cancer issue" while encouraging persistence in consumer use. Wyeth specifically instructed its sales force to "overcome" physicians' concerns about breast cancer and promote HRT for long-term use. (***Id.*** at 16-17.) Wyeth consistently promoted combination HRT for a variety of unproven, off-label benefits including prevention of colon cancer, osteoporosis and cardiovascular disease.

In January 2000, Wyeth became aware of a scientific article raising concerns that Premarin was carcinogenic. A company manager responded in an internal e-mail, copied to Wyeth's future CEO, Bernard Poussot, recommending that Wyeth "let sleeping dogs lie." Even following publication of the WHI study in July 2002, Wyeth told its sales representatives not to discuss the WHI with physicians. Mr. Poussot considered whether Wyeth

could try to connect the increased risk of breast cancer in the study to smoking.

Similarly, as early as 1961, Upjohn knew that Provera was causing mammary cancer in lab rats. By 1963, Upjohn was on notice that Provera was possibly exacerbating breast cancer in humans, but affirmatively chose not to study the risk. Indeed, from 1966 until the early 1990s, the FDA repeatedly denied Upjohn's requests for approval of Provera to be used in combination with exogenous estrogens, citing a lack of data. Despite being told over and over by the FDA that there was insufficient data to approve Provera to be used in combination with exogenous estrogen, Upjohn did not perform any of its own studies and continued to actively promote Provera as "the other half of estrogen replacement therapy." Upjohn's own expert, Dr. Jolson, conceded that Upjohn never conducted any studies despite the ability to do so.

In 1989, Upjohn dismissed a medical article reporting a "very high" increased risk of breast cancer, citing the small sample size and concluding that "the data is not conclusive enough to warrant any immediate change in the way we approach [HRT]." (Kendall's brief at 27.) In 1990, as discussed above, the Degge Group, an independent research group, specifically recommended further epidemiological studies to address any possible association of breast cancer with progestin use, particularly in high-risk groups. The Degge Group informed Upjohn that the relationship of

exogenous progestin exposure to breast cancer was unknown. Again, Upjohn responded by doing nothing.

In 1991, internal documents show that Upjohn was aware of increasing evidence that estrogen therapy may increase the occurrence of breast cancer. (***Id.*** at 28.) Upjohn acknowledged that "epidemiological data concerning breast cancer risk and progestin replacement therapy is inadequate at this time . . . ." (***Id.***) Again in 1992, Upjohn's executives recognized the dearth of studies relating to Provera, stating that "FDA has deemed there to be insufficient long-term data to evaluate the effects of [HRT] on breast cancer . . . ." (***Id.*** at 29.) Interestingly, Upjohn conducted a long-term study of Provera from 1980 to 1990, looking at whether the drug protected against osteoporosis; however, Upjohn never proposed any studies designed to investigate a breast cancer risk.

Upjohn's labeling on Provera never mentioned any increased risk of breast cancer in humans. The "warnings" section of the label mentioned only "mammary nodules" in "male beagle dogs." Indeed, even after 2002, when the WHI study was released, Upjohn did not change its warnings label. Finally, in 2007, Upjohn changed its Provera labeling to include a "black box" warning of an increased risk of breast cancer.

The trial court agreed that punitive damages were warranted in this case, but concluded that $28 million was "excessive." (Trial court opinion, 3/18/10 at 22-23.) The trial court states that the defendants' warning

labels, while negligently insufficient, "indirectly advised" of a possible breast cancer risk. (***Id.*** at 23-24.) In remitting the punitive damages award to $1 million, the trial court also relied on the fact that the defendants complied with FDA regulations and that Dr. Jones, the plaintiff's prescribing physician, did not rely on the defendants' advertising for off-label use. (***Id.*** at 24.)

