IN THE

Supreme Court of Pennsylvania

No. _____, E.A.L. 2011
(Superior Court No. 2626 EDA 2007)

MARY and THOMAS DANIEL,

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 February 7, 2011, at No. 2626 EDA 2007, Reargument Denied, April 14, 2011, Reversing the Orders of the Court of Common Pleas of Philadelphia County, Entered January 30, 2007, February 2, 2007, and August 24, 2007, at June Term, 2004, No. 2368.

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REFERENCE TO THE OPINIONS DELIVERED IN THE COURTS BELOW

On April 23, 2007, the Court of Common Pleas of Philadelphia County (Field, J.) filed its opinion (attached as App'x A) in support of its January 30, 2007 order granting Wyeth's motion for judgment notwithstanding the verdict (JNOV) on Plaintiffs' punitive damages claims (R. 3a).

On September 24, 2008, the Court of Common Pleas of Philadelphia County (Tereshko, J., who was assigned the case after Judge Field died) filed its opinion (attached as App'x B) explaining its August 24, 2007 order granting Wyeth's supplemental motion for post-trial relief based on after-discovered evidence (R. 21a-23a).

On February 7, 2011, the Superior Court issued its opinion (Donohue and Allen, JJ., with Fitzgerald, J. concurring), which reversed the Court of Common Pleas and denied Wyeth's cross-appeal (attached as App'x C, hereinafter referred to as "Op."). The Superior Court's opinion is reported as *Daniel v. Wyeth Pharmaceuticals, Inc.*, 2011 PA Super 23, 15 A.3d 909 (Pa. Super. Ct. 2011), *pet. for reh'g denied* (Pa. Super. Ct. Apr. 14, 2011). On April 14, 2011, the Superior Court denied Wyeth's application for reargument (attached as App'x D).

TEXT OF THE ORDER IN QUESTION

No separate judgment order accompanied the Superior Court's February 7, 2011 opinion. That opinion stated, in pertinent part:

> For these reasons, the trial court's order dated August 24, 2007 granting Wyeth's post-trial motion for a new trial is hereby reversed, and the jury's verdict on compensatory damages is reinstated. Likewise, the trial court's order dated January 30, 2007 granting Wyeth's post-trial motion for JNOV on punitive damages is also reversed, and the jury's verdict awarding punitive damages is reinstated. Wyeth's cross-appeal is denied. (App'x C at 55.)

QUESTIONS PRESENTED FOR REVIEW

1. Whether the Superior Court erred in reversing the trial court's grant of JNOV for Wyeth on Plaintiffs' punitive damages claim under Pennsylvania law, where (a) the FDA exten-

sively reviewed and approved the prescription drug at issue, the sufficiency of the testing for that drug, and the drug's 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 drug was extensively tested and studied by Wyeth and independent researchers?

2. Whether the Superior Court erred in holding *sua sponte* that Wyeth waived its right to challenge the amount of the $8.6 million punitive damages award – despite the fact that the trial court never ruled or entered judgment on Wyeth's pending motion for remittitur?

3. Whether the Superior Court erred in stating that, under Pennsylvania choice-of-law rules, punitive damages are governed by the law of the state where the defendant is headquartered, rather than by the law of the state where the plaintiff purchased and used the product and was injured?

4. Whether the Superior Court erred in this prescription drug case based on an alleged failure to warn, by failing to follow prior Superior Court precedent requiring Plaintiffs to prove proximate cause by offering evidence establishing that a different warning would have changed Plaintiff's physician's decision to prescribe the medication for her?

5. Whether the Superior Court erred in holding that the trial court abused its discretion by granting Wyeth's motion for new trial where Plaintiffs' counsel offered at trial deposition testimony of a medical causation expert who, unknown to Wyeth and the trial court, had recanted his causation opinion prior to trial?

CONCISE STATEMENT OF THE CASE

Prempro is a hormone therapy (HT) prescription drug manufactured by Wyeth and indicated for use in relieving the often debilitating symptoms associated with menopause and to prevent osteoporosis. R. 1212a-13a. Prempro was approved by the FDA as safe and effective for

these uses (R. 1353a) and is still prescribed today to hundreds of thousands of women. 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. R. 1214a-16a. These warnings as to the risk of breast cancer were accurate based on the extant scientific evidence, and their content and wording were specifically approved by the FDA. *Id.*; R. 1328a, 1332a-33a, 1353a. As the trial court found, "'the admissions of [Plaintiffs'] own experts established that Wyeth complied with all federal regulations regarding the testing and labeling for Prempro and at all times provided warnings regarding the risk of breast cancer that were consistent with extant science.'" Op. at 44 (quoting 4/23/07 Trial Ct. Op. at 4).

Dr. John Haggard, an Arkansas physician, prescribed Prempro for Plaintiff Mary Daniel, an Arkansas resident. R. 760a-61a, 766a-67a; Tr. 1/17/07 AM at 4. Mrs. Daniel took Prempro every other day for a total of less than 18 months. R. 791a. In August 2001, Mrs. Daniel was diagnosed with breast cancer. R. 47a. Mrs. Daniel and her husband, also an Arkansas resident, filed suit against Wyeth in Philadelphia in 2004. R. 41a; Tr. 1/17/07 PM at 63-64. Plaintiffs allege that Wyeth's breast cancer warnings were inadequate, claiming that if Wyeth had conducted further testing of Prempro, it would have had greater knowledge of the risk of breast cancer and could have given stronger warnings. Importantly, Plaintiffs do not allege (nor is there any evidence) that the warnings accompanying Prempro misrepresented the scientific information 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 case was tried before the late Judge Myrna Field. In the first phase of the trial, the jury awarded $1,000,000 in compensatory damages to Mrs. Daniel and $500,000 to Mr. Daniel for loss of consortium and found Wyeth liable for punitive damages. Tr. 1/29/07 at 26-27. The

trial court granted Wyeth's motion for JNOV as to punitive damages because "[t]here was no evidence introduced at trial that Wyeth's conduct with regard to Prempro was outrageous, because of an evil motive, or in reckless disregard for patient safety." App'x A at 4. To avoid the need for a retrial in the event JNOV was reversed, the trial court proceeded to conduct a second phase of the trial, permitting the jury to determine an amount of punitive damages. *Id.* at 2. The trial court sealed the jury's Phase II verdict. *Id.* Wyeth moved orally for remittitur of the $8.6 million punitive damages award[1] and, at the trial court's request, formalized its motion in writing. In that motion, which Wyeth entitled a "Preservation Motion," Wyeth stated that it believed that, given the trial court's grant of JNOV on punitive damages, the issue of remittitur was not ripe and would become ripe only if the Superior Court reinstated the verdict on punitive damages. Wyeth's Preservation Mot. for Remittitur, Dkt. Entry Feb. 1, 2007, at 2. In response, Plaintiffs told the trial court that they would fully respond to Wyeth's remittitur motion after the Superior Court had ruled on the underlying issues. Pls. Resp. to Wyeth's Mot. for Remittitur, Dkt. Entry Feb. 12, 2007, at 2. The trial court did not rule on Wyeth's remittitur motion.

Wyeth also timely filed motions seeking JNOV on causation and liability for failure to warn or, in the alternative, a new trial. R. 173a-202a. Wyeth argued that it was entitled to JNOV because there was no evidence that a different breast cancer warning would have caused Dr. Haggard to decide not to prescribe Prempro for Mrs. Daniel, as is required to establish proximate causation. R. 192a. The trial court denied Wyeth's motions. R. 5a-6a.

Wyeth subsequently learned that one of Plaintiffs' causation experts, Dr. Lester Layfield, had recanted his causation opinion before trial – a fact that Plaintiffs' counsel knew but did not disclose to Wyeth or the trial court. Plaintiffs' counsel presented the recanted opinion to the jury

[1] Coordinating Judge Sandra Mazer Moss issued an order, docketed on May 13, 2011, that lifted the seal

by introducing Dr. Layfield's pretrial deposition testimony that HT caused Mrs. Daniel's breast cancer. On August 24, 2007, Judge Allan L. Tereshko, who had taken over the case from Judge Field, granted Wyeth's motion for a new trial based upon the misconduct of Plaintiffs' counsel and the after-discovered evidence. R. 21a-23a.

Plaintiffs appealed the trial court's orders granting JNOV on punitive damages and a new trial on the basis of subsequently-discovered evidence. Wyeth cross-appealed, arguing that it was entitled to JNOV as to liability. On February 7, 2011, the Superior Court, in an opinion written by Judge Donohue, reversed the trial court's order granting JNOV as to punitive damages, reinstated the jury's punitive damages award, held that Wyeth had waived its right to challenge the amount of the punitive award, reversed the trial court's order for a new trial based on after-discovered evidence, and denied Wyeth's cross-appeal. App'x C. On April 14, 2011, the Superior Court denied Wyeth's application for rehearing. App'x D.

