IN THE

Supreme Court of Pennsylvania

No. _____, E.A.L. 2012
(Superior Court No. 694 EDA 2010)

CONNIE J. BARTON,

Plaintiffs-Respondents,

v.

WYETH PHARMACEUTICALS, INC., et al.

Defendant-Petitioner.

PETITION FOR ALLOWANCE OF APPEAL

Petition for Allowance of Appeal from the Order of the Superior Court, Entered January 3, 2012, at No. 694 EDA 2010, 695 EDA 2010, Reargument Denied, March 13, 2012, Affirming the Order of the Court of Common Pleas of Philadelphia County, Entered January 29, 2010, at April Term, 2004, No. 6301.

OF COUNSEL:

SHEILA L. BIRNBAUM
SKADDEN, ARPS, SLATE,
MEAGHER & FLOM LLP
Four Times Square
New York, New York 10036-6522
(212) 735-3000

STEVEN GLICKSTEIN
KAYE SCHOLER LLP
425 Park Avenue
New York, New York 10022-3598
(212) 836-8000

ROBERT C. HEIM (ID. NO. 15758)
JUDY L. LEONE (ID. NO. 41165)
DECHERT LLP
Cira Centre
2929 Arch Street
Philadelphia, Pennsylvania 19104-2808
(215) 994-2570

Attorneys for Defendant-Petitioner
Wyeth Defendants

IN THE

Supreme Court of Pennsylvania

No. _____, E.A.L. 2012
(Superior Court No. 695 EDA 2010)

CONNIE J. BARTON,

Plaintiffs-Respondents,

v.

WYETH PHARMACEUTICALS, INC., et al.

Defendant-Petitioner.

PETITION FOR ALLOWANCE OF APPEAL

Petition for Allowance of Appeal from the Order of the Superior Court, Entered January 3, 2012, at No. 694 EDA 2010, 695 EDA 2010, Reargument Denied, March 13, 2012, Affirming the Order of the Court of Common Pleas of Philadelphia County, Entered January 29, 2010, at April Term, 2004, No. 6301.

OF COUNSEL:

SHEILA L. BIRNBAUM
SKADDEN, ARPS, SLATE,
MEAGHER & FLOM LLP
Four Times Square
New York, New York 10036-6522
(212) 735-3000

STEVEN GLICKSTEIN
KAYE SCHOLER LLP
425 Park Avenue
New York, New York 10022-3598
(212) 836-8000

ROBERT C. HEIM (ID. NO. 15758)
JUDY L. LEONE (ID. NO. 41165)
DECHERT LLP
Cira Centre
2929 Arch Street
Philadelphia, Pennsylvania 19104-2808
(215) 994-2570

Attorneys for Defendant-Petitioner
Wyeth Defendants

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page(s)**

Statutes, Regulations, and Rules

Other Authorities

REFERENCE TO THE OPINIONS DELIVERED IN THE COURTS BELOW

On January 29, 2010, the Court of Common Pleas of Philadelphia County (Ackerman, J.) filed its opinion (attached as App'x A) in support of its order of the same date denying Wyeth's motions for JNOV and for a new trial, but granting Wyeth's motion for remittitur and reducing the $75 million punitive damages award to $5.62 million.

On January 3, 2012, in an opinion by Judge Kate Ford Elliott,[1] the Superior Court affirmed the trial court's denial of Wyeth's motions for JNOV and new trial, but reversed in part the trial court's grant of remittitur and increased the remitted punitive damages award from $5.62 million to $7.49 million (attached as App'x B, hereinafter referred to as "Op."). The Superior Court also denied Wyeth's application to stay resolution of the appeal until this Court issued its decision in *Daniel v. Wyeth Pharmaceuticals, Inc.*, No. 63 EAP 2011. *Id.* at 45-46. On March 13, 2012, the Superior Court denied Wyeth's application for reargument (attached as App'x C).

TEXT OF THE ORDER IN QUESTION

No separate judgment order accompanied the Superior Court's January 3, 2012 opinion. That opinion stated, in pertinent part:

> [W]e will enter a remittitur of the punitive damages to $7,492,689.94, representing a 2:1 ratio between punitive and compensatory damages. . . . [T]he judgment of the trial court is affirmed in part; vacated in part; and remittitur is entered as noted above. . . . Wyeth's application to stay proceedings pending the decision of Pennsylvania Supreme Court in *Daniel, supra*, is denied. (App'x B at 45-46).

QUESTIONS PRESENTED FOR REVIEW

1. Whether the Superior Court erred in affirming the trial court's denial of JNOV for Wyeth on Plaintiff's punitive damages claim under governing Illinois law, where: (a) the FDA

---

[1] Although Judge Stephen J. McEwen Jr. took part in oral argument, he played no part in the disposition of this case. As a result, only Judge Ford Elliott and Senior Judge William H. Platt participated in the disposition of this case. Thus, the case was decided by two judges, only one of whom was a commissioned judge.

extensively reviewed and approved the prescription drugs at issue, the sufficiency of the testing for those drugs, and the drugs' label warnings of the risk of breast cancer; (b) there was no evidence that Wyeth concealed information from or misled the FDA or knew that the risk of breast cancer was greater than disclosed in its warnings; and (c) the drugs were extensively tested and studied by Wyeth and independent researchers?

2. Whether the Superior Court erred in holding that Wyeth was not entitled to JNOV as a matter of due process on Plaintiff's punitive damages claim, where: (a) there was a reasonable disagreement in the scientific and medical communities about the risk of breast cancer from the drugs at issue; and (b) Wyeth, which had complied fully with FDA procedures and regulations, reasonably believed that its conduct was lawful and proper?

3. Whether the Superior Court erred as a matter of Illinois law in reversing in part the trial court's remittitur of the punitive damages award and increasing the remitted punitive damages award from $5.62 million to $7.49 million?

4. Whether the Superior Court's increase of the remitted punitive damages award to $7.49 million contravened due process?

5. Whether the Superior Court erred in upholding the trial court's admission of extensive, prejudicial evidence of marketing and other conduct by Wyeth that had no connection to the decision by Plaintiff's physician to prescribe the drugs to her, based on a theory of presumed reliance that has been rejected by the Illinois Supreme Court and Pennsylvania courts?

6. Whether the Superior Court erred in affirming the admission of the testimony of Plaintiff's regulatory expert, Dr. Cheryl Blume, whose testimony as to the "reasonableness" of Wyeth's conduct lacked any objective standard and was improperly speculative?

CONCISE STATEMENT OF THE CASE

Prempro is a hormone therapy ("HT") prescription medication manufactured by Wyeth

and indicated for use in relieving the often debilitating symptoms associated with menopause and to prevent osteoporosis. R. 5150-51a, 5247-48a. Prempro was and is approved by the FDA as safe and effective for these uses (*see, e.g.*, R. 2638a, 5311a, 5365a, 5371a, 5378a, 5437-38a, 5566-67a) and is still on the market and continues to be prescribed today to hundreds of thousands of women. Prempro is a "combination" HT medication that provides both estrogen and progestin in a single pill. R. 5150-51a. At all relevant times, Prempro's labeling warned that some studies indicated that there was an increased risk of breast cancer associated with the medication although other studies did not so find. R. 5151a, 5153a, 5155a, 5427a. The Prempro warning as to the risk of breast cancer was accurate based on the extant scientific evidence, and its content and wording was specifically approved by the FDA. R. 5427a, 5429a, 5431-32a, 5897a.

In 1997, Dr. James Swingler, an Illinois physician, began prescribing Prempro for Plaintiff Connie Barton, an Illinois resident, to treat "serious" menopausal symptoms including hot flashes, night sweats, and missed menstrual cycles. R. 5219a, 5248a, 1793-94a. Although Dr. Swingler believed that Prempro could provide certain off-label benefits, i.e., for indications not approved by the FDA, Dr. Swingler made clear that if Plaintiff had not been suffering from serious menopausal symptoms, he would "[p]robably not" have prescribed Prempro to her. R. 5221, 5249a. Dr. Swingler was "familiar" with, and Plaintiff read, the Prempro labeling. R. 5220a, 3233-34a. Dr. Swingler testified that he learned of the breast cancer risk associated with HT in medical school and from other sources, including bulletins by the American Congress of Obstetricians and Gynecologists (ACOG) and medical literature. R. 5233-35a. Accordingly, Dr. Swingler "discussed with [Plaintiff] the risk of breast cancer associated with taking hormone therapy" and advised her that the risk was "small." R. 5233a, 5235a. After considering Plain-

tiff's medical history, Dr. Swingler determined that for Plaintiff the "benefits of using Prempro outweighed the risks." R. 5223a.

Dr. Swingler, a practicing OB/GYN who also teaches at medical school, developed his "appreciation for [Prempro's] potential [off-label] benefits . . . based on what the research was showing" (R. 5234a; *see also* R. 5219-20a), *not* based on Wyeth marketing materials. R. 5221-22a, 5255a, 5264-65a. Wyeth sales representatives would deliver to Dr. Swingler "new warning" information for Prempro in addition to "research articles," which he usually considered "accessory" data to that which he already "ha[d] from other sources," such as medical journals. R. 5246-47a; *see* S.R. 152b, 155-56b, 172b (Dr. Swingler "was definitely up on his research" and "the latest journals," and "in many cases he had already seen" the medical journals brought to him). Dr. Swingler also received a Wyeth brochure about the "physiology of menopause," which did not discuss cardiovascular benefits. R. 5229-31a, 5254a. There is no evidence that Dr. Swingler saw, heard, or relied upon any other Wyeth materials when he prescribed Prempro to Plaintiff.[2]

In May 2002, Plaintiff was diagnosed with breast cancer. R. 1826a. She has been cancer free since her surgery in 2002. R. 1827a, 1829a.

Plaintiff alleges that Wyeth's breast cancer warnings were inadequate, claiming that if Wyeth had conducted further testing of combination HT, it would have had greater knowledge of the risk of breast cancer and could have given stronger warnings. Plaintiff does not allege (nor is there any evidence) that the warnings accompanying Prempro misrepresented the scientific in-

[2] Dr. Swingler, and thousands of other physicians, still prescribe Prempro for the treatment of menopausal symptoms today. R. 5236a, 5247a, 5249a, 3694a, 3896a, 4282a. Dr. Swingler testified that Prempro remains "an important treatment option for women when it comes to the treatment of menopausal symptoms" and still prescribes HT in precisely the same dose he prescribed to Plaintiff. R. 5236a, 5247a, 5249a.

formation available at the time, that Wyeth failed to warn of a known risk, or that Wyeth misled the FDA or concealed studies or data from the FDA or the scientific community.