We determine that under Illinois common law, it was an abuse of discretion to grant remittitur. As stated above, the amount of punitive damages to be awarded depends closely upon the fact-finding by the jury. The evidence set forth above, including the defendants' willful refusal to conduct adequate studies, supports the punitive damages award. There was nothing to indicate the amount of punitive damages was the result of passion, partiality or corruption. In fact, the jury's award of $16 million against Wyeth and $12 million against Upjohn strongly suggests, as posited by Kendall, that they were following her argument regarding 16 and 12 "red flags," respectively, that went unheeded by the defendants in this case. The evidence, taken as a whole, strongly suggests that the defendants elevated profits above the public health and the health of women consuming their products, choosing not to conduct adequate studies and willfully ignoring or downplaying any evidence that suggested a link between HRT and breast cancer. To the extent they could claim, prior to the WHI study, that they did not know of a definitive link between E+P and breast cancer, it was a willful ignorance of their own choosing. The $28 million punitive

damages award was not against the manifest weight of the evidence. There was no basis for granting remittitur here.[3]

Next, we turn once again to federal due process, particularly whether the 4.44 to 1 ratio of punitive damages to compensatory damages survives constitutional scrutiny. "Whether the amount of an award of punitive damages violates due process is reviewed ***de novo***." ***Leyshon***, 946 N.E.2d at 880, citing ***International Union of Operating Engineers, Local 150 v. Lowe Excavating Co.***, 225 Ill.2d 456, 312 Ill.Dec. 238, 870 N.E.2d 303 (2006).

> Under the relevant test to determine whether an award of punitive damages is excessive three factors are considered: "'(1) the degree of reprehensibility of the defendant's misconduct; (2) the disparity between the actual or potential harm suffered by the plaintiff and the punitive damages award; and (3) the difference between the punitive damages awarded by the jury and the civil penalties authorized or imposed in comparable cases.'" ***Lowe Excavating Co.***, 225 Ill.2d at 470, 312 Ill.Dec. 238, 870 N.E.2d 303, ***quoting State Farm Mutual Automobile Insurance Co. v. Campbell***, 538 U.S. 408, 418, 123 S.Ct. 1513, 1520, 155 L.Ed.2d 585, 601 (2003) (***Campbell I***).

[3] We also note that it is appropriate to consider the financial status of the defendants. ***Leyshon***, 946 N.E.2d at 877. Although it appears that the plaintiff did not offer evidence of the defendants' financial status, it goes without saying that both Wyeth and Upjohn are multi-billion dollar pharmaceutical giants. At any rate, "the prevailing authority is that a defendant is not entitled to overturn an award of punitive damages on the sole basis that the plaintiff did not present evidence of the defendant's financial status." ***Id.*** at 879, citing ***Deal v. Byford***, 127 Ill.2d 192, 130 Ill.Dec. 200, 537 N.E.2d 267 (1989).

Id. (footnote omitted).

> [The degree of reprehensibility] factor is considered to be the most important in determining the reasonableness of a punitive damages award. ***BMW of North America, Inc. v. Gore***, 517 U.S. 559, 575, 116 S.Ct. 1589, 1599, 134 L.Ed.2d 809, 826 (1996). In determining reprehensibility, the court considers: (1) whether the harm caused was physical as opposed to economic; (2) whether the tortious conduct evinced an indifference to or a reckless disregard for the health and safety of others; (3) whether the target of the conduct was financially vulnerable; (4) whether the conduct involved repeated actions or was an isolated incident; and (5) whether the harm was the result of intentional malice, trickery or deceit, or mere accident. ***Lowe Excavating Co.***, 225 Ill.2d at 470, 312 Ill.Dec. 238, 870 N.E.2d 303, ***citing Campbell I***, 538 U.S. at 419, 123 S.Ct. at 1521, 155 L.Ed.2d at 602.

Id. at 880-881.

> The presence of one of these factors may not be sufficient to support a punitive damages award; the absence of all of the above factors renders any award suspect. ***Campbell I***, 538 U.S. at 419, 123 S.Ct. at 1521, 155 L.Ed.2d at 602. Since it is presumed that the plaintiff was fully compensated by the compensatory damages, the defendant's conduct must be sufficiently reprehensible to warrant the imposition of further sanctions to achieve punishment or deterrence. ***Campbell I***, 538 U.S. at 419, 123 S.Ct. at 1521, 155 L.Ed.2d at 602.