REASONS FOR ALLOWING AN APPEAL

This Court should grant review to address the important issues of Pennsylvania law and public policy raised by the Superior Court's reinstatement of the $8.6 million punitive damages award. This Court has never addressed the legal standard for an award of punitive damages in a prescription drug personal injury case. The issues of Pennsylvania punitive damages law raised herein will affect hundreds, if not thousands, of HT and other prescription pharmaceutical cases pending in Pennsylvania courts. Permitting punitive damages in these circumstances also raises urgent public policy concerns regarding the potential detrimental and long-lasting effects on the development, availability, and cost of prescription drugs. Review by this Court is essential to provide necessary guidance to Pennsylvania trial and intermediate appellate courts confronted by

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on the amount of the punitive damages verdict.

the same or similar issues as are presented by this case.

The Superior Court's decision, if allowed to stand, will create an unprecedented expansion of liability for punitive damages under Pennsylvania law in prescription drug cases. The Superior Court improperly permitted punitive damages to punish conduct that was extensively regulated, rigorously scrutinized, and approved by the FDA with complete knowledge of the scientific data. The undisputed record established that Wyeth's testing of Prempro complied in all respects with the FDA's regulations and requirements and that Prempro's labeling, which at all times disclosed the possible risk of breast cancer, was consistent with the extant science and specifically approved by the FDA. Unlike other prescription drug litigation, there was no allegation or evidence here that Wyeth concealed information from or misled the FDA or knew that the risk of breast cancer was greater than was disclosed in its warnings. Thus, the undisputed record precludes a finding that Wyeth had a "subjective appreciation" of the risk of harm that was different than that of the FDA or the wider scientific community and acted in "conscious disregard" of that "known risk," as required for punitive damages under Pennsylvania law. *See Hutchison ex rel. Hutchison v. Luddy*, 582 Pa. 114, 123-24, 870 A.2d 766, 771-72 (2005).

The Superior Court nevertheless erroneously held that Wyeth's purported failure to perform "additional studies" that were "required to understand the possible association" between Prempro and breast cancer (Op. at 47) warranted punitive damages. Wyeth's alleged failure to test adequately to "understand" the risk of breast cancer does not as a matter of law meet the standard set by this Court of "conscious disregard" of or "'indifference'" to a "*known* risk." *See Hutchison*, 582 Pa. at 123-24, 870 A.2d at 771-72 (emphasis added).[2] Further, in reinstating pu-

[2] On March 15, 2011, this Court granted cross petitions for allowance of appeal raising, *inter alia*, the issue of whether it was error for the Superior Court to hold "that Pennsylvania law would not recognize a claim against a prescription drug manufacturer for negligent failure to test to discover a prescription drug's actual harmful side-effects." *Lance v. Wyeth*, Nos. 600 & 610 EAL 2010, 15 A.3d 429, 429 (Pa.

nitive damages based upon Wyeth's alleged failure to test, the Superior Court improperly disregarded undisputed evidence of the many tests and studies actually conducted and supported by Wyeth, as well as the FDA's determination that "adequate tests by all methods reasonably applicable" had been done. *See, e.g.*, Op. at 48. The Superior Court committed legal error in limiting the scope of its review, contrary to this Court's repeated admonitions that consideration of all the circumstances is required to determine whether a punitive damages award may stand.

This Court should also grant review to correct the Superior Court's erroneous determination, made *sua sponte* and without briefing by the parties, that Wyeth waived its right to challenge the amount of the $8.6 million punitive damages award. That ruling was manifestly improper in light of the fact that there had been no ruling or judgment entered by the trial court on Wyeth's motion for remittitur. The Superior Court's finding of waiver is contrary to accepted judicial practice and raises issues of fundamental fairness that merit this Court's consideration.

In addition, review of the Superior Court's erroneous punitive damages choice-of-law analysis is warranted. Although Mrs. Daniel is an Arkansas resident, on appeal neither party contested the application of Pennsylvania law to her punitive damages claim. The Superior Court nevertheless addressed the issue, stating that "Pennsylvania choice of law rules *require* the application of Pennsylvania punitive damages law" because the conduct that was the basis for the punitive damages claim took place at Wyeth's Pennsylvania offices. Op. at 54-55 n.17 (emphasis added). This attempt to fashion a binding precedent for all HT cases will substantially disrupt the hundreds of cases already pending in the Pennsylvania trial courts, which have been proceeding under a ruling by the coordinating judge that the law of the plaintiff's home state presump-

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2011). This Court's ruling on the failure to test issues in *Lance* may provide clarification on related issues in this case. *See, e.g.*, Point I.B *infra*. Wyeth requests that this Petition be granted for the reasons stated herein. If, however, the Court is not inclined to do so at this time, Wyeth respectfully requests that this Court hold this Petition in abeyance pending the Court's resolution of the failure to test issues in *Lance*.

tively applies. The Superior Court's choice-of-law ruling is harmful to consumers and manufacturers, is contrary to the vast weight of authority, and warrants review by this Court.

The Superior Court also applied an incorrect legal standard in affirming the denial of JNOV for Wyeth as to proximate causation because Plaintiffs presented no evidence that a different warning would have caused Mrs. Daniel's physician to change his decision to prescribe Prempro for her. Mrs. Daniel's physician testified only that, if the warning had been different, the risks of Prempro "might have been more emphasized" by him and his discussion with Mrs. Daniel "[p]robably" would have been different. Tr. 1/17/07 PM at 35. The Superior Court's finding that proximate cause was established on this evidence is directly contrary to prior Superior Court precedent that expressly rejects such a theory of proximate cause.

The Superior Court further erred in reversing the trial court's grant of a new trial based on the trial court's finding that the causation opinion of one of Plaintiffs' expert witnesses, which was presented to the jury by a reading of his deposition, had been recanted before trial. The trial court found that Plaintiffs' counsel knew that the expert had changed his opinion and withheld that fact from the court and that the deposition testimony read to the jury was tainted and a new trial required. Rather than reviewing the record under the appropriate abuse of discretion standard to determine whether the trial court's reasoning was supported, the Superior Court impermissibly did the opposite by searching for arguments to supplant the trial court's decision. The Superior Court's improper reversal of the grant of a new trial warrants review by this Court.

I. THIS COURT SHOULD GRANT REVIEW TO RESOLVE IMPORTANT ISSUES RAISED BY THE SUPERIOR COURT'S REINSTATEMENT OF THE PUNITIVE DAMAGES AWARD

The Superior Court's reinstatement of the $8.6 million punitive damages award in this case improperly creates an enormous expansion of liability for punitive damages under Pennsylvania law in prescription pharmaceutical cases. The Superior Court's decision also presents legal

issues of first impression for this Court that 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, (ii) the availability of punitive damages based on a theory of failure to test adequately, rather than disregard of a known risk, and (iii) the scope of review required for a punitive damages award. Because similar issues are raised in hundreds, if not thousands, of other prescription drug cases pending in Pennsylvania courts, there is a need for prompt and definitive resolution by this Court of the fundamental questions of law and policy raised herein.

A. The Uncontroverted Facts Regarding Wyeth's Compliance with FDA Requirements and Procedures Render Punitive Damages Improper as a Matter of Pennsylvania Law

The imposition of punitive damages in this case is contrary both to public policy and to existing Pennsylvania punitive damages law. As the trial court found, "'the admissions of [Plaintiffs'] own experts established that Wyeth complied with all federal regulations regarding the testing and labeling for Prempro and at all times provided warnings regarding the risk of breast cancer that were consistent with extant science.'" Op. at 44 (quoting 4/23/07 Trial Ct. Op. at 4). There is no allegation or evidence that Wyeth misled the FDA or concealed any information from the FDA regarding the potential risk of breast cancer from taking Prempro. Indeed, Prempro continues to be approved by the FDA and prescribed today.

Plaintiffs did not point to any deficiency in the FDA's regulation of Prempro, including the FDA's approval of the breast cancer warning. Plaintiffs' expert Dr. Cheryl Blume testified that she "never criticized the FDA" for its approval of Prempro and its labeling (Tr. 1/11/07 AM at 43), including the FDA's determination that "adequate information ha[d] been presented [by Wyeth] to demonstrate that the drug products are safe and effective for use as recommended in the submitted draft labeling." R. 1353a. Despite this acknowledgement, Plaintiffs contend that

Wyeth's testing and labeling of Prempro were so outrageous as to merit punitive damages.

Wyeth submits that, 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 are fundamentally inconsistent with, and foreclose, a finding that Wyeth had a "subjective appreciation of [a] risk of harm" greater than was disclosed in its labeling and acted "in conscious disregard of that risk," as required for punitive damages under Pennsylvania law. *See Hutchison*, 582 Pa. at 124, 870 A.2d at 772. Indeed, 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."[3] *Phillips v. Cricket Lighters*, 584 Pa. 179, 191-92, 883 A.2d 439, 447 (2005); *see also* W. Page Keeton et al., *The Law of Torts* § 36, at 233 n.41 (5th ed. 1984) ("In most contexts . . . compliance with a statutory standard should bar liability for punitive damages.").[4]

The FDA regulations, procedures and requirements applicable to prescription drugs such as Prempro go far beyond the safety standards generally applicable to other types of products. In contrast to regulatory schemes for other industries, which often rely on industry self-compliance,

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[3] *Phillips* involved unspecified "safety standards" for cigarette lighters. It did not involve a regulatory program comparable to the FDA's regulatory and oversight regime.

