No.

In the Supreme Court of the United States

WYETH LLC, ET AL., PETITIONERS

v.

DONNA SCROGGIN

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether a partial retrial limited to punitive damages violates the Seventh Amendment.

2. Whether a trial court can admit the testimony of a scientific expert without expressly addressing the applicability of the factors set out in *Daubert* v. *Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).

PARTIES TO THE PROCEEDING AND CORPORATE DISCLOSURE STATEMENT

Petitioners are Wyeth LLC (formerly known as Wyeth), Wyeth Pharmaceuticals Inc., and Pharmacia & Upjohn Company LLC; respondent is Donna Scroggin. Petitioners are indirect wholly owned subsidiaries of Pfizer Inc. Pfizer has no parent corporation, and no publicly held company owns 10% or more of Pfizer's stock.

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PETITION FOR A WRIT OF CERTIORARI

Wyeth LLC, Wyeth Pharmaceuticals Inc., and Pharmacia & Upjohn Company LLC respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Eighth Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-44a) is reported at 586 F.3d 547. The district court's opinion granting judgment as a matter of law on punitive damages (App., *infra*, 47a-110a) is reported at 554 F. Supp. 2d 871. The magistrate judge's order admitting expert testimony (App., *infra*, 114a-123a) and the district court's order overruling petitioners' objections to the

magistrate judge's order (App., *infra*, 111a-113a) are unreported.

JURISDICTION

The judgment of the court of appeals was entered on November 2, 2009. A petition for rehearing was denied on December 16, 2009 (App., *infra*, 45a-46a). The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

CONSTITUTIONAL PROVISION INVOLVED

The Seventh Amendment to the United States Constitution provides:

> In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise re-examined in any Court of the United States, than according to the rules of the common law.

STATEMENT

Respondent brought suit against petitioners in the United States District Court for the Eastern District of Arkansas, alleging that petitioners had inadequately warned her of the risk of breast cancer associated with their medicines. After a magistrate judge ruled that the testimony of respondent's sole expert on specific causation was admissible, App., *infra*, 119a-120a, and the district court overruled petitioners' objections to that ruling, *id.* at 111a-112a, the case went to trial. A jury found petitioners liable and awarded compensatory and punitive damages. The district court granted judgment as a matter of law to petitioners on punitive damages. *Id.* at 71a-110a. The court of appeals affirmed in part, vacated in part, and remanded for a partial new trial on punitive damages. *Id.* at 1a-44a. As is relevant here, the court of

appeals affirmed the district court's decision to admit the testimony of respondent's expert on specific causation, see *id.* at 27a-31a, and held that a retrial limited to punitive damages did not violate the Seventh Amendment, see *id.* at 43a-44a.

1. Petitioners are Wyeth LLC and Wyeth Pharmaceuticals Inc. (collectively "the Wyeth petitioners") and Pharmacia & Upjohn Company LLC (Upjohn). Petitioners produce prescription medicines colloquially known as "hormone therapy," which have been approved for use for many decades to combat the symptoms of menopause and to prevent osteoporosis. For much of that time, there has been extensive scientific investigation and debate as to whether there is a link between hormone therapy and breast cancer. Since 1988, both the doctor labeling and patient information sheet for the Wyeth petitioners' medicines have warned that "[s]ome studies have suggested a possible increased incidence of breast cancer in those women on estrogen therapy taking higher doses for prolonged periods of time." That warning was approved by the Food and Drug Administration (FDA) and reflected the state of scientific knowledge at the time. App., *infra*, 3a, 5a, 13a, 19a-20a.

In 2002, a study by the Women's Health Initiative (WHI), conducted under the auspices of the National Institutes of Health, reported that women who used hormone therapy were relatively more likely to develop breast cancer than women in the control group, although the absolute rate remained low (*i.e.*, at an annual rate of 38 cases of breast cancer per 10,000 women, rather than 30 cases per 10,000). Based on the results of the WHI study, the Wyeth petitioners revised the breast-cancer warning for their medicines and then made further changes in consultation with the FDA, including placing the warning in a so-called "black box." The FDA to this

day approves petitioners' medicines as safe and effective, and doctors continue to prescribe them. App., *infra*, 17a-21a.

2. In the wake of the WHI study, more than 10,000 women who used hormone therapy and developed breast cancer filed suit against petitioners and other pharmaceutical companies, contending, *inter alia*, that the pharmaceutical companies had inadequately warned of the risk of breast cancer.