Id. at 881.

Here, the harm caused Kendall was obviously physical rather than merely economic; she underwent a full mastectomy of her left breast. In addition, the cancer spread to her lymph nodes, necessitating removal of all

31 of her lymph nodes and extensive chemotherapy and radiation treatment. In December 2003, Kendall underwent a second full mastectomy of her right breast. Kendall also had painful reconstructive surgery resulting in extensive scarring. As discussed further below, this distinguishes the instant case from those in which the plaintiff sustained purely economic damages such as ***BMW v. Gore***.

We have already determined, as did the trial court, that the defendants' conduct was willful and wanton and evinced a reckless disregard for the health and safety of others, as described above. Regarding financial vulnerability, it does not appear that any evidence was introduced vis-à-vis Kendall's financial status, although certainly she would be in a disadvantaged position compared to the defendants. The fourth factor in determining degree of reprehensibility is whether the conduct involved repeated actions or was an isolated incident. Clearly, defendants' continuing actions in ignoring or understating the risks associated with taking their drugs was a pattern of misconduct over many years, if not decades. Therefore, it cannot be characterized as an isolated incident. In the same vein, the harm suffered by the plaintiff was not the result of mere accident or happenstance. Rather, it was the result of something at least bordering on intentional malice or deceit; as the plaintiff states, there was evidence that for many years prior to plaintiff's injuries, the defendants were on notice of the need to investigate the breast cancer risk associated with

combination HRT drugs but neither did so. (Kendall's brief at 40.) The defendants aggressively marketed and promoted their products for long-term use and for unapproved and unproven benefits, and downplayed any breast cancer risk in their product labeling. (***Id.*** at 41.) The defendants' misconduct was sufficiently reprehensible to support a substantial punitive damages award.

We now examine the ratio between punitive and compensatory damages, which in this case is 4.44:1 ($28 million to $6.3 million). We determine that this low single-digit ratio, under the particular circumstances of this case, does not offend federal due process guarantees.

> Under the second ***Gore*** factor, the court compares the ratio between the actual harm to the plaintiff and the punitive damages award. ***Blount***, 395 Ill.App.3d at 26, 333 Ill.Dec. 854, 915 N.E.2d 925. This court has recognized that "'an award of more than four times the amount of compensatory damages might be close to the line of constitutional impropriety,' and that 'few awards exceeding a single-digit ratio between punitive and compensatory damages, to a significant degree, will satisfy due process.'" ***Blount***, 395 Ill.App.3d at 26, 333 Ill.Dec. 854, 915 N.E.2d 925, ***quoting Campbell I***, 538 U.S. at 425, 123 S.Ct. at 1524, 155 L.Ed.2d at 606. However, as the court in ***Lowe Excavating Co.*** noted:
>
> > "The Supreme Court has 'consistently rejected the notion that the constitutional line is marked by a simple mathematical formula' [citation] and has declined 'to impose a bright-line ratio which a punitive damages award cannot exceed.'" ***Lowe Excavating Co.***, 225 Ill.2d at 484, 312 Ill.Dec. 238, 870 N.E.2d 303, ***quoting Gore***, 517 U.S. at

> 582, 116 S.Ct. at 1602, 134 L.Ed.2d at 830 and ***Campbell I***, 538 U.S. at 425, 123 S.Ct. at 1524, 155 L.Ed.2d at 605.

Leyshon, 946 N.E.2d at 883.

In ***Leyshon***, a wrongful termination/defamation case, the Illinois appellate court upheld a $6 million punitive damages award, representing a 3:1 ratio to compensatory damages of $2 million. In ***Gore***, the United States Supreme Court struck down punitive damages of $2 million where compensatory damages were only $4,000, representing a "breathtaking" 500:1 ratio. ***Gore***, 517 U.S. at 583. In addition, the malfeasance in ***Gore*** was not particularly egregious and resulted in only a small amount of actual damages. Dr. Gore brought suit against BMW after discovering that his new BMW automobile had been repainted prior to delivery, a fact that was not disclosed by BMW.