[4] *Accord Sloman v. Tambrands, Inc.*, 841 F. Supp. 699, 703 & n.8 (D. Md. 1993) (dismissing punitive damages claim for failure to warn where, *inter alia*, defendant "complied with federal [FDA] regulations"); *Richards v. Michelin Tire Corp.*, 21 F.3d 1048, 1059 (11th Cir. 1994) (courts have "repeatedly held that the issue of punitive damages should not go to the jury when a manufacturer takes steps" pursuant to government regulations "to warn the plaintiff of the potential danger that injured him"); *Nader v. Allegheny Airlines, Inc.*, 626 F.2d 1031, 1035 (D.C. Cir. 1980) (a defendant "may not be condemned as a wanton wrongdoer for conforming to the standards set and the practices approved by the agency charged with the duty of regulating it" – "standards and practices that the agency has found to be in the public interest"). Wyeth is not making a preemption argument, nor are the decisions cited herein based on preemption. Rather, regulatory compliance (and particularly compliance with FDA regulations) negates the intentional or reckless disregard required for punitive damages.

all prescription drugs must pass the FDA's "extensive regulatory scheme" before being approved for use. *Grundberg v. Upjohn Co.*, 813 P.2d 89, 96-97 (Utah 1991). The FDA standard for pre-approval testing is rigorous: the applicant must establish that "adequate tests by all methods reasonably applicable" have been conducted. 21 U.S.C. § 355(d). "Like the testing requirements, the federal labeling requirements [for prescription drugs] are extensive." *White v. Weiner*, 386 Pa. Super. 111, 124, 562 A.2d 378, 385 (1989), *aff'd mem.*, 525 Pa. 572, 583 A.2d 789 (1991). Thus, as a leading commentator has explained, a pharmaceutical company that has complied with the FDA's "extremely stringent regulation" should not be subject to punitive damages:

> Corporations presumably should never be subject to punitive damages for products passing a governmental risk analysis. The pharmaceutical industry provides a valuable case study in this regard because its products are subject to extremely stringent regulation by the [FDA]. In particular, all new drugs must meet rigid standards for safety and efficacy and appropriate risk-balancing criteria before the agency approves them.
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> . . . .
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> Drugs are typically not risk-free, and prescription drugs are available by prescription only because of their risks. Before approving the drug, the FDA in effect makes a risk-benefit judgment that making the drug available is in society's best health interest.

W. Kip Viscusi, *Corporate Risk Analysis: A Reckless Act?*, 52 Stan. L. Rev. 547, 579-80 (2000); *see* 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.").

In reinstating the punitive damages award, the Superior Court disregarded the findings of the trial court and improperly discounted Wyeth's compliance with FDA requirements and the FDA's scrutiny and approval of Prempro, relying on Plaintiffs' expert's characterization of FDA requirements as "'minimum standards.'" Op. at 47 (citation omitted). In fact, the FDA's requirements are "minimum" only in the sense that States through their tort law may require stronger warnings than the FDA. *See Wyeth v. Levine*, 129 S. Ct. 1187, 1196-99, 1201-04 (2009).

In every other respect, FDA requirements are far from "minimal." It is beyond serious dispute that prescription drugs "are today the most heavily regulated consumer products in our society . . . from the standpoint of regulatory control over their development and marketing," J. Richard Crout, *The Drug Regulatory System: Reflections and Predictions*, 36 Food Drug Cosm. L.J. 106, 113 (1981), and "[n]o other class of products is subject to such special restrictions or protections." *Grundberg*, 813 P.2d at 96. The "FDA exercises effectively unchallengeable authority to dictate the number and kinds of studies required to support approval [of a drug] and nearly unreviewable discretion to interpret the results." Richard A. Merrill, *The Architecture of Gov't Regulation of Med. Prods.*, 82 Va. L. Rev. 1753, 1782 (1996). Drug labeling is also "comprehensively and meticulously controlled" by the FDA, Richard M. Cooper, *Drug Labeling & Products Liability: The Role of the Food & Drug Admin.*, 41 Food Drug Cosm. L.J. 233, 233 (1986), and it is "virtually impossible to market a new [drug] without the FDA's review and concurrence." Merrill, 82 Va. L. Rev. at 1753. Obtaining FDA approval involves not only extensive procedures and requirements, but also enormous expense for the applicant. *See, e.g.*, James A. Henderson, Jr. & Aaron D. Twerski, *Drug Designs Are Different*, 111 Yale L.J. 151, 164-66 (2001).

Here, before it approved Prempro in 1994, the FDA itself studied the risk of breast cancer associated with HT drugs, drafted breast cancer warnings as a guide for labeling, and required Wyeth to conduct a randomized clinical trial (Wyeth's Pivotal trial, the largest randomized controlled trial of HT at the time, Tr. 1/9/07 PM at 68); convened multiple Advisory Committee meetings to obtain independent expert advice on HT issues, including the possible risk of breast cancer (R. 1356a-60a; DX-177 at 2-5); reviewed Wyeth's 174-volume, 92,000-page Prempro New Drug Application (NDA), which "include[d] a compilation and summary of the available medical literature" (R. 905a; Tr. 1/22/07 AM at 45); and authorized the National Institutes of

Health to use not-yet-approved Prempro in its comprehensive Women's Health Initiative (WHI) study on HT, which was designed to report, *inter alia*, on the incidence of breast cancer. R. 1366a-67a; DX-207 at 2.[5] The FDA medical officer's 87-page review of Wyeth's Prempro NDA cited and relied on more than 38 studies, at least 14 of which addressed the risk of breast cancer, and mandated specific wording for the breast cancer warning in the Prempro labeling. R. 1328a, 1333a, 1335a, 1340a-42a. The FDA continues to approve Prempro as safe and effective, and Prempro is still marketed in the formulation used by Mrs. Daniel. Tr. 1/22/07 AM at 59.

In short, this is not a case where the plaintiff alleges that the defendant hid facts from the regulatory agency. Nor is this a case where the agency's consideration of the safety issues in question was brief or perfunctory. The legal issue, therefore, is not whether regulatory approval "standing alone" precludes punitive damages. *See* Op. at 47. The legal issue is whether the "extreme remedy" (*Phillips*, 584 Pa. at 188, 883 A.2d at 445) of punitive damages is permissible when, as a matter of undisputed fact, the FDA extensively reviewed the exact scientific question being litigated and with complete knowledge of the extant scientific information, resolved that scientific question differently than Plaintiffs' retained expert. *See Martin v. Johns-Manville Corp.*, 508 Pa. 154, 176, 494 A.2d 1088, 1100 (1985) (plurality) (affirming trial court's refusal to submit punitive damages to jury; distinguishing case where defendants "knew conclusively" that their drug caused injury and "failed to advise [FDA] and the medical profession of the danger").[6]

Expanding punitive damages to conduct that was reviewed and approved by the FDA and

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[5] It should be noted that the United States Supreme Court's discussion in *Wyeth v. Levine* of budgeting and staffing issues at the FDA related to the "resources for postmarketing drug safety work." *See Levine*, 129 S. Ct. at 1203 n.11. Moreover, the FDA remained involved in postmarketing surveillance of the possible risk of breast cancer from HT, including designing and approving the WHI. Tr. 1/9/07 PM at 84.

[6] Although *Martin* was abrogated on other grounds by *Kirkbride v. Lisbon Contractors, Inc.*, 521 Pa. 97, 555 A.2d 800 (1989), the *Martin* Court's analysis of punitive damages is still followed by this Court. *See Hutchison*, 582 Pa. at 122 n.7, 870 A.2d at 771 n.7.

that complied with FDA regulations and procedures in every respect, as the Superior Court has done, will substantially – and detrimentally – affect the public interest in the development, availability and cost of prescription drugs. This Court recognized these policy interests in declining to impose strict liability in prescription drug cases, *see Hahn v. Richter*, 543 Pa. 558, 560-63, 673 A.2d 888, 890-91 (1996), concluding that lowering the proof required in such cases would "'ill serve[]'" the public interest. *Incollingo v. Ewing*, 444 Pa. 263, 286-87, 282 A.2d 206, 219 (1971) (quoting *Henderson v. Nat'l Drug Co.*, 343 Pa. 601, 610, 23 A.2d 743, 748 (1942)), *departed from on different grounds, Kaczkowski v. Bolubasz*, 491 Pa. 561, 421 A.2d 1027 (1980).[7] These policy concerns are heightened in the context of punitive damages because punitive damages do not compensate – their only purpose is to punish and deter. *See Hutchison*, 582 Pa. at 123, 870 A.2d at 771. Applied unwisely in prescription drug cases, punitive damages deter the development of new medicines and have "unfortunate consequences" for the cost, availability and advancement of medical care. *See Brown v. Superior Court*, 751 P.2d 470, 479-80 (Cal. 1988).