Respondent used hormone-therapy medicines produced by petitioners from 1989 to 2000, when she was diagnosed with breast cancer. App., *infra*, 3a. In 2004, respondent brought suit against petitioners in the United States District Court for the Eastern District of Arkansas. As is relevant here, respondent alleged that, notwithstanding the accuracy of petitioners' warnings in light of the state of scientific knowledge at the time, petitioners should have conducted additional testing of the risk of breast cancer from hormone therapy (and that the failure to do so, and to provide different warnings as a result, constituted a failure to warn under Arkansas law).

The Judicial Panel on Multidistrict Litigation established a multidistrict proceeding in the Eastern District of Arkansas, and thousands of similar actions were transferred to that district. After several years of coordinated discovery, the district court began conducting bellwether trials in 2006. The first two trials resulted in defense verdicts; respondent's case was the third to be tried.

As this case comes before the Court, it presents two issues: one concerning the admissibility of the testimony of respondent's principal expert, and the other concerning the permissibility of a retrial limited to punitive damages. With regard to the former issue, respondent

was required to prove at trial that she would not have developed breast cancer but for taking hormone therapy. To that end, respondent relied solely on the testimony of Elizabeth Naftalis, a breast surgeon no longer in active practice, who based her opinion that hormone therapy caused respondent's breast cancer on differential diagnosis—*i.e.*, a method of determining the cause of a patient's illness by considering all of the known causes and individually ruling them out until the most likely causal explanation is left. Citing the factors for the admissibility of expert testimony set out in *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), petitioners moved to exclude Dr. Naftalis's testimony on the ground, *inter alia*, that differential diagnosis is an unreliable methodology for determining the cause of an individual's disease where, as is true for breast cancer, the cause is unknown in the vast majority of cases. App., *infra*, 28a.

A magistrate judge denied petitioners' motion and admitted Dr. Naftalis's testimony. App., *infra*, 119a-120a. The magistrate judge acknowledged that Dr. Naftalis's report was "somewhat conclusive, rather than explanatory." *Id.* at 120a. But he stated that he "c[ould] [not] say that Dr. Naftalis used improper methodology." *Ibid.* Citing the district court's ruling admitting the testimony of another expert in an earlier bellwether trial involving a plaintiff with a different medical history, the magistrate judge concluded that Dr. Naftalis was "qualified to testify that [hormone therapy] more likely than not promoted [respondent's] breast cancer," and added that "[h]er conclusions can be tested during cross-examination." *Ibid.* Critically, although the magistrate judge quoted the *Daubert* factors, he did not expressly apply them or even address their applicability. *Id.* at 116a-120a. The district court summarily overruled peti-

tioners' objections to the magistrate judge's order. *Id.* at 111a-112a.

The case then went to trial. The district court bifurcated the trial proceedings; the first phase covered liability and compensatory damages, and the second covered the availability and amount of punitive damages. In the first phase, the jury found petitioners liable and awarded respondent $2.7 million in compensatory damages. In the second phase, the same jury awarded respondent $19.36 million in punitive damages from the Wyeth petitioners and $7.76 million in punitive damages from Upjohn. App., *infra*, 48a.

As is relevant here, petitioners moved for judgment as a matter of law on punitive damages. The district court granted the motion. App., *infra*, 106a-109a. The court determined that it had improperly admitted the testimony of Suzanne Parisian, a doctor whom respondent had designated as her "regulatory expert." *Id.* at 50a, 69a-71a. The court reasoned that Dr. Parisian's testimony merely "tracked [respondent's] legal arguments" and that "there was very little significant analysis." *Id.* at 70a. The court then determined that, absent Dr. Parisian's testimony, there was insufficient evidence to support an award of punitive damages. *Id.* at 71a-73a, 109a.

3. Respondent appealed the district court's decision to grant judgment as a matter of law on punitive damages; petitioners cross-appealed the district court's judgment for respondent on liability on the underlying claim and compensatory damages. The court of appeals affirmed the judgment on liability and compensatory damages; it affirmed the judgment on punitive damages as to Upjohn, but vacated it as to the Wyeth petitioners and remanded for a new trial limited to the availability and amount of punitive damages against those defendants. App., *infra*, 1a-44a.

With regard to the admissibility of Dr. Naftalis's testimony, the court of appeals noted that respondent "suffered from hormone-dependent breast cancer" and that "published research had concluded that hormone-receptor-positive tumors need hormones to grow, that menopausal symptoms result from hormone deficiency, and that there is a link between breast cancer and hormone replacement therapy." App., *infra*, 29a. The court concluded that "Dr. Naftalis sufficiently established that hormones were necessary to the development of [respondent's] tumors and conducted her differential diagnosis from this starting point." *Id.* at 30a. Like the magistrate judge, the court of appeals cited the *Daubert* factors for admissibility of expert testimony, but did not apply them or state why they were inapplicable. *Id.* at 27a-30a.