The trial court denied Wyeth's pretrial motions for summary judgment on Plaintiff's punitive damages claim, to exclude Plaintiff's regulatory expert, Dr. Cheryl Blume, and to exclude evidence of marketing and other materials not relied upon by Plaintiff's physician. R. 1a, 17a, 114a, 153a, 304a, 427a, 2135a, 2234a, 2566a, 3000-12a, 3336-42a. The case was tried before Judge Norman Ackerman. At trial, Plaintiff was allowed to introduce extensive testimony regarding Wyeth's purported promotion of HT for off-label uses, such as cardiovascular benefits, without any connection between that promotion and Dr. Swingler or his prescription of HT medications to Plaintiff. *See, e.g.*, R. 5187a. The jury returned a verdict in favor of Plaintiff, awarding $3,746,344.97 in compensatory damages and $75 million in punitive damages. App'x B at 2. The trial court denied Wyeth's post-trial motions for JNOV and new trial but granted remittitur, reducing the punitive award to $5,619,517.46, or 1.5 times compensatory damages. *Id.*

On January 3, 2012, the Superior Court affirmed the trial court's denial of JNOV and new trial but reversed in part the trial court's grant of remittitur, increasing the remitted amount of the punitive award from $5,619,517.46 to $7,492,689.94. App'x B. The Superior Court also denied Wyeth's application to stay resolution of the appeal until this Court issued its decision in *Daniel v. Wyeth Pharmaceuticals, Inc.*, No. 63 EAP 2011. *Id.* at 45-46. On March 13, 2012, the Superior Court denied Wyeth's Application for Reargument. App'x C.

REASONS FOR ALLOWING AN APPEAL

The Superior Court's affirmance of liability for punitive damages and its partial vacation of the trial court's remittitur, increasing the remitted punitive damages award to $7.49 million, creates an enormous expansion of liability for punitive damages in prescription pharmaceutical cases. Illinois law, which governs in this case, is similar to Pennsylvania law in requiring a wan-

ton disregard of a *known* risk to support punitive damages in the products liability context. Thus, the Superior Court's decision presents legal issues very similar to those raised in the appeal now pending before this Court in *Daniel*. Indeed, the Superior Court relied heavily on and quoted extensively from its opinion in *Daniel* to justify upholding the punitive damages award in this case. *See, e.g.*, Op. at 27, 31-32, 37-38. The Superior Court denied Wyeth's application to stay its resolution of the appeal in this case pending this Court's opinion in *Daniel*. *Id.* at 45-46. The Superior Court's denial of the stay application puts Wyeth's rights in unnecessary peril, as a reversal by this Court of the Superior Court's decision in *Daniel* clearly would call into question the correctness of the Superior Court's opinion in this case. Given the key similarities between Illinois and Pennsylvania punitive damages law, this Court's decision in *Daniel* could well be determinative of the punitive damages issues in this case. Accordingly, this Court should allow Wyeth's appeal to prevent the manifest injustice that would occur if the Superior Court's decision in *Daniel* is reversed, but the decision in this case were allowed to stand.

As in *Daniel*, the punitive damages issues in this case are of substantial public importance, including: (i) the propriety of awarding punitive damages to punish conduct that was extensively regulated, thoroughly scrutinized, and approved by the FDA with complete knowledge of the scientific data; and (ii) the availability of punitive damages based on a theory of failure to test adequately, rather than disregard of a known risk. This case also presents further important issues regarding the propriety under Illinois law and federal due process of imposing punitive damages for conduct that had no demonstrable nexus to Plaintiff's use of HT, including advertisements and other marketing materials upon which Plaintiff's doctor did not rely and that had no connection to his decision to prescribe HT to Plaintiff. Because similar issues are raised in hundreds, if not thousands, of other prescription drug cases pending in Pennsylvania courts, un-

der the laws of Illinois, Pennsylvania and other states, there is a need for prompt and definitive resolution by this Court of the fundamental questions of law and policy raised herein.

Plaintiff should not be heard to argue that because Illinois law governs this action it does not merit this Court's review.[3] Plaintiff chose to file suit in the Philadelphia Court of Common Pleas to avail herself of the perceived benefits of litigating her case in the Pennsylvania courts in spite of the fact that Illinois law would apply. Plaintiff should not now be permitted to use her freedom to do so as a shield against review. Considerations of consistency in the application of the law and deference to the underlying policy concerns of the state whose law is to be applied may (and in this instance do) make review by this Court necessary and appropriate. Fundamental fairness requires that defendants in pharmaceutical and mass tort cases brought in Pennsylvania by out-of-state plaintiffs are not deprived of the opportunity for review by this Court.

Review is warranted to address the fundamental legal errors committed by the Superior Court not only in upholding punitive damages for conduct that complied at all times with FDA regulations and requirements, but also in upholding punitive damages based on Plaintiff's theory that Wyeth should be punished for not conducting additional definitive testing of HT to ascertain the potential risk of breast cancer. Illinois Supreme Court precedent, which the Superior Court disregarded, required Plaintiff to prove that Wyeth failed to warn of a "*known* defect" before punitive damages could be imposed. *Loitz v. Remington Arms Co.*, 563 N.E.2d 397, 403 (Ill. 1990) (emphasis added). Here, Wyeth always warned in its FDA-approved labeling of a possible risk of breast cancer associated with Prempro. There was no evidence that Wyeth knew of or failed to disclose a risk of breast cancer beyond that which it warned of in its labeling. Illinois law does not permit courts to punish defendants for failing to warn of unknown risks of using their

[3] It is undisputed that Illinois law applies to Plaintiff's claims because Plaintiff is an Illinois resident, was

products that additional testing might have revealed. The Superior Court committed further legal error in disregarding uncontroverted evidence of extensive HT testing and studies conducted and supported by Wyeth that tested for benefits while monitoring for and producing data regarding the possible risk of breast cancer. Such testing and studies were done both prior to and during the entire time Plaintiff used Prempro.

The Superior Court's affirmance of punitive liability also raises fundamental due process issues that merit this Court's consideration. Because the FDA reviewed and approved not only Wyeth's breast cancer warnings, but also the sufficiency of the testing and scientific data submitted by Wyeth in support of Prempro, Wyeth justifiably believed that its conduct was reasonable and lawful. Wyeth therefore lacked the constitutionally required fair notice that it could be subjected to punishment. Moreover, punitive damages cannot be imposed, consistent with due process, where (as here) there is an ongoing scientific debate about the risks of a particular drug and there is no evidence of concealment of a known risk from the FDA and the scientific community.

In addition, review is warranted to address the legal and policy issues raised by the Superior Court's partial reversal of the trial court's remittitur and increase of the remitted punitive damages award to $7.49 million. As the Illinois Supreme Court has held, under the applicable abuse of discretion standard, a trial court's remittitur is to be reversed only where "'there is no recognizable basis in the record to support it.'" *Slovinski v. Elliot,* 927 N.E.2d 1221, 1226 (Ill. 2010) (citation omitted). Under *Slovinski,* the controlling inquiry "may be expressed in a single question: Is there a basis in the record to support the remittitur entered by the [trial] court?" *Id.* at 1227; *accord id*. at 1226. Here, the answer is, inarguably, yes. The trial court gave reasons, supported in the record, for ordering remittitur, including the fact that Wyeth's labeling warned

---

prescribed HT in Illinois, and was diagnosed with breast cancer in Illinois.

of a possible breast cancer risk. Moreover, the Superior Court's reasons for increasing the remitted punitive award were erroneous as a matter of Illinois law because they improperly discounted the warnings of the risk of breast cancer in Wyeth's FDA-approved labeling and relied upon purported conduct by Wyeth that lacked any demonstrable direct and proximate connection to Plaintiff's physician's prescribing decision. As discussed more fully below, the legal and policy issues that are raised by Superior Court's increase of the remitted award are important and, given their constitutional dimensions, transcend the application of any particular state's law. These issues merit the Court's review.

The Superior Court also ignored controlling Illinois law by holding that extensive and unfairly prejudicial evidence on marketing, off-label promotion, and "ghostwritten" articles was admissible to show liability, both for compensatory and punitive damages. Plaintiff's physician, Dr. Swingler, learned of the risk of breast cancer associated with HT in medical school and medical literature, and he based his decision to prescribe Prempro to Plaintiff on "what the research was showing" (R. 5234a), not on Wyeth marketing materials. The Superior Court recognized that "Dr. Swingler testified that he did not prescribe Prempro to Barton based on ***any*** specific marketing by Wyeth." Op. at 25 (emphasis added). The Illinois Supreme Court's rulings in *De Bouse v. Bayer AG*, 922 N.E.2d 309, 319 (Ill. 2009), and *Batteast v. Wyeth Laboratories, Inc.*, 560 N.E.2d 315, 323-24 (Ill. 1990), make clear that marketing-related evidence that was not relied on by Dr. Swingler and had no demonstrable causal connection to Dr. Singler's prescribing decision is irrelevant and inadmissible. In affirming the admission of such evidence, the Superior Court improperly presumed reliance, speculating that despite his testimony Dr. Swingler's belief in the benefits of HT somehow "likely originated from Wyeth's marketing efforts" and "certainly . . . was rooted, at least indirectly, in Wyeth's active promotion of its products." Op. at

21, 25. The Superior Court's erroneous theory of presumed reliance dramatically expands tort liability and, if allowed to stand, will have substantial, adverse public policy consequences on the development and availability of prescription drugs.

The Superior Court also committed legal error in affirming the trial court's admission of the "reasonable company" testimony of Plaintiff's regulatory expert, Cheryl Blume, Ph.D. Her testimony was not based on objective government or industry standards, but consisted of speculation and hindsight criticism about what Wyeth purportedly "could" have done. The issue of the admissibility of Dr. Blume's or similar "expert" testimony is of crucial importance not only in this case but in other HT and pharmaceutical cases and warrants this Court's review.

I. REVIEW SHOULD BE GRANTED TO RESOLVE IMPORTANT ISSUES RAISED BY THE SUPERIOR COURT'S AFFIRMANCE OF PUNITIVE DAMAGES LIABILITY

The Superior Court's affirmance of the imposition of punitive damages raises fundamental policy concerns and legal questions that merit review by this Court. Illinois law, like Pennsylvania law, requires wanton disregard of a *known* risk to justify the imposition of punitive damages. That requirement is not met by a defendant's failure to conduct additional studies. Permitting punitive damages based on a hindsight view of what different or additional studies ought to have been done at an earlier time would open the door to punitive damages claims in almost any case where a risk is later determined to be greater or more certain than it was previously known to be. Permitting punitive damages on such a basis is also erroneous as a matter of Illinois law where, as here, the defendant, a prescription drug manufacturer, has complied fully with FDA requirements and its testing, product, and labeling have been approved by the FDA. The Superior Court committed further legal error in failing to consider the particular, relevant facts and circumstances, including the extensive tests and studies actually conducted, and in looking to evidence of marketing and other conduct with no demonstrable connection to Plain-

tiff's doctor's prescribing decision. The issues presented are similar to the punitive damages issues under Pennsylvania law that are before this Court in *Daniel* and merit review in this case.