The ***Gore*** Court also stated that additional potential harm could support a higher ratio. ***Id.*** at 582. In this case, the defendants' own expert conceded that Kendall's chance of recurrence is 75%. (Kendall's brief at 38.) Therefore, Kendall is threatened with additional potential harm due to the defendants' conduct, unlike the plaintiff in ***Gore***.

The defendants rely on language in ***Campbell I*** to the effect that where compensatory damages are substantial, as in the case ***sub judice***, then a lesser ratio is appropriate: "When compensatory damages are substantial, then a lesser ratio, perhaps only equal to compensatory

damages, can reach the outermost limit of the due process guarantee." ***Campbell I***, 538 U.S. at 425. Of course, in this case a 1:1 ratio would still result in punitive damages of over $6 million, not the remitted amount of $1 million. ***Campbell I*** also followed up the previous sentence by stating, "The precise award in any case, of course, must be based upon the facts and circumstances of the defendant's conduct and the harm to the plaintiff." ***Id.***

Campbell I is readily distinguishable on its facts; in that case, State Farm refused to settle for the policy limits despite the fact that its insured was clearly liable, resulting in an excess verdict. On the ensuing bad faith claim, Campbell received compensatory damages of $1 million and punitive damages of $145 million, a 145:1 ratio. In striking down the punitive damages award, the United States Supreme Court emphasized that while the Campbells allegedly suffered emotional distress and humiliation, they did not sustain any physical injuries:

> The harm arose from a transaction in the economic realm, not from some physical assault or trauma; there were no physical injuries; and State Farm paid the excess verdict before the complaint was filed, so the Campbells suffered only minor economic injuries for the 18-month period in which State Farm refused to resolve the claim against them.

Id. at 426. The court in ***Campbell I*** also reiterated that single-digit multipliers, particularly in the 4:1 range, can usually survive constitutional scrutiny:

> In [***Pacific Mut. Life Ins. Co. v. Haslip***, 499 U.S. 1 (1991)], in upholding a punitive damages award, we

> concluded that an award of more than four times the amount of compensatory damages might be close to the line of constitutional impropriety. We cited that 4-to-1 ratio again in ***Gore***. The Court further referenced a long legislative history, dating back over 700 years and going forward to today, providing for sanctions of double, treble, or quadruple damages to deter and punish. While these ratios are not binding, they are instructive. They demonstrate what should be obvious: Single-digit multipliers are more likely to comport with due process, while still achieving the State's goals of deterrence and retribution, than awards with ratios in range of 500 to 1, or, in this case, of 145 to 1.

Id. at 425 (citations omitted).

It is interesting to note that on remand to the Utah Supreme Court, the court determined that a 9:1 ratio yielding a little more than $9 million in punitive damages was appropriate and conformed to the demands of due process. ***Campbell v. State Farm*** ("***Campbell II***"), 98 P.3d 409 (Utah 2004), ***cert. denied***, 543 U.S. 874 (2004). ***See also TXO Production Corp. v. Alliance Resources Corp.***, 509 U.S. 443 (1993) (upholding a $10 million punitive damages award representing a 10:1 ratio). In the instant case, we determine that the 4.44:1 ratio between punitive and compensatory damages satisfies due process. While the compensatory damage award was substantial, the defendants' conduct was significantly reprehensible and resulted in devastating physical and emotional injuries to the plaintiff, as well as potential future harm.