With regard to punitive damages, the court of appeals held that the district court had correctly excluded Dr. Parisian's testimony but had erred by determining that, absent that testimony, there was insufficient evidence to support an award of punitive damages against the Wyeth petitioners. App., *infra*, 38a-43a. Notwithstanding the absence of any evidence that the Wyeth petitioners had withheld any information regarding the risk of breast cancer or failed to give accurate warnings to respondent and her doctor based on the state of scientific knowledge at the time, the court of appeals determined that, when "[v]iewed as a whole," the evidence "could allow a jury to find or infer that [the Wyeth petitioners] w[ere] guilty of malicious conduct within the meaning of Arkansas law." *Id.* at 42a.

Because "[t]he admission and the jury's consideration of Dr. Parisian's testimony * * * amounted to prejudicial error," the court of appeals held that "the appropriate remedy is a new trial." App., *infra*, 43a. The

court, however, rejected petitioners' contention that a partial retrial limited to punitive damages would be inconsistent with the Seventh Amendment. See Wyeth C.A. Br. 103; Upjohn C.A. Br. 52-53. The court stated, without elaboration, that "a new trial may be had on punitive damages alone without injustice to the parties." App., *infra*, 43a-44a (citing *England* v. *Gulf & Western Mfg. Co.*, 728 F.2d 1026, 1029 (8th Cir. 1984), and *Gasoline Products Co.* v. *Champlin Refining Co.*, 283 U.S. 494, 500 (1931)).

REASONS FOR GRANTING THE PETITION

This case presents two recurring issues of enormous practical significance for civil litigants. In the decision below, the Eighth Circuit held, first, that a partial retrial limited to punitive damages is consistent with the Seventh Amendment, and second, that a trial court can admit the testimony of a scientific expert where the trial court failed to address the applicability of the factors set out in *Daubert*, *supra*. The courts of appeals are in disarray on both issues; the decision below is wrong in both respects; and it is beyond dispute that each issue frequently recurs in modern civil litigation, particularly multidistrict tort litigation of the type at issue here. In cases such as this one, the issues of liability and punitive damages (and the evidence relevant to those issues) will substantially overlap, and a partial retrial limited to punitive damages would thus pose a significant risk of prejudicial confusion. And where a trial court admits expert testimony without expressly considering the *Daubert* factors, there is a very real danger that the resulting ruling will sanction the admission of junk science and sow confusion both on appeal and in other cases involving the same or similar testimony. For those reasons, the Court should grant review and reverse the judgment below.

A. This Court Should Grant Review To Decide Whether A Partial Retrial Limited To Punitive Damages Violates The Seventh Amendment

1. The Courts Of Appeals Are Divided On The Permissibility Of A Partial Retrial Limited To Punitive Damages

a. At English common law, the right to trial by jury was understood as a right to have the same jury hear and decide all of the issues in a case. See *Gasoline Products*, 283 U.S. at 497. Accordingly, "there was no practice of setting aside a verdict in part," and, "[i]f the verdict was erroneous with respect to any issue, a new trial was directed as to all." *Ibid.* As Blackstone explained, an order granting a new trial was understood to "preserve[] [e]ntire * * * that most excellent method of decision"—the jury trial—"which is the glory of the English law." 3 William Blackstone, *Commentaries on the Laws of England* 391 (1768). When a court granted a new trial, therefore, it was "as if [the case] had never been heard before": there was "little prejudice to either party," and neither party could claim an "advantage" from the earlier verdict. *Ibid.*

In relevant part, the Seventh Amendment provides that, "[i]n Suits at common law, * * * the right of trial by jury shall be preserved." As this Court has long recognized, the "right of trial by jury" that the Seventh Amendment "preserve[s]" is "'the right which existed under the English common law when the Amendment was adopted.'" *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370, 376 (1996) (quoting *Baltimore & Carolina Line, Inc.* v. *Redman*, 295 U.S. 654, 657 (1935)). Although all of the particulars of the right to a jury trial are not "fixed at 1791," *Gasperini* v. *Center for Humanities, Inc.*, 518 U.S. 415, 436 n.20 (1996), the Seventh

Amendment does "preserve the *substance* of the common-law right." *Baltimore & Carolina Line*, 295 U.S. at 657 (emphasis added).