Pharmaceutical products "present a special combination of circumstances" that increase "the dangers of overdeterrence" from punitive damages:

> They are products with public health benefits that depend heavily on innovation; the regulatory regime carefully balances therapeutic risk and benefit in approving products on a case by case basis; there are inevitably some residual harms that cannot be prevented; there are also pervasive reporting requirements, a comprehensive and detailed regime of regulatory controls, and strong market incentives to generate safer products . . . .

Enterprise Responsibility for Personal Injury, supra, at 103-04. Thus, the "compelling reasons" to preclude punitive damages in cases such as this one include "the chilling effect that punitive

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[7] *See also Henderson*, 343 Pa. at 610, 23 A.2d at 748 ("If those who make and compound drugs and medicines . . . , under the strict conditions prescribed by the National Food and Drug Act . . . for use by the public, can be mulcted in damages every time some person uses such drugs or medicines with harmful results, the making and selling of such products would be a most pecuniariliy hazardous enterprise.").

damages can have on the development of new drugs, the delay that punitive damages can potentially cause in new drugs becoming publicly available, and the increased cost to the public of those drugs once they become publicly available." *Kobar ex rel. Kobar v. Novartis Corp.*, 378 F. Supp. 2d 1166, 1175-76 (D. Ariz. 2005); *see Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 967 (6th Cir. 2004) (punitive damages can "threaten the financial viability of many enterprises and could add substantially to the cost and unavailability of many drugs"). These policy concerns, which are given increased urgency by the large number of HT and other pharmaceutical products liability cases pending in Pennsylvania courts, warrant this Court's review of the punitive award.

B. Wyeth's Purported Failure to Conduct Adequate Testing Does Not Justify Punitive Damages as a Matter of Pennsylvania Law

In reinstating the punitive damages award, the Superior Court did not quarrel with the trial court's findings that "'Wyeth complied with all federal regulations regarding the testing and labeling for Prempro and at all times provided warnings regarding the risk of breast cancer that were consistent with extant science,'" Op. at 44 (quoting 4/23/07 Trial Ct. Op. at 4), or the fact that in approving Prempro, the FDA determined that Wyeth had provided the results of "adequate tests by all methods reasonably applicable" to establish Prempro's safety. *See* 21 U.S.C. § 355(d); *see also* R. 1353a. Nonetheless, the Superior Court held that punitive damages were warranted – not because Wyeth disregarded or failed to warn of a known risk, but because Wyeth failed to conduct further testing of Prempro to ascertain definitively the level of risk. Op. at 47 (finding that, based on the testimony of Plaintiffs' expert Dr. Blume, "a jury could reasonably find that Wyeth knew that additional studies were required to understand the possible association between its products and breast cancer in menopausal women"). The Superior Court expressly discounted the FDA's informed scientific and medical determination that Prempro had been adequately tested, holding that "[i]t was for the jury to decide whether Wyeth had per-

formed adequate testing of its product before marketing it for sale." *Id.* at 48.

The Superior Court's decision is legal error and is contrary to the policy and purposes of Pennsylvania punitive damages law. To permit punitive damages for a drug manufacturer's failure to conduct what a jury deems to be adequate testing will effectively negate the punitive damages requirement under Pennsylvania law that "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*, 582 Pa. at 124, 870 A.2d at 772. Under this standard, a "failure to appreciate the degree of risk from a known danger" is not sufficient for punitive damages, even where "'a reasonable man in [the defendant's] position would do so.'" *Id.* (quoting *Martin*, 508 Pa. at 171, 494 A.2d at 1097). There must be more: "[a]n '*indifference*' to a *known* risk." *Id.* at 123, 870 A.2d at 771 (emphasis added) (quoting *Martin*, 508 Pa. at 171, 494 A.2d at 1097).

Pennsylvania's "known risk" standard is not met by a failure to test, particularly when there is no evidence that Wyeth had a subjective appreciation that the risk was any greater than disclosed on the product label. Here, the labeling warned of the possibility of the risk of breast cancer, and, as the trial court found, the warning was consistent with the extant scientific knowledge. Thus, the conduct punished here did not rise even to the level of "failure to appreciate the degree of risk from a known danger." Rather, Wyeth was impermissibly punished for not doing more to discover the degree of risk from a danger whose existence was the subject of scientific debate.[8] As in *Thomas v. American Cystoscope Makers, Inc.*, 414 F. Supp. 255, 266 (E.D. Pa.

[8] As Wyeth's Prempro warning stated, *inter alia*, in language mandated or approved 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 relationship." R. 1214a; *see* R. 1328a. This warning was revised after the results of the WHI were published.

1976), which this Court quoted with approval in *Martin*, 508 Pa. at 173 n.13, 494 A.2d at 1098 n.13, "the most that can be said from the evidence is that, measured by an objective standard of care, this defendant should have done more," which is insufficient "to demonstrate that subjective kind of awareness that is the distinguishing element of reckless conduct."

Allowing punitive damages in cases such as this one places drug manufacturers at risk of unforeseeable, arbitrary and unavoidable punishments that do not serve the deterrent purpose of punitive damages awards. *See Hutchison*, 582 Pa. at 123-24, 870 A.3d at 771-72; *Feld v. Merriam*, 506 Pa. 383, 395-96, 485 A.2d 742, 747-48 (1984). In the prescription drug context, there are always risks of side effects and always scientific uncertainty, requiring companies and the FDA to make judgments. In the face of genuine disagreement or uncertainty in the scientific or medical community, this Court and many other courts have been unwilling to impose punitive damages for a judgment that turns out to be mistaken. *See, e.g., Martin*, 508 Pa. at 175-77 & n.15, 494 A.2d at 1099-1100 & n.15 (rejecting punitive damages where uncertainties existed as to the level of health risks faced by installers of asbestos-containing products); *Berroyer v. Hertz*, 672 F.2d 334, 341-42 (3d Cir. 1982) (finding "insufficient support for an award of punitive damages" where there was "a difference of medical opinion on the degree of the cancer risk").[9]

Here, Plaintiffs' expert's hindsight disagreement with the judgment of the FDA that ade-

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However, the relative risk of breast cancer reported by the WHI and given in the revised labeling (1.24) was "actually slightly less" than the relative risks of 1.3 to 2.0 given in Wyeth's original Prempro label. Tr. 1/24/07 AM at 104, 107, 135.

[9] *See also AMPAT/Midwest, Inc. v. Ill. Tool Works Inc.*, 896 F.2d 1035, 1044 (7th Cir. 1990) (rejecting punitive damages given the "disagreement between [experts] over the gravity of the defects" in the products); *Satcher v. Honda Motor Co.*, 52 F.3d 1311, 1317 (5th Cir. 1995) (vacating punitive award because "there [was] a genuine dispute in the scientific community"); *Hillrichs v. Avco Corp.*, 514 N.W.2d 94, 100 (Iowa 1994) ("an award of punitive damages is inappropriate when room exists for reasonable disagreement over the relative risks and utilities of the conduct and device at issue"); *Mercer v. Pittway Corp.*, 616 N.W.2d 602, 618 (Iowa 2000) (reversing punitive award against manufacturer of smoke detectors who followed UL standards, because there existed grounds for "reasonable disagreement"); *Burke v. Deere & Co.*, 6 F.3d 497, 511 (8th Cir. 1993) ("An award of punitive damages is not appropriate when

quate testing and information supported the approval of Prempro simply illustrates that scientific judgments can always be second-guessed in light of later scientific developments. If that were a basis for punitive damages, punitive damages could be awarded in virtually every prescription drug case. Accordingly, as the trial court stated, a prescription drug manufacturer's "mere failure to conduct a particular test in addition to or instead of those tests it admittedly conducted" should not and cannot "without more, rise to the level of 'outrageous' conduct." 4/23/07 Trial Ct. Op. at 4 (quoting *Olsen v. United States*, 521 F. Supp. 59, 70 (E.D. Pa. 1981), *aff'd mem. sub nom. Ford Motor Co. v. Cooper*, 688 F.2d 820 (3d Cir. 1982)). "While [Plaintiff] may argue that [Wyeth's HT] testing was not as comprehensive as could have been, it cannot be said that [Wyeth] was malicious. [Wyeth] was aware of a breast cancer risk, disclosed it in its Prempro label and further aided the medical community in better understanding its drug." *Nelson v. Wyeth*, No. 1670, 2007 Phila. Ct. Com. Pl. LEXIS 316, at *21-22 (Pa. Ct. Com. Pl. Dec. 5, 2007), *aff'd mem.*, 970 A.2d 489 (Pa. Super. Ct. 2009), *appeal denied*, 4 A.3d 1054 (Pa. 2010).