A. Illinois, Like Pennsylvania, Does Not Permit the Imposition of Punitive Damages for a Failure to Perform Additional Testing, But Requires Disregard of a Known Risk

In this case, as in *Daniel*, the Superior Court erred by affirming liability for punitive damages where the facts establish that the defendant did not disregard a known risk. Here, as in *Daniel*, the uncontroverted facts show that Wyeth complied with FDA regulations, and the FDA thoroughly reviewed the testing and studies conducted by Wyeth and others, examined, revised, and approved Wyeth's labeling, including the label warnings as to the possible risk of breast cancer, and approved Prempro as safe and effective. R. 5566-68a. The FDA determined that Wyeth's warning labels accurately reflected the available scientific knowledge, and Plaintiff's regulatory expert Dr. Blume agreed that the FDA "did the right thing when [it] approved th[e] [Prempro] label," including the breast cancer warning. R. 3136a; *see also* R. 2637a. There is no allegation or evidence that Wyeth misled or concealed information from the FDA regarding the potential risk of breast cancer. Thus, the record establishes that to the extent Wyeth knew of a possible risk of breast cancer, Wyeth properly disclosed that risk to the FDA and on its labeling. There was no showing that Wyeth knew that the possible risk of breast cancer was greater or more certain than Wyeth's labeling disclosed, and there is thus no evidence of disregard of or a failure to warn of a known risk, as required for punitive damages under Illinois (and Pennsylvania) law.

Punitive damages are "not favored" under Illinois law, and "courts must be cautious in seeing that they are not improperly or unwisely awarded." *Deal v. Byford*, 537 N.E.2d 267, 272 (Ill. 1989). Punitive damages may be awarded only "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.'" *Slovinski*, 927 N.E.2d at 1225 (citation omitted); *see also Loitz*, 563 N.E.2d at 402 (requiring "'conduct involving some element of outrage similar to that usually found in crime'" (citation omitted)).

Illinois recognizes that "the threat of multiple recoveries [of punitive damages] in mass tort cases" may lead manufacturers to "curtail their research and development of new and beneficial products." *Loitz*, 563 N.E.2d at 402-03 (citation omitted). Accordingly, like Pennsylvania, Illinois in the products liability context requires a plaintiff seeking punitive damages to establish the manufacturer's "'failure to warn of a *known* defect in flagrant disregard of the public safety.'" *Id.* at 403 (emphasis added) (citation omitted). Thus, Illinois courts have approved punitive damages in pharmaceutical cases where a defendant "knew of the adverse effects" from its medication but told "no one," including the FDA. *Proctor v. Davis*, 682 N.E.2d 1203, 1209, 1212-15, 1216 (Ill. App. Ct. 1997); *see also id.* & n.16 (manufacturer's conduct takes on "a pernicious quality when coupled with its *knowledge* of the dangers" (emphasis added)); *Kopczick v. Hobart Corp.*, 721 N.E.2d 769, 779 (Ill. App. Ct. 1999) (granting JNOV as to punitive damages where there was "scant evidence of defendant's pre-injury knowledge of defect"). Likewise, under Pennsylvania law, punitive damages require reckless or deliberate "'indifference' to a *known* risk," and can be awarded only if "a defendant had a subjective appreciation of the risk of harm to which the plaintiff was exposed" and acted "in conscious disregard of that risk." *Hutchison v. Luddy*, 582 Pa. 114, 123-24, 870 A.2d 766, 771-72 (2005) (emphasis added).

Unable to point to any record evidence that Wyeth disregarded a known risk, the Superior Court erroneously held that Wyeth's purported failure to conduct additional testing provided a basis for punitive damages. *See* Op. at 30-32 (opining that Wyeth "purposefully failed to study

the matter further" and that Wyeth "'failed and refused to conduct adequate studies'" (quoting its earlier opinion in *Daniel*)). In holding that this purported failure to conduct further studies warranted punitive damages, the Superior Court erroneously relied upon *Proctor v. Davis*, 682 N.E.2d at 1211-12, as supporting punitive damages where the defendant "should have known" of the risk. Op. at 31. The passage from *Proctor* quoted and relied upon by the Superior Court has nothing to do with punitive damages and is relevant only to the Illinois negligence standard.

The *Proctor* decision addresses negligence and punitive damages in separately numbered sections. Section I (beginning at 682 N.E.2d at 1211) discusses compensatory liability for failure to warn, whereas Section II (beginning at 682 N.E.2d at 1215) provides a separate discussion of liability for punitive damages. In its analysis of punitive damages, the court in *Proctor* makes clear that a more stringent standard of actual knowledge applies, not a "should have known" standard. In affirming the punitive award, the Illinois court stressed that there was evidence that the defendant actually "*knew* of the adverse effects of periocular use of Depo-Medrol." *Proctor*, 682 N.E.2d at 1216 (emphasis added). Thus, *Proctor* accords with other Illinois decisions on punitive damages. *See Loitz*, 563 N.E.2d at 403 (requiring a "'failure to warn of a *known* defect in flagrant disregard of the public safety'" (emphasis added) (citation omitted)); *Kopczick*, 721 N.E.2d at 779 (requiring "pre-injury knowledge of defect").

The Superior Court's opinion squarely presents the issue of whether Illinois law permits punitive damages in the absence of failure to warn of a *known* defect. That same issue under Pennsylvania law is currently before this Court in *Daniel*, and it should be reviewed in this case as well. The Pennsylvania courts have undertaken to try a large volume of HT cases with plaintiffs who reside and were prescribed HT in other states. Review by this Court of the basic legal issues in such cases is crucial to ensuring fair and just results in this and other mass tort litiga-

tions.

B. The Uncontroverted Facts Regarding Wyeth's Compliance with FDA Regulations Render Punitive Damages Improper as a Matter of Illinois Law

The Superior Court erroneously affirmed the imposition of punitive damages and, citing its earlier decision in *Daniel*, held that "compliance with industry and governmental safety standards, in and of itself, does not insulate a defendant from punitive damages" and that "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." Op. at 27. Here, as in *Daniel*, Wyeth's compliance with extensive and stringent FDA regulations regarding the testing of Prempro and its labeling and warnings of the possible risks of breast cancer precludes a finding of willfulness and wanton disregard as a matter of law. As in *Daniel*, there is no evidence that Wyeth misled or concealed information from the FDA.

At all relevant times, the FDA-approved Prempro labeling warned of a possible risk of breast cancer.[4] R. 5151-53a. As noted above, Plaintiff's regulatory expert, Dr. Cheryl Blume, agreed that the FDA "did the right thing when [it] approved th[e] Prempro label," including the breast cancer warning. R. 3136a; *see also* R. 2637a. Extensive medical data was submitted in support of Wyeth's New Drug Application (NDA) for Prempro. *See* R. 5311-12a, 5364-67a. Dr. Susan Allen, a former FDA medical officer, testified "it's very unusual to have this many studies on a drug before that drug is approved," especially "extensive published literature" on "a particular risk" for a new drug, such as the "breast cancer risk" for Prempro. R. 4215a. In reviewing

[4] As Wyeth's Prempro warning stated, *inter alia*, in language approved and mandated by the FDA: "*Breast Cancer*. Some studies have reported a moderately increased risk of breast cancer (relative risk of 1.3 to 2.0) in those women on estrogen replacement therapy taking higher doses, or in those taking lower doses for prolonged periods of time, especially in excess of 10 years. The majority of studies, however, have not shown an association in women who have ever used estrogen replacement therapy. The effect of added progestin on the risk of breast cancer is unknown, although a moderately increased risk in those taking combination estrogen/progestin therapy has been reported. Other studies have not shown this rela-

the NDA, the FDA examined data from Wyeth's Pivotal trial and from fourteen other HT studies, including three meta-analyses of data from 96 studies. R. 5371a, 5378a, 5439-41a. FDA medical officer Dr. Linda Golden also reviewed Wyeth's proposed labeling and made specific revisions to the warnings of the possible risk of breast cancer. R. 5427a, 5429a, 5431-32a. In approving the NDA, the FDA expressly "concluded that adequate information ha[d] been presented to demonstrate that [Prempro was] safe and effective for use as recommended in the submitted [revised] draft labeling." R. 5566a.[5] Contrary to the Superior Court, Wyeth did not "'wait[ ] 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.'" Op. at 31 (quoting *Proctor*, 682 N.E.2d at 1211-12). Wyeth's labeling, at all relevant times, warned of the possible risk of breast cancer.

In 1997, when Wyeth submitted a supplemental NDA for a new dosage of Prempro, the FDA again reviewed the adequacy of the Prempro labeling (R. 5844-55a), and the scientific studies and analyses on HT. The FDA approved the new dosage, concluding that it did not appear to increase the incidence of breast cancer. R. 5852-55a. Plaintiff's expert Dr. Blume testified that she does not criticize these FDA decisions. R. 3150a.

Plaintiff's position is fundamentally inconsistent and untenable. According to Plaintiff, the FDA, having all the relevant scientific data, was reasonable in approving Prempro and its la-

---

tionship." R. 5151a.

[5] As part of the review process, the FDA must determine whether there are sufficient scientific studies of such quality as "to permit an evaluation of the drug's effectiveness and safety." 21 C.F.R. § 312.22(a); *see also id*. § 312.21. An NDA must include "full reports of investigations . . . to show whether or not such drug is safe for use and whether such drug is effective in use," and must include the proposed labeling for the drug. 21 U.S.C. § 355(b)(1); *see also* 21 C.F.R. § 314.50(d)(5)-(6), (e). The FDA must deny an NDA if it "do[es] not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under . . . the proposed labeling," if the FDA "has insufficient information to determine whether such drug is safe for use," or if "based on a fair evaluation of all material facts, [the] labeling is false or misleading in any particular." 21 U.S.C. § 355(d); *see also* 21 C.F.R. § 314.125(b).

beling, but yet Wyeth's conduct in marketing these FDA-approved medications with the FDA-approved labeling was wanton and reckless and merited punitive damages. Contrary to the Superior Court's decision, the undisputed facts as to Wyeth's compliance with FDA requirements and the FDA's rigorous review of the testing and labeling of Prempro foreclose a finding that Wyeth's conduct involved a "'failure to warn of a known defect in flagrant disregard of the public safety'" or an "'element of outrage similar to that usually found in crime,'" as required by for punitive damages under Illinois law. *Loitz*, 563 N.E.2d at 402 (citation omitted).

This Court and courts around the country look to compliance with government regulations and industry standards in assessing whether the facts of a given case permit an award of punitive damages. This Court has reversed punitive damages where (as here) a manufacturer "complied with all safety standards," recognizing that while "compliance with safety standards does not, standing alone, automatically insulate a defendant from punitive damages[,] it is a factor to be considered in determining whether punitive damages may be recovered."[6] *Phillips v. Cricket Lighters*, 584 Pa. 179, 191-92, 883 A.2d 439, 447 (2005); *see also Prosser and Keeton on the Law of Torts* § 36, at 233 n.41 (W. Page Keeton et al. eds., 5th ed. 1984) ("In most contexts . . . compliance with a statutory standard should bar liability for punitive damages."); *Sloman v. Tambrands, Inc.*, 841 F. Supp. 699, 703 & n.8 (D. Md. 1993) (dismissing punitive damages claim where defendant "complied with [FDA] regulations"); *Richards v. Michelin Tire Corp.*, 21 F.3d 1048, 1059 (11th Cir. 1994) (punitive claim "should not go to the jury when a manufacturer takes steps" pursuant to government regulations "to warn the plaintiff of the potential danger"); *In re Miamisburg Train Derailment Litig.*, 725 N.E.2d 738, 752-53 (Ohio Ct. App. 1999) (defendants' compliance with federal regulation "overwhelm[ed] any suggestion that [de-

[6] *Phillips* involved unspecified "safety standards" for cigarette lighters. It did not involve a regulatory

fendants] acted with conscious disregard for safety," negating punitive damages claim).