Gore's final guidepost is the difference between the punitive damages awarded by the jury and the civil penalties authorized or imposed in comparable cases. Plaintiff points to Illinois' deceptive trade practices statute, which prohibits conduct creating a likelihood of confusion or misunderstanding and provides for a penalty of $50,000. 815 ILCS 510/2(a)(12); 815 ILCS 505/7(b). Illinois' Act 505, the Consumer Fraud and Deceptive Business Practices Act, also provides for a civil penalty of up to $50,000 per violation if the court finds intent to defraud. 815 ILCS 505/7(b). Defendants claim that the statute does not apply because their warning labels were specifically approved by the FDA. (Wyeth's brief at 67 n.44.) ***See Bober v. Glaxo Wellcome PLC***, 246 F.3d 934, 941 (7th Cir. 2001) ("the state CFA will not impose higher disclosure requirements on parties than those that are sufficient to satisfy federal regulations. If the parties are doing something specifically authorized by federal law, section [815 ILCS 505/] 10b(1) will protect them from liability under the CFA."). "On the other hand, the CFA exemption is not available for statements that manage to be in technical compliance with federal regulations, but which are so misleading or deceptive in context that federal law itself might not regard them as adequate." ***Id.***

Without making a specific determination whether Illinois' Consumer Fraud and Deceptive Business Practices Act applies to defendants' conduct, it does not change our conviction that a $28 million punitive damages award is

appropriate. In ***Campbell II***, the Utah Supreme Court astutely recognized that "the quest to reliably position any misconduct within the ranks of criminal or civil wrongdoing based on penalties affixed by a legislature can be quixotic." ***Campbell II***, 98 P.3d at 419. The fact of the matter is that in any failure to warn case involving wanton and willful misconduct resulting in significant physical injuries, any applicable civil penalty is likely to be dwarfed by the punitive damages award. The United States Supreme Court has not endorsed any particular ratio between civil or criminal penalties and punitive damages. In ***Campbell II***, the court decided that the relevant $10,000 fine for fraud supported a punitive damages award of over $9 million. ***Id.***

Similarly, in ***Axen v. American Home Products Corp.***, 158 Or.App. 292, 974 P.2d 224 (1999), a pharmaceutical failure to warn case in which the plaintiff permanently lost his eyesight, the court upheld a $20 million punitive damage award where the maximum penalty was approximately $60,000 in fines. ***Id.*** at 322-323, 974 P.2d at 244. The ***Axen*** court also considered the fact that federal regulations allow the FDA to seize misbranded drugs and to enjoin manufacturers from distributing or selling them, which would presumably cause the defendant to suffer large economic losses. ***Id.*** The ***Axen*** court stated that,

> While it is true that the State of Oregon does not have the power to impose those sanctions, their existence nevertheless indicates the seriousness with which conduct such as that in which AHP engaged is

> viewed by the federal government and the severity with which that conduct can be punished.

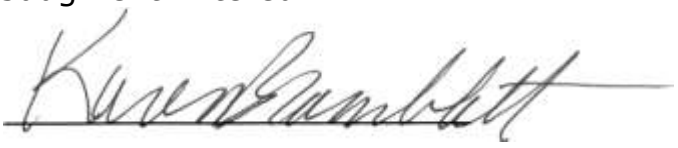
Id. at 323, 974 P.2d at 244. The court ultimately concluded that the third prong of the ***Gore*** test weighed neither for nor against the jury's award, and also implied that it was the least important of the various factors that bear on the constitutionality of a punitive damage award, degree of reprehensibility being the most important as discussed above. ***Id.***[4]

In conclusion, we find that the jury's punitive damages award of $28 million was not unconstitutionally excessive and that the trial court abused its discretion in granting the defendants' motion for remittitur. Therefore, we reverse that order and reinstate the original punitive damages award. The judgment is affirmed in all other respects.

Judgment affirmed in part and reversed in part. Kendall's application for leave to submit supplemental authority is denied. Wyeth's and Upjohn's joint application to stay proceedings pending the Pennsylvania Supreme Court's decision in ***Daniel***, ***supra***, is denied. Jurisdiction is relinquished.

[4] We also note that in ***Axen***, the Oregon Court of Appeals upheld a punitive damage award approximately eight times compensatory damages. In fact, the ***Axen*** court concluded that even if it erred in including plaintiff-wife's damages for loss of consortium, the ratio would be approximately 10.5:1 which would still not violate the Due Process Clause under the facts of that case. ***Id.*** at 322 n.26, 974 P.2d at 243 n.26.

Judgment Entered.



Date: 1/3/2012