Moreover, Pennsylvania law does not recognize a cause of action for failure to test. *See Lance v. Wyeth*, 2010 PA Super 137 ¶¶ 27-30, 4 A.3d 160, 168-69 (2010), *appeal granted*, 15 A.3d 429 (Pa. 2011); *see also* Op. at 29 n.13. "[T]he claim for 'negligent failure to test' is not a viable cause of action recognized by our courts, and we have found no 'duty to test' that would be the basis of such a claim." *Viguers v. Philip Morris USA, Inc.*, 2003 PA Super 446 ¶ 21, 837 A.2d 534, 541 (2003), *aff'd mem.*, 584 Pa. 120, 881 A.2d 1262 (2005); *accord Oddi v. Ford Motor Co.*, 234 F.3d 136, 143-44 (3d Cir. 2000) (Pennsylvania law). This Court has long recognized that non-actionable conduct cannot give rise to punitive damages. *See Hutchison*, 582 Pa. at 122-24, 870 A.2d at 771-72; *see also Kirkbride*, 521 Pa. at 101-02, 555 A.2d at 802-03. Thus,

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room exists for reasonable disagreement over the relative risks and utilities of the conduct at issue.").

for this further reason, the Superior Court erred in holding that punitive damages can be awarded for "failure to perform adequate tests." Op. at 47-49.

In sum, the Superior Court's rationale for imposing punitive damages in prescription drug cases is contrary to this Court's punitive damages jurisprudence, improperly expands punitive damages liability in prescription drug cases and jeopardizes important public policy interests.

C. In Reinstating the Punitive Award, the Superior Court Failed to Consider "All the Circumstances" as Required by Pennsylvania Law

This Court has held that punitive damages are justified only in "rare instances" and are "subject to strict judicial controls." *Martin*, 508 Pa. at 169, 494 A.2d at 1096. Appellate review therefore requires careful consideration of "'all the circumstances.'" *Feld*, 506 Pa. at 395, 485 A.2d at 748 (quoting *Chambers v. Montgomery*, 411 Pa. 339, 345, 192 A.2d 355, 358 (1963)). Here, the Superior Court's analysis failed to adhere to the scope of review delineated by this Court, improperly relying almost exclusively on the testimony of Plaintiffs' expert Dr. Blume, while disregarding undisputed countervailing evidence as to the extensive testing conducted or supported by Wyeth. Consideration of all the circumstances of this case, even in the light most favorable to Plaintiffs, requires reversal of the punitive award.[10]

The Superior Court improperly disregarded the particular circumstances of Mrs. Daniel's short-term use of HT and the particular issues as to "subjective appreciation" by Wyeth of the purported risk of short-term use. As the trial court properly noted in granting JNOV on punitive damages, there is a "lack of an appreciable risk of harm for short-term users of Prempro," such as

[10] Wyeth anticipates that Plaintiffs, in response to this Petition, will rely upon decisions applying the law of different states and involving different factual records. Such decisions do not provide a basis for the determination of the issues here. *See, e.g., McCaffrey v. Pittsburgh Athletic Ass'n*, 448 Pa. 151, 162, 293 A.2d 51, 57 (1972) ("[I]t is black letter law that an appellate court cannot consider anything which is not a part of the record in the case."); *Commonwealth v. DePasquale*, 509 Pa. 183, 190 n.4, 501 A.2d 626, 630 n.4 (1985) ("A court is bound to decide the case before it based upon the evidence presented to it by the parties; it has no authority to seek out additional testimony in the records of unrelated cases on the matters

Mrs. Daniel. 4/23/07 Trial Ct. Op. at 4. Plaintiffs did not show that the further testing that their expert claimed should have been conducted (which Wyeth was punished for failing to conduct) would have revealed that short-term use can cause breast cancer. On the contrary, there is no reliable scientific evidence that short-term use of Prempro (approximately three years or less) can cause breast cancer, as the MDL court found after an extensive examination of the data from the WHI study. *In re Prempro Prods. Liab. Litig.*, 2011 WL 178572, at *1, 10-11 (W.D. Ark. Jan. 19, 2011), *aff'd*, No. 6:04-cv-6042-BRW, Order (W.D. Ark. Jan. 21, 2011), ECF No. 117; *see* Op. at 38-39 (Plaintiffs' experts conceded "the general lack of published and peer-reviewed studies" showing a risk of breast cancer from short-term use of HT and "acknowledged that the WHI study . . . found no increased risk of breast cancer after using Prempro for two years or less").

The record also shows that Wyeth's HT testing was, as a matter of undisputed fact, far more extensive than the Superior Court acknowledged. The Superior Court began its analysis by citing Plaintiffs' expert's testimony that Wyeth was aware of "the potential risk of breast cancer" associated with estrogen alone in the mid 1970s, and asserting that the "record does not reflect" that Wyeth "undertook any studies on these issues at this time." Op. at 44-46. In fact, the record establishes that Wyeth provided financial support to the Nurses' Health Study, an observational study that began in 1976, involved 120,000 participants, and monitored for the risk of breast cancer. Tr. 1/9/07 PM at 80-82, 131. Similarly, the Superior Court accepted Dr. Blume's contention that although the FDA granted Wyeth permission to conduct a study in the early 1980s on the combined use of estrogen and progestin, "Wyeth never did so." Op. at 46. In fact, Dr. Blume admitted that the reason that Wyeth "couldn't get the study done" was difficulties in recruiting

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at issue before it.").

and enrolling women in the study. Tr. 1/10/07 PM at 118-19 (Blume). Though the study was not completed, Wyeth sent data obtained from the study to the FDA. Tr. 1/24/07 AM at 49-50.

The Superior Court also relied on Dr. Blume's testimony that Wyeth should have conducted an epidemiological study of the kind conducted by Drs. Andrew Glass and Robert Hoover in 1990. Op. at 46-47. Again, the Superior Court disregarded record evidence that (i) as the FDA medical officer's 1994 review of Prempro stated, "years of epidemiological study" had not "settled" the breast cancer issue and further studies of the same kind would not "likely resolve the issues related to breast cancer associated with [HT]" (R. 1278a), and (ii) Wyeth financially supported an extensive meta-analysis of such studies and the risk of breast cancer that was published in 1993 and was also funded by the National Cancer Institute. Tr. 1/9/07 PM at 83, 138-39. In light of differing opinions regarding the need for a further epidemiological study, Wyeth's not conducting one cannot be deemed so extreme and outrageous as to merit punitive damages.[11]

In fact, the record is replete with testimony and evidence regarding studies and clinical trials of HT that Wyeth conducted or supported, all of which monitored for and reported on breast cancer. These studies included not only Wyeth's Pivotal trial (referred to by the Superior Court as the "Prem-Pack Protocols," Op. at 48), which supported Wyeth's Prempro NDA,[12] but

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[11] In addition, Dr. Blume did not base her opinion that Wyeth should have done further testing on any FDA regulation, industry standard, or other objective standard. The MDL court and other courts have criticized Dr. Blume's testimony as impermissibly subjective and speculative and as lacking any objective standard against which to judge Wyeth's actions. *See, e.g., Wilson v. Wyeth, Inc.*, No. 3:05CV00078-WRW, Order at 4-7 (E.D. Ark. Sept. 16, 2010), ECF No. 72 (Dr. Blume's testimony "as to what tests would have been 'appropriate' for Defendants to conduct" was improperly "subjective" and was not based on any objective industry or government standard), *aff'd*, Order at 1 (E.D. Ark. Sept 23, 2010), ECF No. 113; *LaFarerra v. Wyeth, Inc.*, No. 4:04CV02271-WRW, Order at 4-7 (E.D. Ark. June 29, 2010), ECF No. 105 (same); *Vance v. Wyeth, Inc.*, No. 06-C-351P, slip op. at 3-5 (W. Va. Cir. Ct. Aug. 13, 2010) (excluding Dr. Blume's testimony "about what a 'reasonable' pharmaceutical company should have done to test the safety of its hormone therapy products"; stating that Dr. Blume was "unable to point to any objective standard establishing the reasonable standard of care . . . with regard to testing either [Wyeth's] own or other manufacturers' products").