After the Constitution was ratified, some courts began to depart from the common-law practice and permit partial retrials (including in cases governed by state constitutional counterparts to the Seventh Amendment, which does not apply in state-court proceedings, see *Walker* v. *Sauvinet*, 92 U.S. 90, 92-93 (1875)). See, *e.g.*, *Simmons* v. *Fish*, 210 Mass. 563, 565 (1912) (permitting partial retrial of "readily separated" issue). Other courts adhered to the traditional common-law rule and held that a partial retrial, "where the whole case is not submitted in toto to a jury * * *, is not the trial by jury guaranteed by the Seventh Amendment." *McKeon* v. *Central Stamping Co.*, 264 F. 385, 391 (3d Cir. 1920).

b. In *Gasoline Products*, this Court for the first time addressed the constitutionality of partial retrials, in the context of an error involving the calculation of damages on a defendant's breach-of-contract counterclaims. See 283 U.S. at 495-496. The Court determined that the amount of damages on the defendant's counterclaims could not be retried separately from the plaintiff's liability on those counterclaims (although it determined that those issues could be tried separately from the plaintiff's claim for breach of a different contract). *Id.* at 500-501.

The Court acknowledged that all partial retrials were prohibited at common law, but explained that "the form of the ancient rule" was not dispositive because "the Constitution is concerned, not with form, but with substance." *Gasoline Products*, 283 U.S. at 498. The Court instead held, without elaboration, that a partial retrial "may not properly be resorted to unless it clearly appears that the issue to be retried is so distinct and separ-

able from the others that a trial of it alone may be had without injustice." *Id.* at 500.

Applying that standard, the Court concluded that "the question of damages on the counterclaim[s] is so interwoven with that of liability that the former cannot be submitted to the jury independently of the latter without confusion and uncertainty, which would amount to a denial of a fair trial." *Gasoline Products*, 283 U.S. at 500. The Court reasoned that, "upon [a] new trial, the jury cannot fix the amount of damages unless also advised of the terms of the contract," and "the dates of formation and breach may be material, since it will be open to [the plaintiff] to insist upon the duty of [the defendant] to minimize damages." *Id.* at 499.

c. This Court has not addressed the permissible scope of a partial retrial in the nearly eighty years since its decision in *Gasoline Products*. In the meantime, lower courts have struggled to apply *Gasoline Products*' "distinct and separable" standard. Courts have recognized that the *Gasoline Products* standard is "quite difficult to apply in practice" and leads to conflicting results. *Olsen* v. *Carriero*, Civ. No. 92-10961, 1995 WL 62101, at *3 (D. Mass. Feb. 3, 1995) (Saris, J.); see *Hosie* v. *Chicago & N.W. Ry.*, 282 F.2d 639, 642 (7th Cir. 1960), cert. denied, 365 U.S. 814 (1961). One appellate judge criticized the *Gasoline Products* standard on the grounds that "the degree to which facts concerning liability and damages are interrelated seems a quixotic venture with little direct bearing on the justice or injustice of separate trials" and that "it does not lead to any workable standard." *Pryer* v. *C.O. 3 Slavic*, 251 F.3d 448, 461 (3d Cir. 2001) (Mansmann, J., dissenting in part).

In addressing the specific issue whether a partial retrial limited to punitive damages is consistent with the

Seventh Amendment, courts of appeals have generally taken three different approaches.

i. At one end of the spectrum, some courts of appeals have taken a broad view of the Seventh Amendment's protections and concluded that a partial retrial of punitive damages is improper. For example, in *Mason* v. *Texaco, Inc.*, 948 F.2d 1546 (1991), cert. denied, 504 U.S. 910 (1992), the Tenth Circuit upheld a district court's decision on remand to retry the entire case, including both liability and punitive damages. In so doing, the Tenth Circuit explained, in categorical terms, that liability on the underlying claim and punitive damages are interwoven issues:

> A punitive damage claim is not an independent cause of action or issue separate from the balance of a plaintiff's case. It is part and parcel of a liability determination and does not have any independent being until a jury has decided, based on the preponderance of the evidence, that not only was a defendant's conduct negligent, but that it was gross, willful, wanton or malicious. Proof of gross, willful, wanton or malicious conduct by a defendant is not separate from proof of a defendant's negligence. The evidence proving negligence establishes liability and the degree of negligence is determinative in the award of punitive damages. Upon remand in this case, the entire issue of liability was subject to retrial.

948 F.2d at 1554; see, *e.g.*, *Malandris* v. *Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 703 F.2d 1152, 1177-1178 (10th Cir. 1981) (en banc) (holding that, if the plaintiff refused to accept remittitur of a punitive-damages award, "there should be a new trial on all issues since we feel that a new trial on less than all the issues could not be had without confusion and uncertainty, which would

amount to a denial of a fair trial"), cert. denied, 464 U.S. 824 (1983). As recently as last year, the Tenth Circuit reaffirmed its broad view of the Seventh Amendment's protections and refused to remand for a damages-only retrial. See *Haynes Trane Serv. Agency, Inc.* v. *American Standard, Inc.*, 573 F.3d 947, 966-967 (2009).