The FDA regulations, procedures, and requirements applicable to prescription drugs such as HT medications go far beyond the safety standards generally applicable to other types of products. *See, e.g., Grundberg v. Upjohn Co.*, 813 P.2d 89, 96 (Utah 1991) ("[n]o other class of products is subject to such special restrictions or protections"); *see also White v. Weiner*, 386 Pa. Super. 111, 124, 562 A.2d 378, 385 (1989) ("Like the testing requirements, the federal labeling requirements [for prescription drugs] are extensive."), *aff'd mem.*, 525 Pa. 572, 583 A.2d 789 (1991). A pharmaceutical company that has complied with the FDA's "extremely stringent regulation" should not be subject to punitive damages. *See* W. Kip Viscusi, *Corporate Risk Analysis: A Reckless Act?*, 52 Stan. L. Rev. 547, 579-80 (2000); *see also* 2 Am. L. Inst., Reporters' Study, *Enterprise Responsibility for Personal Injury* 101 (1991) ("If a defendant has fully complied with regulatory requirements and fully disclosed all material information relating to risk," it is "hard to justify the jury's freedom to award punitive damages.").

Contrary to Plaintiff's contentions below, Wyeth's argument that its compliance with FDA regulations, requirements, and procedures should foreclose punitive damages is not based on federal preemption. It is based on the fundamental inconsistency between the undisputed facts surrounding the FDA's regulation and approval of HT and the strict requirements established under Illinois law for the imposition of punitive damages. *None* of the cases cited by Wyeth on this point is based on federal preemption. Rather, these cases held that defendants' actions taken in compliance with government regulations did not meet state law standards for punitive damages. For example, in *Miamisburg*, the Ohio appellate court found *as a matter of state law* that the defendants' compliance with a federal regulation governing the retrofitting of

---

program comparable to the FDA's regulatory and oversight regime.

tank cars "overwhelm[ed] any suggestion that [defendants] acted with conscious disregard for safety." 725 N.E.2d at 752. The court expressly acknowledged that the regulation had "no *preemptive* effect" on plaintiff's underlying negligence claim, but explained that "[n]o reasonable person could reconcile the [defendants'] compliance with the regulation in question with the notion that their behavior was somehow 'outrageous,' 'flagrant,' or 'criminal,'" as required under state law for punitive damages. *Id*. (emphasis added).

C. In Affirming Punitive Damages, the Superior Court Failed to Consider Relevant Facts and Circumstances and Erroneously Relied on Unrelated Conduct

Under Illinois law, in reviewing an award of punitive damages, "[i]t is vital that each case be carefully assessed in light of the specific facts involved, and the ultimate determination should be governed by the circumstances of each particular case." *Deal*, 537 N.E.2d at 272. To ensure that punitive damages are not "improperly or unwisely awarded," *id.*, the Illinois Supreme Court considers "the evidence itself and not merely the statements concerning the facts as set forth in the opinion of the Appellate Court." *Watts v. Bacon & Van Buskirk Glass Co.*, 163 N.E.2d 425, 427 (Ill. 1959). The question of "whether the facts of a particular case justify the imposition of punitive damages is properly one of law," *Kelsay v. Motorola, Inc.*, 384 N.E.2d 353, 359 (Ill. 1978), and is reviewed *de novo*. *LaSalle Nat'l Bank v. Willis*, 880 N.E. 2d 1075, 1083 (Ill. App. Ct. 2007). Only facts and circumstances that have a "direct and proximate connection" with Plaintiff's injury are relevant to a claim for punitive damages. *Batteast*, 560 N.E.2d at 323; *see also Kopczick*, 721 N.E.2d at 779 ("Punitive damages must derive from the wrongful conduct giving rise to a cause of action.").

As shown below, the Superior Court improperly disregarded evidence of the numerous tests and studies of HT conducted or supported by Wyeth, while relying on irrelevant evidence that had no direct and proximate connection to Plaintiff's injury. An examination of the relevant

facts and circumstances of this case demonstrates that the Superior Court's affirmance of liability for punitive damages was erroneous as a matter of Illinois law.

1. In Affirming Punitive Damages, the Superior Court Disregarded Uncontroverted, Relevant Record Evidence

In upholding punitive damages, the Superior Court failed to examine the trial court's "statements concerning the facts," *Watts*, 163 N.E.2d at 427, but simply adopted the trial court's rendition of the evidence verbatim, with a 14-page single-spaced quotation from the trial court's opinion. Op. at 3-17. Thus, the Superior Court adopted the trial court's erroneous characterization of the evidence, including its repeated statements that Wyeth "did not conduct any testing," *id*. at 7, "never conducted a single study charting the risk of cancer and Prempro," *id.* at 8, "shied away from testing about risks," *id*. at 10, "took no action" regarding the "need for E+P testing," *id*. at 13, and "prevent[ed] studies from examining . . . HRT's risk of breast cancer and refused to conduct its own studies." *Id*. at 14. *See also* Op. at 6, 10, 13, 28, 30. Notably, the trial court opinion, to the extent it cites to the record, relies mostly on the testimony of Plaintiff's regulatory expert Dr. Blume,[7] as did the Superior Court's opinion in *Daniel*.

These misstatements as to the lack of testing, which pervade the trial court's and the Superior Court's opinions, are flatly contradicted by the actual record evidence. Even a cursory review of the record evidence demonstrates that Wyeth conducted numerous studies that "chart[ed] the risk of cancer and Prempro" (Op. at 8), that independent researchers, including the National Institutes of Health, also undertook such studies, and that no one was ever prevented by Wyeth from doing so. More than two decades before Dr. Swingler prescribed Prempro to Plaintiff in

[7] This reliance on the factual narrative of a paid advocate is inherently problematic. As with any expert, this witness was not an "unbiased scientist[]," and "the potential for exaggeration and fraud on the court," required a "close inspection and careful consideration of the record." *Turpin v. Merrell Dow Pharms., Inc.*, 959 F.2d 1349, 1352-53 (6th Cir. 1992). Dr. Blume's testimony never received this close inspection from the trial court or the Superior Court. *See also* Point VI *infra*.

1997, scientists had been conducting HT studies that monitored for breast cancer (R. 5291a), and by May 2002, there were more than 50 published studies on combination HT. *See, e.g.*, R. 2629a, 2901a, 2922a, 2932-33a, 2938a, 2943-48a, 3140a, 3725-26a, 5301-06a, 5434a, 5571a, 5787-88a, 5852-53a, 5913-14a, 6386-88a. Moreover, the uncontroverted record evidence establishes that, between 1979 and 2002 Wyeth supported or conducted at least 20 HT studies that monitored and evaluated the breast cancer risk. *See, e.g.*, R. 1426-27a, 2922-48a, 5301-06a, 5571a, 6387-88a.

As early as 1983, Wyeth attempted to conduct a clinical trial on combination HT but was unable to recruit enough women, forcing the trial's cancellation in 1988. R. 2921-22a. Between 1989 and 1992 (a time when Dr. Blume asserted that "Wyeth took no action" in response to the "need for E+P testing" (Op. at 13)), Wyeth conducted the Pivotal trial. At the time, the Pivotal trial constituted the "largest randomized controlled trial of E plus P that had ever been done." R. 2951a. The FDA characterized the Pivotal trial as both "large scale" and "adequately controlled." R. 4176a. The results of the Pivotal trial, which found "no difference in the incidence of breast cancer" relative to the general population (R. 2930a), were reviewed by the FDA and included in the Prempro labeling. R. 5151-53a. During this same period, Wyeth also supported the PEPI trial (1989-1994), providing both pills and research crucial to the study's design. R. 2932-33a, 2936a. Like the Pivotal trial and the Women's Health Initiative ("WHI") study, the PEPI trial was a randomized, placebo-controlled trial which addressed the association between E+P and the risk of breast cancer. *Id*. Wyeth also supported numerous other studies, including the WISDOM study (1997-2002) and the landmark WHI study (1993-2002).[8] R. 3871-79a, 5571a.

The Superior Court also ignored the substantial financial support Wyeth provided for

[8] The WHI reported an overall 1.24 relative risk of breast cancer, which was lower than the relative risk

numerous other studies, including the Nurses' Health Study (which began in 1979), the HOPE trial (1995-2000), for which Wyeth provided $30 million, and the HERS study (1993-2000), for which Wyeth provided $40 million. R. 2937-38a, 2942-44a, 2947-48a, 3860a, 3997a. The HERS study, designed by Wyeth, found a relative risk of 1.27, virtually identical to that of the WHI study. R. 2942-44a. In other words, the uncontroverted evidence shows that contrary to the Superior Court's opinion (Op. at 10), Wyeth funded, supported and conducted studies "assessing the risks associated with the combination of E+P." Op. at 10. Significantly, the Superior Court did not address any of the undisputed evidence marshaled by Wyeth in its appeal brief demonstrating the extensive testing and study of HT that Wyeth conducted and supported.

Plaintiff below improperly criticized Wyeth's testing as not being specifically "breast cancer studies." Such criticism is frivolous because it would be unethical to study a drug solely to determine its adverse effects. As Plaintiff's expert Dr. Blume had to concede, medical ethics forbid conducting a "breast cancer study":

> Q. And can you design a study specifically to look for breast cancer so that you set the study up to look for that issue?
>
> A. Well, *we are not permitted to design studies, placebo-controlled studies that are specifically designed to look for harm.* We track harm and it can be one of the end points we are looking for, but generally we design placebo-controlled studies as benefit studies.

R. 3032-33a (emphasis added). Indeed, the WHI – the study Plaintiff claims Wyeth should have conducted – was not a breast cancer study, but a study that primarily tested the cardiovascular benefits of combination HT while tracking incidents of breast cancer. R. 4411-12a. Thus, the trial court's statement, adopted by the Superior Court, that "Wyeth only conducted tests aimed at verifying the off-label benefits of Prempro and shied away from testing about risks" (Op. at 10)

---

of 1.3 and 2.0 reported in Wyeth's Prempro label. R. 5238a, 5151a.

is based upon the fundamentally erroneous premises that: (1) a "breast cancer study" can and should be conducted; and (2) the clinical trials conducted and supported by Wyeth did not "chart" the risk of breast cancer (Op. at 8), when in fact *all* of them did.