[12] Although the Superior Court referred to Wyeth's Pivotal trial as "involv[ing] only 1,700 women" (Op.

also other "major randomized clinical trials," such as the three year PEPI trial, for which Wyeth provided the necessary pills and preliminary research and which functioned as a feasibility study for the WHI study; the HOPE trial, with 2,673 participants; the four year HERS trial; and the WHI itself. *See* Tr. 1/9/07 PM at 65, 67, 75-77, 79-80, 94-101; Tr. 1/24/07 AM at 79, 100; DX-3123 at 1-2.[13]

Improperly disregarding this and other such evidence, the Superior Court concluded that "sufficient evidence of record exists to support a jury's finding that from the middle 1970s and forward, Wyeth knew or strongly suspected that hormone replacement therapy increased the risk of breast cancer in post-menopausal women but failed and refused to conduct adequate studies." Op. at 48. The Superior Court then held that the jury could further infer that "Wyeth's failure to perform adequate tests of the risk of breast cancer was intentional" because Wyeth "did not want confirmation of those risks and the resulting loss of sales and profits." *Id.* at 48-49. Such an inference is impermissible speculation and conjecture, *Smith v. Bell Tel. Co. of Pa.*, 397 Pa. 134, 138, 153 A.2d 477, 479-80 (1959); *Brinich v. Jencka*, 2000 PA Super 209 ¶ 42, 757 A.2d 388, 402 (2000), and is squarely contradicted by the extensive record evidence, summarized above, of the testing conducted and supported by Wyeth. The Superior Court's punitive damages analysis was skewed and one-sided and failed to consider "all the circumstances" as required by the puni-

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at 48), the Pivotal trial was in fact a "*large-scale* . . . safety and efficacy study," as the FDA medical officer stated in her review of Wyeth's Prempro NDA. R. 1279a (emphasis added); *see also* Tr. 1/9/07 PM at 68 (Pivotal trial "was the largest clinical trial of hormone therapy ever conducted at that time").

[13] Plaintiffs belittled these studies as not "breast cancer studies" because they studied benefits as well as the risk of breast cancer. Yet, Plaintiffs' counsel conceded that "[y]ou cannot study a drug just on risks. I mean you can't just go and say, we want to give you a bunch of drugs and see if a bad thing happens to you. Studies have to be set up to where we're giving you a benefit. It's going to be offset by a risk. We're going to assess both of them and decide whether the risks outweigh the benefits . . . ." Tr. 1/3/07 at 53. *See also Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1319 (2011) ("[E]thical considerations may prohibit researchers from conducting randomized clinical trials to confirm a suspected causal link for" "an adverse event").

tive damages jurisprudence of this Court. This Court should grant review to provide guidance to the Pennsylvania courts as to the proper scope of the punitive damages analysis in prescription drug cases and should reverse the punitive award here in light of all the circumstances.

II. THIS COURT SHOULD REVIEW THE SUPERIOR COURT'S ERRONEOUS RULING THAT WYETH WAIVED ITS RIGHT TO SEEK REMITTITUR OF PUNITIVE DAMAGES

This Court should grant review to correct the Superior Court's erroneous *sua sponte* determination that Wyeth waived its right to challenge the amount of the $8.6 million punitive award found by the jury in Phase II of the trial – despite the fact that there had been no ruling or judgment by the trial court on Wyeth's motion for remittitur. The Superior Court's finding of waiver raises issues of procedure and fundamental fairness that merit this Court's consideration.

In the bifurcated trial of this case, the trial court granted JNOV as to Plaintiffs' claim for punitive damages after Phase I. For reasons of judicial efficiency, the trial court proceeded with Phase II of the trial to determine the amount of punitive damages "so that the Superior Court would not have to remand the case . . . for a re-trial if the Superior Court reversed her ruling on JNOV." 4/23/07 Trial Ct. Op. at 2. After the Phase II verdict, to ensure that the issue of remittitur was preserved, Wyeth first made an oral motion for remittitur of the punitive award, and then formalized that motion in writing at the trial court's request. In its motion (entitled "Preservation Motion for Remittitur as to Phase II Proceeding"), Wyeth explained that

> [u]pon reflection, counsel for Wyeth has come to the view that the motion may not yet be ripe for decision because the amount determined in the Phase II proceeding is not effective and could become effective only in the event that an appellate court were to reinstate the jury's verdict on Plaintiffs' claim for punitive damages. Thus, *Wyeth files this motion only as a protective measure to avoid any claim of waiver* in the unlikely event that an appellate court were to take such action as would make the amount determined in Phase II effective and thus subject to remittitur.

Dkt. Entry Feb. 1, 2007 (emphasis added). In response, Plaintiffs told the trial court that they would "provide a full and complete response to Wyeth's request for remittitur once the appellate

court rules on the underlying issues." Pls. Resp. at 2 (Dkt. Entry Feb. 12, 2007). The trial court did not rule on remittitur, apparently regarding it as moot in light of its grant of JNOV. Consistent with its view that remittitur was not ripe, Wyeth did not include remittitur in its Rule 1925(b) statement and did not brief remittitur on appeal. *See* Wyeth's P.R.A.P. 1925(b) Statement.[14]

The Superior Court, with Justice Fitzgerald disagreeing, held that by failing to include the issue in its appeal brief, Wyeth waived its right to seek remittitur. *See* Op. at 10-11 n.6, 55 n.18; Concurring Op. at 4 (Fitzgerald, J.). Wyeth has found no other instance of the Superior Court holding that an appellant waived an issue still pending in and undecided by the trial court. Indeed, when reversing grants of JNOV or new trial, the Superior Court routinely remands undecided motions for remittitur back to the trial court. *See Mammoccio v. 1818 Market P'ship*, 1999 PA Super 144 ¶ 1, 734 A.2d 23, 24 (1999) (reversing grant of new trial; "upon remand, the lower court must consider appellees' outstanding motions for remittitur"), *aff'd*, 560 Pa. 248, 744 A.2d 265 (2000); *Friter v. Iolab Corp.*, 414 Pa. Super. 622, 633, 607 A.2d 1111, 1116 (1992) ("[n]ow that we have reversed the trial court's order [granting JNOV], the trial court will necessarily have to consider remittitur"); *Capital Care Corp. v. Hunt*, 2004 PA Super 64, ¶ 23, 847 A.2d 75, 86 (2004) (reversing JNOV; remanding for determination of undecided issues including remittitur).

The Superior Court's finding of waiver in this case is thus contrary to accepted judicial practice and, if allowed to stand, would arbitrarily and unfairly deprive Wyeth of its opportunity, required by Pennsylvania and federal due process guarantees, to contest the amount of the $8.6

[14] Wyeth's Rule 1925(b) statement included two other issues regarding the Phase II proceedings, which Wyeth stated would require a new trial on the amount of punitive damages should JNOV be reversed. The first issue was the trial court's "subject matter jurisdiction" to hold the Phase II proceeding after granting JNOV on punitive damages, and the second was the trial court's denial of Phase II jury instructions proposed by Wyeth. *See* Wyeth's P.R.A.P. 1925(b) Statement ¶¶ 8, 9. Wyeth's Rule 1925(b) Statement did not include remittitur and, contrary to the Superior Court, did not "raise[] the amount of punitive damages awarded by the jury." Op. at 55 n.18. The Superior Court's conclusion that Wyeth waived remittitur by not briefing on appeal the separate Phase II issues regarding jurisdiction and jury instructions

million punitive damages award. *See Honda Motor Co. v. Oberg*, 512 U.S. 415, 432-34 (1994). In the event that this Court does not reverse the Superior Court's reinstatement of the punitive award, the Court should reverse the Superior Court's ruling on waiver and instruct that this case be remanded to the trial court for consideration of Wyeth's motion for remittitur.

III. THE COURT SHOULD GRANT LEAVE TO APPEAL TO CORRECT THE SUPERIOR COURT'S PUNITIVE DAMAGES CHOICE-OF-LAW ANALYSIS

Although Mrs. Daniel is from Arkansas, on appeal both parties *agreed* to apply Pennsylvania law to her punitive damages claim. The Superior Court, however, stated that "Pennsylvania choice-of-law rules *require* the application of Pennsylvania punitive damages law" because the conduct that was the basis for the punitive damages claim took place at Wyeth's Pennsylvania offices. Op. at 54-55 n.17 (emphasis added). This attempt to convert an agreement in one case into a binding precedent for all cases will wreak havoc with Pennsylvania's choice-of-law rules. It is harmful to both consumers and businesses and contrary to the vast weight of authority.

The overwhelming case law in this State[15] and elsewhere[16] holds that punitive damages are governed by the law of plaintiff's home state, where the plaintiff used the product and suffered injury. This precedent includes four Pennsylvania HT cases against Wyeth applying the punitive damages law of Illinois, Alabama, and Indiana to claims of those states' residents.[17] The

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is not supported by any Pennsylvania precedent.

[15] *See, e.g., Knipe v. SmithKline Beecham*, 583 F. Supp. 2d 602, 637-38 (E.D. Pa. 2008); *Kukoly v. World Factory, Inc.*, 2007 WL 1816476, at *2-3 (E.D. Pa. June 22, 2007); *see also Apple v. Ford Motor Co.*, 69 Pa. D. & C. 4th 236, 238-40 (Pa. Ct. Com. Pl. 2004) (applying the punitive damages law of Pennsylvania, where plaintiff was injured); *Wolfe v. McNeil-PPC, Inc.*, 703 F. Supp. 2d 487, 493-94 (E.D. Pa. 2010) (applying punitive damages law of Maine, where plaintiff purchased and took the drug at issue).