2. The Superior Court Improperly Adopted Numerous Plainly Incorrect Findings by the Trial Court

The Superior Court adopted numerous other erroneous findings by the trial court without examination or analysis. For example, the Superior Court quoted the trial court's statement that Wyeth ignored the results of a Swedish study (the Bergkvist study) in 1989, and "instructed its sales people not to discuss th[e] study, and, if pressed, to respond with facts about the drug." Op. at 7. According to the court, rather than respond to this "red flag" with "testing to discover the relative risk of taking E+P," Wyeth "adopted a policy of 'dismiss and distract.'" *Id.* In fact, it is undisputed that Wyeth sent a Dear Doctor Letter to inform physicians of the Bergkvist study the same month it was published and invited Dr. Bergkvist to present his data at a symposium on estrogen. R. 2891a, 2897-98a; *see* R. 4850a. Moreover, the Bergkvist study results regarding synthetic estrogen were based on a sample of only 10 patients and were later revised down to a relative risk of 1.6, consistent with the Prempro label at the time of Plaintiff's use. R. 2888-89a, 2892-93a, 5151a. These uncontroverted facts refute the inferences drawn by the trial court and adopted by the Superior Court.

The Superior Court also repeated the trial court's erroneous assertion that, despite the FDA's request that Wyeth "conduct additional 'level four' [sic] studies to determine the breast cancer risk of E+P,"[9] Wyeth was "fearful the result of level four testing would be "embarrassing" and "never conducted a single study charting the risk of cancer and Prempro." Op. at 8.

[9] A Phase 4 study is a study done when a drug is already approved and on the market. 21 C.F.R. § 312.85. The FDA may ask for Phase 4 trials in order to "delineate additional information about the drug's risks, benefits, and optimal use." *Id.*

The document that is the basis for the assertion that Wyeth thought testing would be "embarrassing" dates from 1983, long before the Prempro NDA was submitted (in 1992), and had nothing to do with Phase IV studies and, as one federal district court recognized, "ha[d] nothing to do with breast cancer."[10] *Wilson v. Wyeth*, No. 3:05CV78-WRW, Tr. at 32 (E.D. Ark. Oct. 1, 2010); *see also* R. 4857-58a. Moreover, the uncontroverted evidence reveals that, rather than "thumb[ing] its nose at the FDA" by not conducting a Phase IV study after Prempro was approved (Op. at 28), Wyeth submitted a protocol for the Phase IV study to the FDA (R. 5452-55a) and worked closely with the FDA to determine whether the study would advance the scientific knowledge about HT.

The uncontroverted evidence also reveals that it was an FDA medical officer, Dr. Bruce Stadel, who "had 'second thoughts' regarding the feasibility of conducting the Phase IV trial," and who raised concerns that such a study might prove redundant, given the concurrent WHI study. R. 5456-58a. Those concerns were validated by the refusal by the National Institutes of Health ("NIH"), which sponsored the WHI, to "support the idea" of a second study because of the possibility that it might "interfer[e] with the recruitment for WHI." R. 5911. Thus, contrary to the trial court's and Superior Court's conclusion that Wyeth attempted to avoid Phase IV testing, the decision to defer to, and support, the WHI was the product of consultation and agreement between the FDA, the NIH, and Wyeth. R. 4275-76a. At trial, former FDA medical officer Dr. Susan Allen testified that the FDA was not "frustrated" by Wyeth's actions (R. 4356a) and that, "with regard to the development and approval of [Prempro]," Wyeth "behave[d] appropriately and responsibly." R. 4291a.

[10] The memorandum in fact addressed the possibility that the FDA *might* require testing to show that combination HT was more effective than estrogen alone. R. 4857-58a. Because progestin was not added to increase effectiveness but to reduce the risk of endometrial cancer from estrogen alone, obviously it was doubtful that testing for increased effectiveness would have been successful.

Likewise, the Superior Court, quoting the trial court, mischaracterized Wyeth's 1993 denial of a request that it supply pills for a HT study by the Eastern Cooperative Oncology Group ("ECOG") as part of its purported "pattern of distract and dismiss." Op. at 13 (citing testimony by Plaintiff's expert Dr. Blume). The indisputable evidence establishes not only that in 1993 Wyeth was conducting and supporting studies and trials, but that there was nothing improper about Wyeth's decision not to provide pills for the ECOG study. The Wyeth document underlying Dr. Blume's testimony on the ECOG study shows that Wyeth refused to supply pills to the study, not because it was a breast cancer study, but because the researchers planned to study the effects of HT on women who had already been diagnosed with breast cancer – and for whom HT use was *contraindicated on the Prempro label*. R. 3290-99a, 4898a, 5151a. As Dr. Blume explained, a contraindication means "the risks of the drug outweigh the benefits," and, as a result, HT was "not to be used for those uses." R. 2413-14a. Wyeth's policy of refusing supply pills for studies on women already diagnosed with breast cancer cannot reasonably be interpreted as evidence of willful or wanton conduct or of a "pattern of distract and dismiss."[11]

The Superior Court also adopted and quoted the trial court's discussion of and reliance on evidence that was not presented at the trial of this case. For example, the trial court twice cited the testimony of "Plaintiff's expert, Dr. Parisian," referring to Dr. Suzanne Parisian, a frequent plaintiffs' expert in HT cases. *See* Op. at 8, 16. However, Dr. Parisian *was not a witness* in this case. Nonetheless, the Superior Court adopted trial court's findings based upon Dr. Parisian's opinions regarding the FDA's authority to demand Phase IV testing (Op. at 8) and the FDA's requirements regarding labeling. Op. at 16. The courts' reliance on this evidence was significant:

[11] Moreover, contrary to the Superior Court's opinion, Wyeth during trial never "maintained that it always denied requests for independent studies using its drugs" – an assertion for which the trial court (quoted by the Superior Court) cited testimony by Dr. Blume, not testimony by Wyeth. Op. at 13. In fact, Wyeth provided pills and placebo to the WHI and other studies. R. 2933a, 3871-75a, 5571a.

the courts cited Dr. Parisian's "testimony" as a direct rebuttal to Wyeth's assertions that it acted responsibly and diligently in disseminating information related to the WHI study results. *See* Op. at 16 (stating that Dr. Parisian "explained that [the] label change was mandated by the FDA" and not the result of "Wyeth's good motive.").

The Superior Court, quoting the trial court, also discussed and relied upon other purported evidence that was never introduced at trial, in order "to highlight some of Wyeth's conduct that may have been used during the jury's determination that Wyeth was willful and wanton in its promotion of Prempro." Op. at 12. For instance, the trial court stated, without citation to the record, that Wyeth conditioned support for "a British scientist's request for Wyeth's patients' mammograms on the agreement that the scientist would not review any links between HRT and breast cancer." Op. at 13. This statement, which was quoted and relied upon by the Superior Court, appears to have been derived not from the record in this case, but from the federal appellate court's opinion in *In re Prempro Products Liability Litigation (Scroggin v. Wyeth)*, 586 F.3d 547 (8th Cir. 2009). *See id.* at 557 ("a British scientist requested mammograms used in previous Wyeth studies" and "Wyeth agreed on condition that there be 'no review of issues'" concerning "'HRT and breast cancer'" and that "the scientist will agree to accept the views of the Premarin Study Review Committee'").[12]

In sum, the Superior Court's opinion fell far short of the required consideration of "the evidence itself and not merely the statements concerning the facts," *see Watts*, 163 N.E.3d at 427,

[12] Other "findings" by the trial court, which the Superior Court quoted and relied upon, also appear to have been taken from *Scroggin*. The trial court's statement that the "FDA wrote that [a Wyeth marketing] campaign 'internationally [sic] misleads the reader'" (quoted by the Superior Court at Op. 13) appears to have come from *Scroggin*, 586 F.3d at 558 (the FDA wrote "that the campaign '*intentionally* misleads the reader'") (emphasis in original). *Compare also, e.g.*, Op. at 6 ("Wyeth's reaction to the [Hoover] study was an attempt to, 'mitigate the possible adverse effects'"), *with Scroggin*, 586 F.3d at 555-56 (Wyeth internal document suggested "formulat[ing] a plan to 'mitigate the possible adverse effects' of the [Hoover] study").

that were set forth in the trial court's opinion. As a matter of Illinois law, the evidence in this case does not support or permit punitive damages. The lengthy discussion of the "facts" that the Superior Court adopted from the trial court's opinion does not identify any evidence that Wyeth had knowledge of a risk greater than that disclosed in its labeling as required for punitive damages under Illinois law. It also does not identify any evidence that Wyeth concealed information from the FDA, which approved Prempro, its labeling, and the sufficiency of Wyeth's testing and of the scientific data that Wyeth submitted in support of its Prempro NDA. In the absence of such evidence and given the uncontroverted record evidence of the tests actually supported and conducted by Wyeth, punitive damages should not have been allowed as a matter of law.

3. The Superior Court Committed Legal Error in Affirming Punitive Damages Based on Evidence with No Connection to Plaintiff

The Superior Court disregarded controlling law by allowing punitive damages based upon evidence of marketing and other alleged "bad company" conduct (including much of the evidence discussed above) that had no causal connection to Plaintiff's physician's prescribing decision and Plaintiff's use of HT. Although stating that "Dr. Swingler testified that he did not prescribe Prempro to Barton based on any specific marketing by Wyeth," the Superior Court held – with no analysis or authority – that marketing conduct was admissible "to show willful and wanton misconduct" as well as "reprehensibility" for punitive damages. Op. at 25.

There was no evidence establishing that Dr. Swingler saw or relied upon any Wyeth promotional materials regarding off-label benefits, that Dr. Swingler ever received a "lavish gift" from a Wyeth sales representative, that Dr. Swingler saw or relied upon any "ghostwritten article," or that any such materials had any effect on his decision to prescribe Prempro to Plaintiff. Despite the lack of any demonstrable link to Dr. Swingler's prescribing decision, the Superior Court explicitly cited and relied upon such unrelated evidence in upholding the punitive damages

award. *See, e.g.*, Op. at 9-10, 19, 28, 29.

In affirming the imposition of punitive damages on this basis (Op. at 19, 29-30), the Superior Court erroneously disregarded the Illinois Supreme Court's holding in *Batteast* that for conduct to be relevant to punitive damages, the plaintiff's "injury must have a direct and proximate connection" to that conduct, which is "a question of law for the court." 560 N.E.2d at 323. In *Batteast*, the Illinois Supreme Court ruled that punitive damages could not be imposed for marketing conduct that allegedly violated FDA regulations without evidence that the conduct was "the proximate cause of the [plaintiff's] injury." *Id.* at 323-24; *see also Kopczick*, 721 N.E.2d at 779 ("Punitive damages must derive from the wrongful conduct giving rise to a cause of action."). Accordingly, the extensive unrelated evidence of marketing and other conduct in this case was "improperly submitted to the jury" and "improperly considered in reference to punitive damages." *Batteast*, 560 N.E.2d at 324.

Moreover, neither the Superior Court nor Plaintiff identified any allegedly "ghostwritten" article that misrepresented the state of science or the available scientific knowledge. Under Illinois law, a drug company's circulation of "laudatory articles" to medical journals is "totally irrelevant on the issue[] of . . . punitive damages." *Hagen v. Richardson-Merrell, Inc.*, 697 F. Supp. 334, 340 (N.D. Ill. 1988). The court in *Torkie-Tork v. Wyeth*, in excluding evidence of supposedly "ghostwritten" articles, rejected the plaintiff's argument that such articles "affected the medical literature as a whole" as "far too tenuous." No. 1:04cv945, Tr. at 211 (E.D. Va. Nov. 16, 2010); *see also Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1364 n.4, 1371 (S.D. Fla. 2007) (summary judgment for medical device company; ghostwritten articles irrelevant). Indeed, "[i]n the marketing of any product, the manufacturer has the right to circulate positive literature regarding the product as long as the information contained therein is not false." *Hagen*, 697 F.

Supp. at 339-40.

In sum, the relevant facts and circumstances do not justify the imposition of punitive damages against Wyeth as a matter of Illinois law, and their award implicates fundamental principles as to the purpose of punitive damages and public policy. Similar issues under Pennsylvania law are now pending before this Court in *Daniel*. Granting review here will provide guidance to the Pennsylvania courts as they address issues of punitive damages in other HT cases pending before them.

II. THIS COURT SHOULD REVIEW THE FUNDAMENTAL DUE PROCESS ISSUES RAISED BY THE SUPERIOR COURT'S AFFIRMANCE OF PUNITIVE DAMAGES LIABILITY

The Superior Court's decision affirming punitive liability raises important due process issues that warrant this Court's review. Whether federal due process permits punitive damages in a given case is a legal issue reviewed *de novo* and requires a "thorough, independent review" by the Court. *See Cooper Indus., Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424, 435, 437, 441 (2001). Due process prohibits the imposition of arbitrary punishments, and "[e]lementary notions of fairness enshrined in our constitutional jurisprudence dictate that a person receive fair notice . . . of the conduct that will subject him to punishment." *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 574 (1996). The '"point of due process – of the law in general – is to allow citizens to order their behavior. A State can have no legitimate interest in deliberately making the law so arbitrary that citizens will be unable to avoid punishment based solely upon bias or whim.'" *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 418 (2003) (citation omitted). Where a defendant has ordered its behavior in a way it justifiably believed to be reasonable and lawful, the infliction of punishment for that conduct "depart[s] from the fundamental principles of justice embraced in the recognized conception of due process of law" and is "so plainly arbitrary and oppressive as to be nothing short of a taking of [the defendant's] property without due

process of law." *Sw. Tel. & Tel. Co. v. Danaher*, 238 U.S. 482, 490-91 (1915). The Illinois Supreme Court has embraced that same constitutional principle:

> If we held that punitive damages could be awarded in the present case we would be permitting the jury to punish defendants for conduct which they could not have determined beforehand was even actionable. The assessment of punitive damages has some of the same functions as the sanctions of criminal law. The sanctions of the criminal law cannot constitutionally be imposed when the criminality of the conduct is not capable of being known beforehand.

Kelsay, 384 N.E.2d at 360 (citations omitted). Under these principles, prescription drug manufacturers must be permitted to proceed on the principle that if they comply with the FDA's regulations and disclose the risks of their drugs in a manner approved by the FDA as consistent with the extant scientific evidence – even if that evidence is still developing or uncertain – their conduct will not be deemed in hindsight so wanton or reckless as to permit punitive damages.[13]

Due process does not permit punitive damages where, as here, there is a "good-faith dispute" over what course of action should be taken. *See* Dorsey D. Ellis, Jr., *Fairness & Efficiency in the Law of Punitive Damages*, 56 S. Cal. L. Rev. 1, 23 (1982) ("reckless conduct" should be "narrowly defined to exclude reasonable disagreement over the relative danger and utility of an act"). Thus, many courts have barred punitive damages where the defendant complied with government regulations or where experts disagreed over the safety of a product or a genuine dispute existed in the scientific community. *See, e.g.*, *AMPAT/Midwest, Inc. v. Ill. Tool Works Inc.*, 896 F.2d 1035, 1044 (7th Cir. 1990).[14]

---

[13] That is precisely the case here. There is no contention that Wyeth concealed information from the FDA, and the labeling at all times disclosed what was known about the possible risk of breast cancer. The FDA made an informed scientific judgment to approve Prempro and its labeling after extensive review of the scientific data, including data on the risk of breast cancer. The FDA also determined how the label should disclose the risk. *See* Point I.B *supra*. These facts are irreconcilable with Plaintiff's assertions of wanton or reckless disregard and reprehensibility.

[14] *See also Satcher v. Honda Motor Co.*, 52 F.3d 1311, 1317 (5th Cir. 1995) (vacating punitive award where "there is a genuine dispute in the scientific community"); *Burke v. Deere & Co.*, 6 F.3d 497, 511 (8th Cir. 1993) (punitive damages "not appropriate when room exists for reasonable disagreement over

These due process principles do not permit the imposition of punitive damages against Wyeth. The FDA's approval of Prempro, the accompanying breast cancer warnings, and the studies and scientific assessments that supported Wyeth's and the FDA's shared belief that the warnings accurately reflected the known risks, should have precluded punitive damages as a matter of due process. Review by this Court is warranted.

III. THIS COURT SHOULD GRANT REVIEW OF THE SUPERIOR COURT'S ERRONEOUS INCREASE OF THE REMITTED PUNITIVE AWARD

This Court should also review the important issues relevant to the *amount* of the punitive damages award. The jury's $75 million punitive award in this case was remitted to $5.62 million by the trial court, but was increased to $7.49 million by the Superior Court. In increasing the remitted punitive award, the Superior Court committed clear legal error.

The Illinois Supreme Court held in *Slovinski* that, under the applicable abuse of discretion standard, a trial court's remittitur is to be reversed only where "'there is no recognizable basis in the record to support it.'" 927 N.E.2d at 1226 (citation omitted). The Superior Court here disregarded that standard and, relying on the decision of an Illinois intermediate appellate court, stated that "'[t]he underlying question is whether the trial court was correct in ordering the remittitur.'" Op. at 39 (quoting *Leyshon v. Diehl Controls N. Am.*, 946 N.E.2d 864, 876 (Ill. App. Ct. 2010)).

As noted in *Slovinski*, Illinois by statute provides that the "'trial court, may, in its discretion, with respect to punitive damages, determine whether a jury award for punitive damages is excessive, and if so, enter a remittitur.'" 927 N.E.2d at 1225 (quoting 735 Ill. Comp. Stat. Ann. 5/2-1207). An abuse of discretion standard is thus applied by Illinois appellate courts when re-

---

the relative risks and utilities of the conduct at issue"); *Kehm v. Proctor & Gamble Mfg. Co.*, 724 F.2d 613, 623 (8th Cir. 1983) (similar); *Hillrichs v. Avco Corp.*, 514 N.W.2d 94, 100 (Iowa 1994) (similar).

viewing a trial court's determination that a punitive damages award is excessive and any attendant remittitur. *See id.* The law in Illinois, as in Pennsylvania, is clear: "[i]n determining whether there has been an abuse of discretion, we may not substitute our judgment for that of the trial court." *Simmons v. Garces*, 763 N.E.2d 720, 737 (Ill. 2002); *see Hoy v. Angelone*, 554 Pa. 134, 148, 720 A.2d 745, 752 (1998). In determining whether a trial court has permissibly exercised its discretion, the controlling inquiry "may be expressed in a single question: Is there a basis in the record to support the remittitur entered by the circuit court?" *Slovinski*, 927 N.E.2d at 1227. Here, the trial court set forth a basis in the record that supported its remittitur, and the Superior acknowledged that "[u]nder the facts of this case, this court cannot say that the trial court abused its discretion in granting Wyeth's request for remittitur." Op. at 44. Accordingly, it was legal error for the Superior Court to substitute its judgment for the trial court's by increasing the amount of the remitted punitive award by nearly $2 million.

As the Superior Court recognized, the trial court evaluated Wyeth's conduct in light of the record facts, concluding that '"Wyeth's label divulged some (albeit a confusing and misleading) explanation of the possible risks associated with the drug.'" Op. at 43 (citing 1/29/2010 trial court op. at 59). The trial court reasoned that Wyeth's conduct was therefore less blameworthy than the conduct at issue in *Proctor v. Davis*, 682 N.E.2d 1203 (Ill. App. Ct. 1997), where the Illinois Appellate Court determined that remittitur of a $35 million punitive damages award was necessary and lowered the award to $6.09 million, twice the compensatory damages award. Therefore, the trial court here remitted the punitive award to a 1.5:1 ratio that was lower than the 2:1 ratio in *Proctor*. Because that remittitur was supported by the record, it should have been affirmed.

The Superior Court's reasons for increasing the remitted punitive award not only fail to

apply the abuse discretion standard correctly, but they are also improper as a matter of Illinois law. The Superior Court increased the remitted award to punish for Wyeth's purported conduct that, as shown above, was unrelated to Dr. Swingler's prescribing decision, namely Wyeth's purported "'distribut[ion of] ghostwritten materials, tamper[ing] with the medical standard of care, and tout[ing] the benefits of unverified off-label uses.'" Op. at 44 (citing 1/29/2010 trial court op. at 59). *See Batteast*, 560 N.E.2d at 323 (punitive damages can be imposed only for conduct that has "a direct and proximate connection" to Plaintiff's injury); *Kopczick*, 721 N.E.2d at 779 ("Punitive damages must derive from the wrongful conduct giving rise to a cause of action.").

In contrast, in *Proctor*, the defendant's conduct was all relevant to the off-label use (periocular injection) that harmed the plaintiff. The defendant knew of the risk that serious injury could be caused by periocular injection, but gave no warnings and "encouraged the unapproved use" that actually harmed the plaintiff. 682 N.E.2d at 1206-07. Here, Plaintiff was prescribed Prempro for the approved on-label purpose of treating menopausal symptoms, not for the off-label uses purportedly promoted by Wyeth. Moreover, the Superior Court improperly discounted Wyeth's labeling warning of the possible risk of breast cancer, stating it did "not find the fact that Wyeth included a 'confusing and misleading' warning label on its drug downplaying the possible risks to be a meaningful distinction" from *Proctor*. Op. at 44. This analysis improperly disregarded the fact that the Prempro warning label was revised and approved by the FDA, as consistent with the extant scientific data, all of which had been made available to the FDA. *See* Point I.B *supra*. Thus, *Proctor* involved disregard of, and complete failure to warn of, a known risk, while in this case Wyeth warned of the breast cancer risk and had no knowledge of any additional or heightened risk beyond that warned of in its labeling. *See id.* Likewise, in contrast to *Proctor*, Wyeth supported and conducted extensive testing that monitored for the risk at issue.

See Point I.C.1 *supra*. The facts of this case are materially different from the facts in *Proctor*, and *Proctor* does not support the imposition of any punitive damages and certainly does not support the Superior Court's nearly $2 million increase in the remitted punitive damages award.