[16] *See, e.g., In re Prempro Prods. Liab. Litig.*, 2008 WL 1699211, at *3-4 (E.D. Ark. Apr. 9, 2008); *In re Baycol Prods. Litig.*, 218 F.R.D 197, 207, 215-16 (D. Minn. 2003); *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. 61, 70-71, 74 (S.D.N.Y. 2002); *Moody v. Ford Motor Co.*, 2006 WL 346433, at *1-3 (N.D. Okla. Feb. 13, 2006); *Kramer v. Showa Denko K.K.*, 929 F. Supp. 733, 740-41 (S.D.N.Y. 1996); *Harlan Feeders, Inc. v. Grand Labs., Inc.*, 881 F. Supp. 1400, 1409-10 (N.D. Iowa 1995); *Dodson v. Ford Motor Co.*, 2006 WL 2642199, at *2-3, 7-8 (R.I. Super. Ct. Sept. 5, 2006).

[17] *Kendall v. Wyeth Pharms., Inc.*, 2010 WL 1285451 (Pa. Ct. Com. Pl. Mar. 18, 2010) (Illinois) (appeal

only case cited by the Superior Court, *Kelly v. Ford Motor Co.*, 933 F. Supp. 465 (E.D. Pa. 1996), "is an outlier" and represents "the minority viewpoint." *Dodson*, 2006 WL 2642199, at *5-6.

Review should be granted because the Superior Court's choice-of-law analysis, which, even though *dicta*, is already being cited in the Pennsylvania trial courts, would have the perverse effect of depriving Pennsylvania citizens of the benefits of Pennsylvania punitive damages law when they buy products sold by out-of-state companies. For if, as the Superior Court concluded, the determinative factor is the location of the corporate defendant, it follows that if the defendant is located in another state or country, the punitive damages law of that state or country should apply to transactions with Pennsylvania citizens, who use a product in Pennsylvania and sustain injury here.

Many states prohibit punitive damages – either in all product liability cases[18] or in prescription drug cases.[19] Most foreign countries prohibit punitive damages.[20] Accordingly, if the Superior Court's ruling is allowed to stand, a Pennsylvania citizen injured by a car made in

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pending); *Barton v. Wyeth*, 2010 WL 1285450 (Pa. Ct. Com. Pl. Jan. 29, 2010) (Illinois) (appeal pending); *Singleton v. Wyeth*, Jan. Term 2005, No. 2885 (Pa. Ct. Com. Pl. Feb. 22, 2010) (Alabama) (appeal pending); *Foust v. Wyeth Pharm., Inc.*, June Term 2004, No. 4606 (Pa. Ct. Com. Pl. 2010) (Indiana).

Although both parties here agreed to Pennsylvania law on appeal, the issue was disputed in the trial court. Wyeth argued that Plaintiffs waived application of any law other than Pennsylvania's because they pled only Pennsylvania law in the complaint. Plaintiffs argued that choice-of-law rules required the law of their home state. No one argued that choice of law – as opposed to waiver – mandated Pennsylvania law. The Coordinating Judge granted Wyeth's motion but limited its application to the initial bellwether cases, including this case. In later trials, the punitive damages law of plaintiff's home state has applied.

[18] *See, e.g., Casey v. Auto Owners Ins. Co.*, 729 N.W.2d 277, 286 (Mich. Ct. App. 2006); *Ivory v. Pfizer Inc.*, 2009 WL 3230611, at *8 (W.D. La. Sept. 30, 2009); *Distinctive Printing & Packaging Co. v. Cox*, 443 N.W.2d 566, 574 (Neb. 1989); *Noble v. Corporacion Insular de Seguros*, 738 F.2d 51, 54 (1st Cir. 1984) (Puerto Rico law); *Dailey v. N. Coast Life Ins. Co.*, 919 P.2d 589, 590 (Wash. 1996); Wash. Rev. Code § 7.72.010-60.

[19] Ariz. Rev. Stat. § 12-701; N.J. Stat. § 2A:58C-5(c); N.D. Cent. Code § 32-03.2-11(6); Ohio Rev. Code Ann. § 2307.80; Or. Rev. Stat. § 30.927; Utah Code Ann. § 78B-8-203.

[20] *See, e.g., Exxon Shipping Co. v. Baker*, 554 U.S. 471, 497 (2008) ("Noncompensatory damages are . . . unavailable in such countries as France, Germany, Austria, and Switzerland."); *Creager v. Yoshimoto*, 2006 WL 680555, at *4 (N.D. Cal. Mar 14, 2006) (punitive damages unavailable under Japanese law).

Michigan, Germany, or Japan will not be able to obtain punitive damages because the defendant's home jurisdiction does not allow punitive damages. This would harm Pennsylvania consumers and "undermine Pennsylvania's interest in discouraging [out-of-state] companies from bringing dangerous products into the Commonwealth." *Kukoly*, 2007 WL 1816476, at *3.

The Superior Court's choice-of-law ruling will in many cases favor out-of-state businesses over Pennsylvania businesses. Under the Superior Court's ruling, two companies selling the same product to Pennsylvania customers could be governed by different punitive damages law, depending on where they are headquartered. For example, New Jersey drug manufacturers (and there are many) would be immunized by New Jersey statute from a punitive damages claim, even when they sell to a Pennsylvania resident, but Wyeth could be punished for identical conduct to the same Pennsylvania resident. *See supra* at 26 n.19. This puts Pennsylvania companies at a disadvantage *vis-a-vis* their out-of-state competitors, creating a powerful incentive for them to relocate across the Delaware River. Review should be granted to assure a rational choice-of-law system whereby the same punitive damages law applies to all sales within Pennsylvania.

IV. THE SUPERIOR COURT ERRED IN AFFIRMING THE DENIAL OF JNOV FOR WYETH WHERE PLAINTIFFS PRESENTED NO EVIDENCE THAT A DIFFERENT WARNING WOULD HAVE CAUSED MRS. DANIEL'S PHYSICIAN TO CHANGE HIS PRESCRIBING DECISION

The Superior Court erred in affirming the denial of JNOV for Wyeth on the issue of proximate cause. Applying an improper legal standard that was rejected in *Lineberger v. Wyeth*, 2006 PA Super 35 ¶¶ 23-24, 894 A.2d 141, 150-51 (2006), the Superior Court held here that "[s]ufficient evidence of record exists in this case permitting the jury to find that if Wyeth had issued adequate warnings regarding the risk of breast cancer, Dr. Haggard would have altered his prescribing practices for Prempro (by specifically advising Daniel of the risk of breast cancer), and Daniel's injury would have been avoided since Daniel would have declined the prescription." Op. at 32. *Lineberger* expressly rejected this precise theory of proximate cause:

> [Appellant argues that i]f Wyeth had issued an adequate warning, Dr. Lafferty would have altered his prescribing methods; and, Appellant's injury would have been avoided. Dr. Lafferty testified that he would have passed information about the material risk of valvular heart disease to his fen-phen patients if he thought a patient faced a material risk. Appellant further certifies she would not have taken the drugs if she had known about the risk of valvular heart disease. On these grounds, Appellant concludes her case should have gone to a jury. We cannot agree.

2006 PA Super ¶ 15, 894 A.2d at 147.[21] *Lineberger* recognized that the learned intermediary doctrine requires a plaintiff to show that a "different warning would have changed [her physician's] *decision to prescribe* [the medication]" to her. *Id.* ¶ 24, 894 A.2d at 151 (emphasis added). Other decisions by the Superior Court also require that plaintiffs "establish proximate causation with evidence that the physician *would not have prescribed a drug* had the physician known of the non-disclosed risk," *Cochran v. Wyeth, Inc.*, 2010 PA Super 131 ¶ 30, 3 A.3d 673, 681 (2010) (emphasis added), *appeal denied*, 2011 Pa. LEXIS 911 (Pa. Apr. 18, 2011), and that "'[i]t is for the prescribing physician to use his independent medical judgment, taking into account the data supplied to him from the manufacturer, other medical literature, and any other sources available to him, and weighing that knowledge against the personal medical history of his patient, *whether to prescribe* a given drug.'" *Taurino v. Ellen*, 397 Pa. Super. 50, 53, 579 A.2d 925, 927 (1990) (emphasis added; quoting *Makripodis v. Merrell-Dow Pharms., Inc.*, 361 Pa. Super. 589, 596-97, 523 A.2d 374, 378 (1987)); *accord Owens v. Wyeth*, 2009 WL 3244890 (Pa. Ct. Com. Pl. Aug. 17, 2009), *aff'd*, 6 A.3d 572 (Pa. Super. Ct. 2010).

Thus, contrary to the Superior Court's decision here, it is not enough for the physician to testify only that he might have had a different discussion with his patient. As *Lineberger* and other Pennsylvania cases instruct, the causation inquiry must focus on whether the physician

[21] The Superior Court in *Lineberger* held in alternative holdings that the plaintiff failed to demonstrate proximate causation under the learned intermediary rule and waived her appeal of the trial court's decision. 2006 PA Super, ¶¶ 21-25, 894 A.2d at 149-51. Both alternative holdings are binding precedent. *See Pa. Turnpike Comm'n v. Commonwealth*, 587 Pa. 347, 369, 899 A.2d 1085, 1098 (2006).

would have altered his decision to prescribe the medication to the plaintiff.[22] In this case, there is no evidence that a different warning would have changed Dr. Haggard's prescribing decision, nor did the Superior Court purport to rely on such (non-existent) evidence. Dr. Haggard was not asked whether he would have prescribed HT to Mrs. Daniel if he had received a different warning. Nor was he asked whether he would have continued to recommend HT to patients. Since Dr. Haggard retired prior to the release of the WHI in 2002, there was no evidence of his prescribing pattern after the WHI. R. 785a-87a. Thus, the type of evidence required by *Lineberger*, reflecting the physician's actual prescription decision, is absent.

The only evidence cited by the Superior Court was Dr. Haggard's testimony that his discussion with a patient "[p]robably" would have been different and "might have . . . emphasized" risk information more. R. 787-88a. Yet, Dr. Haggard's testimony established that he believed the risk of breast cancer disclosed in the WHI was consistent with the risk disclosed in the operative warning label at the time he prescribed to Mrs. Daniel, that based on the WHI results, Mrs. Daniel was not at any increased risk of getting breast cancer, and that it was "encouraging" that "the study didn't show that [HT users] were overwhelmingly at increased risk [of breast cancer] having taken the medication." R. 795a-97a. Under any standard, this record was insufficient for

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[22] *Lineberger* is binding on subsequent panels of the Superior Court under *stare decisis*. *See Ario v. Reliance Ins. Co.*, 602 Pa. 490, 505, 980 A.2d 588, 597 (2009); *Marks v. Nationwide Ins. Co.*, 2000 PA Super 341 ¶¶ 12-13, 762 A.2d 1098, 1101 (2000). The Superior Court never addressed the conflict between its holding and *Lineberger*, but relied instead on *Simon v. Wyeth Pharms., Inc.*, 2009 PA Super 263 ¶ 44, 989 A.2d 356, 375 (2009). The Superior Court erroneously held that under *Simon* proximate cause was shown if sufficient evidence existed to permit the jury to find that the plaintiff's doctors "'would have permitted [plaintiff] to decide, based on the cancer risk that the WHI study revealed, whether to accept prescriptions for HRT.'" Op. at 31-32 (alteration in original; quoting *Simon*, 2009 PA Super, ¶ 44, 989 A.2d at 375). But *Simon* did not simply rely on evidence of the plaintiff's decision making process. Rather, *Simon* noted that in *Lineberger* the prescribing physician "specifically testified that even if the drug's literature had included a specific warning, he still would have prescribed the drug in question," *Simon*, 989 A.2d at 372, while in *Simon* "the jury permissibly found that Appellant's physicians would not have *prescribed* Provera to her if adequate warnings had been provided." *Id.* ¶ 44, 984 A.2d at 376 (emphasis added). Also, *Simon* cited evidence that after the WHI the prescribing physician "took every single

Plaintiffs to meet their burden. This Court should grant review to resolve the conflict in the decisions of the Superior Court and to establish the proper legal standard for proximate cause in a prescription pharmaceutical case in Pennsylvania.

V. THE SUPERIOR COURT ERRED IN REVERSING THE GRANT OF A NEW TRIAL WHERE PLAINTIFFS PRESENTED EXPERT TESTIMONY THAT WAS RECANTED BEFORE TRIAL

The Superior Court improperly reversed the trial court's grant of a new trial to Wyeth based on the trial court's finding that one of Plaintiffs' key expert witness, Dr. Lester Layfield, in light of the short duration of Mrs. Daniel's use of Prempro, had recanted his opinion that HT caused her cancer and that Plaintiffs' counsel was aware of the recantation prior to trial. During trial, in lieu of calling Dr. Layfield live (ostensibly due to unavailability), Plaintiffs read his deposition testimony to the jury, including his opinion that "the use of combined hormone replacement therapy was indeed a substantial factor in the development of the breast carcinoma" in Mrs. Daniel (R. 812a-13a) and his "professional opinion" that before beginning HT, Mrs. Daniel had "a premalignant lesion that was not obligated to progress to cancer." R. 810a.[23] Unbeknownst to Wyeth at the time, Dr. Layfield was not called live because he had informed Plaintiffs' counsel that he could no longer opine to a "reasonable degree of medical certainty" that Mrs. Daniel's cancer was caused by her HT use.

A few months after the trial of this case, Wyeth deposed Dr. Layfield in another HT case. When asked why he did not testify live at the trial of this case, Dr. Layfield said that, after his

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patient off the pill" and did not prescribe combination HT. *Id.* ¶ 40, 989 A.2d at 374.

[23] Contrary to the Superior Court's analysis, this testimony shows that Dr. Layfield did *not* "consistently and without exception refuse[] to opine" as to which of the "three possible conditions [non-malignant hyperplasia, ductal carcinoma in situ, and a small invasive breast cancer] existed at the time Daniel began to take Prempro." Op. at 20. Moreover, the fact that on cross-examination at his deposition in this case, Wyeth's counsel was able to elicit from Dr. Layfield that all three were possibilities but that – "'on the basis of review of those slides'" – he could not say (in a carefully qualified response) which was more likely (*id.* at 16 (citation omitted)), does not undo the harm from the admission of the above quoted recanted testimony. Moreover, Dr. Layfield's deposition testimony in the later case made it evident that he

deposition in this case, he told Plaintiffs' counsel that given Mrs. Daniel's short-term use of HT, he was no longer willing to offer a causation opinion that Prempro caused her breast cancer:

> Q: Okay. And so you shared with plaintiffs' counsel after your deposition that you were concerned that the duration of use would mean to you that you really couldn't give an opinion that her cancer was caused by hormone therapy?
>
> A: To a reasonable degree of medical certainty, that would be correct.
>
> Q: Yeah, you couldn't say, to a reasonable degree of medical certainty, her cancer was caused by HT?
>
> A: Because of the short duration.

R. 249a. Dr. Layfield's recanted ultimate causation opinion was not cumulative of the opinions of Plaintiffs' expert Dr. Elizabeth Naftalis or any other expert. Rather, Dr. Naftalis's causation testimony was based, in part, on Dr. Layfield's opinion. Dr. Layfield's subsequent admission, in sworn testimony, that he had reconsidered his opinion and could not testify at trial as he had in his deposition, directly contradicted Dr. Naftalis's causation testimony.

After reviewing "the record as a whole," the trial court exercised its broad discretion to grant a new trial, finding that Dr. Layfield recanted his opinion on the ultimate causation issue in this case. R. 21a-23a. The trial court found that Plaintiffs' counsel knew Dr. Layfield changed his testimony and withheld that fact from the court. R. 23a. The Superior Court was bound to affirm the trial court's decision absent a "palpable abuse of discretion." *Martin*, 508 Pa. at 163, 494 A.2d at 1094. But "[r]ather than reviewing the record to determine whether the trial court's reasons found support," the Superior Court "searched for an argument to counter the trial court's decision." *Morrison v. Commonwealth Dep't of Pub. Welfare*, 538 Pa. 122, 136, 646 A.2d 565, 572 (1994).[24] The Superior Court's extensive re-review of the evidence was improper. *Id.*[25]

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had come to view a non-malignant hyperplasia as the least likely of the three possibilities. R. 248a-50a.

[24] Contrary to Plaintiffs' contentions, it is of no legal significance that Wyeth's motion for new trial was assigned to a new judge because Judge Field, who presided at trial, passed away shortly after the conclu-

As the trial court recognized, when the influence of a trial error on a jury cannot be determined, the proper remedy is a new trial. *See* 9/24/08 Trial Ct. Op. at 7 (citing *Lobalzo v. Varoli*, 409 Pa. 15, 20-21, 185 A.2d 557, 560-61 (1962)). Plaintiffs should not have presented the deposition testimony of an expert witness who declined to appear live because he was no longer able to provide the desired causation testimony. The trial court acted well within its discretion to find that the testimony was tainted and fairness required a new trial. The Superior Court erred in setting aside the trial court's analysis that "Dr. Layfield's recanted testimony changed his prior deposition testimony that Daniel's use of Prempro caused her breast cancer and it is likely that this information would have compelled a different result at trial." *Id.* at 6.

CONCLUSION

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

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sion of trial. That fact does not change the standard of review. *See, e.g., Magnum v. Pa. Fin. Responsibility Assigned Claims*, 449 Pa. Super. 1, 4, 672 A.2d 1324, 1326 (1996).

[25] The Superior Court improperly credited Dr. Layfield's self-serving statement in his affidavit that he had not recanted his testimony. As the Superior Court observed, however, the "best source for determining whether the depositions were contradictory were the transcripts of the depositions" (Op. at 22 n.9), which is precisely what the trial court looked to in reaching its conclusion. In any event, his later assertion that he did not recant cannot be reconciled with his statement, not disputed by Plaintiffs' counsel, that he told counsel he could not give the same testimony at trial that he had given at his deposition.

PROOF 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 counsel via first-class mail:

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