IV. THE SUPERIOR COURT'S INCREASE OF THE REMITTED PUNITIVE AWARD RAISES IMPORTANT DUE PROCESS ISSUES WARRANTING REVIEW BY THIS COURT

The Superior Court's increase of the remitted punitive damages award to $7.49 million, or a 2:1 ratio to the compensatory award, violates due process constraints on the permissible amount of a punitive damages award. First, the U.S. Supreme Court has held that where, as here, "compensatory damages are substantial," a 1:1 ratio "can reach the outermost limit of the due process guarantee." *State Farm*, 538 U.S. at 425. Since *State Farm*, the Court has reaffirmed the ratio analysis that applies to substantial compensatory awards. *Exxon Shipping Co. v. Baker*, 554 U.S. 471, 514 (2008).[15] Consistent with the Supreme Court's admonitions, courts have reduced punitive awards to amounts equal, or nearly equal, to compensatory awards, even when the harm is personal injury. For example, in *Boerner v. Brown & Williamson Tobacco Co.*, where the defendant's conduct was found to be "highly reprehensible" and where the defendant's cigarettes caused lung cancer and death, the appellate court concluded that remittitur of the jury's $15 million punitive award to $5 million was required given the substantial $4.025 million compensatory award, since "a ratio of approximately 1:1 would comport with the requirements of due process." 394 F.3d 594, 602-03 (8th Cir. 2005).

The ratio guidepost must be applied in support of the principle that an excessive award is

[15] The Court in *Exxon Shipping* summarized its previous punitive damages decisions, stating that the Court "ha[s] announced due process standards that every award must pass," including the rule that "'[w]hen compensatory damages are substantial, then a lesser ratio, perhaps only equal to compensatory damages, can reach the outermost limit of the due process guarantee.'" 554 U.S. at 501, 514 (alteration in original; quoting *State Farm*, 538 U.S. at 425). While the Court's ultimate determination in *Exxon Shipping* was made under federal maritime law, the Court made plain that its adoption of a 1:1 ratio as an "upper limit" in maritime cases was informed by its due process reasoning in *State Farm*. *See id*. at 514.

arbitrary because it "furthers no legitimate purpose" and that punitive damages should not exceed the amount needed "to achieve punishment or deterrence." *State Farm*, 538 U.S. at 417, 419. Excessiveness not only requires assessment of the amount of the punitive damages award itself, but also of the punitive effect of the compensatory damages award. *See id.* at 419 ("[P]unitive damages should only be awarded if the defendant's culpability, after having paid compensatory damages, is so reprehensible as to warrant the imposition of further sanctions to achieve punishment or deterrence."). Here, the Superior Court acknowledged that the "compensatory damages are substantial." Op. at 44. The compensatory award was over $3.7 million, and delay damages of over $1.2 million were also awarded. Op. at 2. These substantial awards already serve the goals of punishment and deterrence. Therefore, from a constitutional standpoint, a near 1:1 ratio was warranted, *see State Farm*, 538 U.S. at 425, and under the facts of this case, the Superior Court's increase of the remitted punitive award to $7.49 million, or a 2:1 ratio, amounted to an arbitrary deprivation of property.[16]

As part of its analysis, the Superior Court observed that "Barton emphasized" – and the trial court noted – "that Wyeth is a pharmaceutical giant with a net worth of over $19 billion." Op. at 42; *see also id.* at 41. Yet, as a matter of due process, "[t]he wealth of a defendant cannot

[16] The reprehensibility and comparable civil penalties guideposts under *State Farm* and *BMW* also do not support the Superior Court's increase of the remitted punitive damages award. As shown above, the "conduct that harmed the plaintiff," *see State Farm*, 538 U.S. at 423, was minimally reprehensible, if at all. The FDA approved Prempro and its labeling, after a thorough review of the testing and scientific data, and Wyeth complied at all times with FDA regulations and requirements. *See* Point I.B *supra*. Plaintiff argued below that the relevant comparable civil penalties were the federal law sanctions enforceable by the FDA wherein the agency has authority to seize misbranded drugs or to enjoin their sale. Those penalties have no relevance here given that Prempro is still approved by the FDA and is still prescribed for hundreds of thousands of women. Significantly, the Illinois Consumer Fraud Act (ICFA) embodies a legislative judgment that conduct that is "specifically authorized by federal law," including FDA-approved prescription drug labeling, should be "protect[ed] . . . from liability under the [ICFA]," *Bober v. Glaxo Wellcome PLC*, 246 F.3d 934, 941 (7th Cir. 2001), rendering the comparable penalty zero. Furthermore, even if the maximum $50,000 penalty provided by the ICFA were deemed the relevant guidepost, that penalty is "dwarf[ed]" by (and almost 150 times less than) the increased $7.49 million punitive damages

justify an otherwise unconstitutional punitive damages award." *State Farm*, 538 U.S. at 427. A defendant's wealth has no bearing on any of the factors identified by the U.S. Supreme Court as relevant to a punitive damages determination, such as reprehensibility, the relationship between the penalty and the harm, and comparable civil penalties. *See Philip Morris v. Williams*, 549 U.S. 346, 351 (2007); *State Farm*, 538 U.S. at 418; *Gore*, 517 U.S. at 575-85.

Further, the defendant's wealth is the product of its businesses as a whole, overwhelmingly derived from conduct that is not challenged as wrongful and that is entirely unrelated to the plaintiff. Due process prohibits punishing a defendant for its lawful conduct. *State Farm*, 538 U.S. at 421; *Gore*, 517 U.S. at 573; *Cooper*, 532 U.S. at 441. Moreover, even where conduct justifies punitive damages, due process "forbids a State to use a punitive damages award to punish a defendant for injury that it inflicts upon nonparties." *Philip Morris*, 549 U.S. at 353. The defendant's wealth is also overwhelmingly derived from business activity outside of Illinois. Due process constrains an "award of punitive damages [that] is based to a significant degree on an accumulation of wealth generated outside the jurisdiction where the wrong was suffered." *Ace v. Aetna Life Ins. Co.*, 40 F. Supp. 2d 1125, 1135 (D. Alaska 1999). Nor may punitive damages be used to punish "the perceived deficiencies of [defendant's] operations throughout the country." *State Farm*, 538 U.S. at 420.

On multiple levels, the Superior Court's increase of the remitted punitive award was improper and violated due process. The issues raised by the Superior Court's decision are important and, given their constitutional due process dimensions, can transcend the application of any particular state's law. This case presents an appropriate vehicle for this Court to address, for the first time, the issue of remittitur of punitive damages in pharmaceutical and mass tort cases.

---

award, underscoring the excessiveness of the increased award. *See State Farm*, 538 U.S. at 428.

V. THIS COURT SHOULD REVIEW THE SUPERIOR COURT'S ERRONEOUS ADOPTION OF AN UNPRECEDENTED LEGAL THEORY OF PRESUMED RELIANCE

The Superior Court disregarded controlling Illinois Supreme Court precedent in ruling that extensive and unfairly prejudicial evidence of marketing, off-label promotion, and "ghost-written" articles was admissible to show liability. *See, e.g.*, Op. at 20-21, 25, 44. This evidence tainted the entire trial, and admitting it was reversible error because the record refutes any sufficient link between this evidence and the decision by Plaintiff's physician, Dr. Swingler, to prescribe HT to Plaintiff.[17] Absent such a link, that evidence is irrelevant and inadmissible. *De Bouse* 922 N.E.2d at 311, 319; *Batteast*, 560 N.E.2d at 323-24. The Superior Court's decision contravenes not only this governing Illinois precedent, but also analogous rulings by this Court and other Pennsylvania courts. This Court should grant review of the Superior Court's erroneous theory of presumed reliance, which, unless reversed, would radically expand tort liability and would have substantial, adverse policy consequences on the development and availability of prescription drugs.

Dr. Swingler, an OB/GYN who teaches at medical school, developed his "appreciation for [Prempro's] potential [off-label] benefits" "based on what the research was showing" in medical journals. R. 5233-34a. Dr. Swingler testified that scientific studies suggested that HT may reduce the severity of Alzheimer's diseases and confer heart benefits. R. 5221-22a, 5255a, 5265a. The Superior Court acknowledged that "Dr. Swingler testified that he did ***not*** prescribe Prempro to Barton based on *any* specific marketing by Wyeth" and "was unable to pinpoint the source of his belief that Prempro had substantial off-label benefits." Op. at 20-21, 25 (emphasis added). There is *no* evidence that Dr. Swingler relied upon any Wyeth marketing or other mate-

[17] Dr. Swingler "function[ed] as a learned intermediary between the prescription drug manufacturer and the patient," and the duty to warn runs to the prescribing physician, not to the particular patient. *Kirk v. Michael Reese Hosp. & Med. Ctr.*, 513 N.E.2d 387, 392-93 (Ill. 1987).

rials when he prescribed Prempro to Plaintiff or in forming his belief as to off-label benefits.

In the absence of such evidence, the Superior Court made its own speculative findings: that Dr. Swingler's belief in off-label uses of Prempro for the brain or heart "likely originated from Wyeth's marketing efforts" and "certainly . . . was rooted, at least indirectly, in Wyeth's active promotion of its product." *Id.* at 21, 25. From this wholesale conjecture, the Superior Court concluded that Wyeth's alleged marketing conduct was "circumstantial evidence of the source of Dr. Swingler's belief that Prempro had off-label benefits." *Id.* at 21.

The Superior Court's speculative conclusion is refuted by the record and violates controlling precedent. The Illinois Supreme Court's opinion in *Batteast*, which the Superior Court disregarded, is directly on point and should have governed the application of Illinois law in this case. In *Batteast*, the Illinois Supreme Court held that, absent a proven causal link between the plaintiff's marketing evidence and her injury, "the evidence was improperly submitted to the jury" as a matter of law, necessitating a new trial. 560 N.E.2d at 324.

The Illinois Supreme Court reaffirmed this principle in *De Bouse*, in which the plaintiff "fail[ed] to allege that her particular doctor was actually deceived by any of Bayer's advertisements or statements" when prescribing a drug. 922 N.E.2d at 319. The plaintiff instead claimed that the court should presume that her physician was deceived because "'consumers, the medical community, the health care insurance industry, and the public'" were purportedly deceived. *Id.* The Illinois Supreme Court flatly rejected this contention and held that a plaintiff cannot sustain a claim based on marketing conduct by merely "alleg[ing] the deception of unspecified persons having *no demonstrated connection* to her." *Id.* at 318-19 (emphasis added).

Here, the Superior Court adopted the same legal theory that the Illinois Supreme Court specifically rejected in *De Bouse*. The Superior Court refused to apply *De Bouse* on the grounds

that it involved a consumer fraud claim instead of a personal injury claim. Op. at 23, 25. The Superior Court's distinction is unsupported by law or logic. It is a fundamental principle of tort law that a plaintiff must prove a causal connection between her injury and the defendant's conduct that forms the basis for liability, including marketing-related conduct. *De Bouse*, 922 N.E.2d at 316; *Pitts v. Basile*, 219 N.E.2d 472, 475 (Ill. 1966). The Illinois Supreme Court required proof of just such a causal connection between the marketing conduct and the personal injury claimed by the plaintiff in *Batteast*, 560 N.E.2d at 323-24. Thus, whether an injury is personal or economic, Illinois law expressly requires Plaintiff to prove a "proximate," *id.*, and "demonstrated connection" between the injury and marketing conduct. *De Bouse*, 922 N.E.2d at 319. There was no evidence of reliance or any demonstrable causal connection proven here.

The Superior Court refused to apply the principles enunciated by the Illinois Supreme Court and instead relied on an intermediate appellate decision in *Proctor v. Davis*, 682 N.E.2d 1203 (Ill. Ct. App. 1997), which the Superior Court misread and misapplied. *See* Op. at 21-23. The drug manufacturer in *Proctor* sought JNOV on the basis that the particular risk at issue "was too remote to require a warning." 682 N.E.2d at 1211. The court reviewed the defendant's marketing-related conduct to assess its knowledge of this risk and found that "evidence demonstrate[d] that [the defendant] knew or should have known of the risks and dangers attendant to the use of Depo-Medrol, thereby requiring warning." *Id.* at 1215. There are no such issues here, where Wyeth actually warned what was known about the risk of breast cancer in a manner vetted and approved by the FDA, where the marketing evidence was not relevant to show additional knowledge on the part of Wyeth, and where Dr. Swingler learned of the risk of breast cancer associated with HT not only from the label but also in medical school and in the medical literature. *See supra* at 3-4, 14-15, 26-27, 36-37. Moreover, in *Proctor*, unlike here, issues of the admissi-

bility of marketing evidence and presumed reliance by the doctor were neither raised nor addressed. The Superior Court plainly erred by looking to (and misreading) *Proctor* instead of following directly relevant decisions by the Illinois Supreme Court in *Batteast* and *De Bouse.*

The Superior Court's decision is also inconsistent with decisions by Pennsylvania courts. This Court has held that "[t]here is no authority which would permit a private plaintiff to pursue an advertiser because an advertisement might deceive members of the audience and might influence a purchasing decision when the plaintiff himself was neither deceived nor influenced." *Weinberg v. Sun Co.*, 565 Pa. 612, 617-18, 777 A.2d 442, 446 (2001). Likewise, in *Clark v. Pfizer*, the court rejected a presumption of reliance in the pharmaceutical context, holding that plaintiffs must '"demonstrate *doctor-by-doctor* that defendants' fraudulent misrepresentations or omissions . . . *caused the doctor to prescribe the medicine*.'" 2010 PA Super 6, 990 A.2d 17, 27 (2010) (citation omitted) (emphasis added). As with the Illinois Supreme Court's decision in *DeBouse*, the Superior Court distinguished *Clark* on the basis that it was not a personal injury case. Op. at 25. That distinction is irrelevant. Contrary to the Superior Court's opinion, "[e]vidence of Wyeth's marketing campaign" was not "relevant to show negligent failure to warn" (Op. at 25), unless there was some proximate causal connection between the marketing campaign, the purported failure to warn, and Plaintiff's injury. The Superior Court's holding that, despite Dr. Swingler's testimony that "he did not prescribe Prempro to Barton based on any specific marketing by Wyeth" (Op. at 25), his beliefs about Prempro and its potential benefits were "rooted, at least indirectly, in Wyeth's active promotion of its product" (Op. at 25) is an impermissible presumption of reliance and of a proximate connection between Wyeth's marketing and Dr. Swingler's prescribing decision. That presumption of reliance is directly contrary to *Clark,* and the inconsistency between the Superior Court's opinions in this case and in *Clark* merits re-

view by this Court.

Here, the Superior Court's erroneous theory of presumed reliance pervaded its analysis of both compensatory and punitive damages issues. If that theory is left to stand, evidence of unrelated conduct will continue to be a central focus in HT trials and in other pharmaceutical and products liability cases in the Pennsylvania courts, causing unfair prejudice to defendants. Review by this Court is warranted to correct the Superior Court's misinterpretation of binding legal authority and to remedy the unjust result in this case.

VI. THIS COURT SHOULD REVIEW THE SUPERIOR COURT'S AFFIRMANCE OF THE ADMISSION OF THE TESTIMONY OF PLAINTIFF'S REGULATORY EXPERT DR. CHERYL BLUME

The Superior Court also committed reversible legal error in affirming (Op. at 38) the trial court's decision to permit Plaintiff's expert, Cheryl Blume, Ph.D., a pharmacologist, to testify as to her subjective opinion that Wyeth should have conducted more studies about the possible risk of breast cancer from HT and thus deviated from a standard of "reasonable" care. *See, e.g.*, R. 2403-04a, 3142-48a. The Prempro MDL court and other courts have excluded Dr. Blume's "reasonable company" testimony, holding that it is speculative and lacks any objective standard.[18] As the MDL court found, Dr. Blume's opinions rested largely on what she "believe[s] Defendants *could have done*" instead of "what industry or governmental standards *require them to do*." *Wilson*, slip op. at 4 (emphasis added).

[18] *See, e.g., Wilson v. Wyeth*, No. 3:05CV78-WRW, Order at 4 (E.D. Ark. Sept. 16, 2010), (MDL court excluding Dr. Blume's "reasonable" company testimony), *aff'd*, Order at 1 (E.D. Ark. Sept. 23, 2010); *Vance v. Wyeth*, No. 06-C-351P, slip op. at 4 (W. Va. Cir. Ct. Aug. 13, 2010) (Dr. Blume was "unable to point to any objective standard establishing the reasonable standard of care"); *Esposito v. Wyeth*, No. 05-1606-CI-13, slip op. at 3 (Fla. Cir. Ct. Apr. 15, 2010) (excluding Dr. Blume's testimony as to her "personal conclusions about the reasonableness or unreasonableness of [Wyeth's] conduct"); *Cross v. Wyeth*, No. 8:06-cv-429-T-23AEP, slip op at 11 (M.D. Fla. Aug. 10, 2011) (excluding as "irrelevant" Dr. Blume's "testimony about research that a 'reasonable' pharmaceutical company would have performed on a hormone therapy product"); *Allen v. Wyeth*, No. 4:04-CV-507-Y, slip op at 4 (N.D. Tex. Jan. 12, 2012) (Dr. Blume did not "cite to any specific statute, regulation, custom or practice that supports [her] 'failure to test opinions.'").

Dr. Blume in this case also failed to base her "reasonable company" opinion on any objective standard – she did not rely upon any specific government regulations, nor she did delineate any agreed-upon or *de facto* industry standard, but merely referred vaguely to FDA regulation as a source of industry standards. *See, e.g.*, R. 2285-86a. Likewise, although Dr. Blume identified PhRMA as an industry group to which Wyeth belonged and claimed that PhRMA "develop[ed] standards for the proper development, marketing and advertising" of pharmaceutical products (*id.*), Dr. Blume never identified any actual standards created by PhRMA or related her opinions to any specific PhRMA standard. Moreover, although Dr. Blume repeatedly cited the WHI as a study that a "reasonable company" would have done (*see, e.g.*, R. 2399-402a, 3028-31a), she conceded that when the WHI was developed, "[i]t [wa]s doubtful" whether the study could "clearly define" the relationship between HT and breast cancer. R. 3095-96a. She made no showing that Wyeth or any other drug company actually could have carried out the WHI or that any drug company had ever carried out a study of that scope, much less that industry customs or regulatory standards required it to do so.

To the extent Dr. Blume attempted to rely on her own experience – which does not include experience working at the FDA – she never connected her purported experience to her opinions, or explained how any such "experience lead to [her] conclusions, why [her] experience is a sufficient basis for [her] opinions," or "how [her] experience is reliably applied to the facts of this case." *Allen*, slip op. at 4. As the MDL court held, Dr. Blume's purported "expertise does not qualify [her] to provide a jury with a reasonable standard of care or a custom or practice, for no other reason than one has not been shown to exist." *Wilson*, slip at 4.

A standard of care must be an objective one that can be known and followed at the time of the conduct at issue, not one that, like Dr. Blume's, judges conduct based on the "clarity of

hindsight." *See Yates v. Shackelford*, 784 N.E.2d 330, 338 (Ill. App. Ct. 2002). As this Court has long recognized, while "[h]indsight is better than foresight . . . and it is easy to criticize after the event . . . the law holds men responsible only for such consequence as can, in the exercise of reasonable prudence, be foreseen." *Small v. Pittsburg Rys. Co.*, 216 Pa. 584, 589, 66 A. 76, 78 (1907); *see also Mutter v. Slaymaker*, 404 Pa. 369, 376, 171 A.2d 779, 782 (1961) ("Hindsight isn't the test of negligence . . . . 'What would have been wise, simply in view of what is learned after an occurrence like this, is no criterion of care.'") (citation omitted).

The issues as to the admissibility of Dr. Blume's "reasonable company" testimony are of importance not only in this case and in other HT cases, but also in the many other types of cases in which parties may seek to introduce similar expert testimony. This Court's review of these issues is warranted.

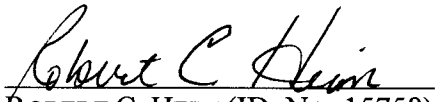
CONCLUSION

For all the foregoing reasons, Wyeth respectfully requests the Court to allow this appeal.

OF COUNSEL:

SHEILA L. BIRNBAUM
SKADDEN, ARPS, SLATE,
MEAGHER & FLOM LLP
Four Times Square
New York, New York 10036-6522
(212) 735-3000

STEVEN GLICKSTEIN
KAYE SCHOLER LLP
425 Park Avenue
New York, New York 10022-3598
(212) 836-8000



ROBERT C. HEIM (ID. NO. 15758)
JUDY L. LEONE (ID. NO. 41165)
DECHERT LLP
Cira Centre
2929 Arch Street
Philadelphia, Pennsylvania 19104-2808
(215) 994-2570

Counsel for Defendant-Petitioner
Wyeth Defendants

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on this day I caused a true and correct copy of the foregoing Petition for Allowance of Appeal to be served upon the following opposing counsel via first-class mail:

Michael J. Quirk
Esther Berezofsky
Kevin Haverty
Samuel Abloeser
WILLIAMS CUKER BEREZOFSKY LLC
1515 Market Street, Suite 1300
Philadelphia, PA 19102

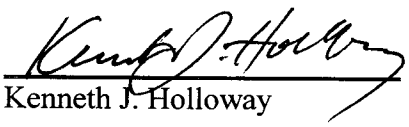
Howard J. Bashman
2300 Computer Ave
Suite G 22
Willow Grove, PA 19090

Robert K. Jenner
JANET, JENNER & SUGGS, LLC
Commerce Centre East
1777 Reisterstown Road
Suite 165
Baltimore, MD 21208

Tobias L. Millrood
POGUST BRASLOW & MILLROOD LLC
8 Tower Bridge, Suite 1520
161 Washington Street
Conshohocken, PA 19428

Michael T. Scott
Andrew J. Trevelise
REED SMITH LLP
2500 1 Liberty Pl.
1650 Market St.
Philadelphia, PA 19103

James A. Morris, Jr.
MORRIS LAW FIRM
11614 Bee Caves Road, Suite 220
Austin, TX 78738



Kenneth J. Holloway

Dated: April 12, 2012