Similarly, the Third Circuit—which had held before *Gasoline Products* that the Seventh Amendment prohibited partial retrials altogether, see *McKeon*, 264 F. at 390—has long suggested that liability and punitive damages are so inherently intertwined that "the determination of the amount of punitive damages * * * cannot appropriately take place except in connection with the consideration by the jury of the whole question of the defendant's liability and of all the circumstances which it is asserted give rise to that liability." *Smyth Sales, Inc.* v. *Petroleum Heat & Power Co.*, 141 F.2d 41, 45 (1944). More recent Third Circuit decisions are to the same effect. See, *e.g.*, *Simone* v. *Golden Nugget Hotel & Casino*, 844 F.2d 1031, 1040-1041 (1988) (noting that "the issues of liability and damages are interwoven warp and woof on this record" on the ground, *inter alia*, that, "on the question of punitive damages, the jury would have to assess the conduct of the [defendant] to determine whether it acted with malice or in willful disregard of [the plaintiff's] rights"); *Spence* v. *Board of Education*, 806 F.2d 1198, 1202 (1986) (stating that "[t]he liability and damage issues are further intertwined in this case because the plaintiff is seeking punitive damages from the defendants," and explaining that, "[i]n order to prove that the defendants' conduct warranted punitive damages, plain-

tiff would have to present to the jury all the facts leading up to defendants' decision to transfer her").[1]

The Ninth Circuit, while declining to adopt a bright-line rule, has likewise held that "the issues of liability and damages, exemplary or normal, are not so distinct and separable that a separate trial of the damage issues may be had without injustice." *United Air Lines, Inc.* v. *Wiener*, 286 F.2d 302, 306, cert. denied, 366 U.S. 924 (1961). The Ninth Circuit explained that "[t]he question of damages is so interwoven with that of liability that the former cannot be submitted to the jury independently of the latter without confusion and uncertainty which would amount to a denial of a fair trial." 286 F.2d at 306; cf. *Sears* v. *Southern Pac. Co.*, 313 F.2d 498, 503 (9th Cir. 1963) (determining that, "because the evidence [on liability and damages] would largely be the same, a jury should be permitted to consider and apply it, with the aid of the court's instructions, to all issues rather than the isolated one of damages").

ii. At the other end of the spectrum, some courts of appeals have taken a narrow view of the Seventh Amendment's protections and generally permitted partial retrials of punitive damages—often, as in the decision below, with only minimal analysis of the relationship between liability and punitive damages. See, *e.g.*, App., *infra*, 43a-44a; *Grimm* v. *Leinart*, 705 F.2d 179, 183 (6th Cir. 1983) (permitting partial retrial on the ground that "the finding of liability and the award of compensatory damages are in no way intermingled with the improper

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[1] The Third Circuit has suggested that a partial retrial would also be impermissible if the error in the initial trial actually infected other portions of the verdict. See, *e.g.*, *Pryer*, 251 F.3d at 454-455; see generally pp. 15-18, *infra*.

punitive damages instruction"), cert. denied, 465 U.S. 1066 (1984).

In permitting partial retrials of punitive damages (or damages more generally), some courts—most notably, the Seventh Circuit—have recognized "the possibilities for injustice inherent in [partial] new trials." *Watts* v. *Laurent*, 774 F.2d 168, 181 (7th Cir. 1985). Those courts continue to allow partial retrials, but impose conditions on how such retrials should be conducted in an effort to "avoid, or at least minimize, the problems inherent in a procedure" whereby a new jury resolves an issue such as punitive damages without having been present for the initial trial. *Id.* at 181-182. Those conditions include (1) allowing the parties "an opportunity to present to the second jury" any relevant evidence from the initial trial and (2) instructing the second jury that "the relevant issues of liability have been previously decided" and further instructing the jury as to the "legal basis of * * * liability." *Ibid.*; cf. *MCI Communications Corp.* v. *AT&T Co.*, 708 F.2d 1081, 1168 (7th Cir.) (noting, after imposing similar conditions, that "[t]he most difficult part of the decision to remand for a partial new trial on damages is the formulation of rules to guide such a proceeding"), cert. denied, 464 U.S. 891 (1983).[2]

iii. Still other courts of appeals have taken a different approach altogether, focusing not on the extent to

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[2] At least one district court has gone further and concluded that, even where issues of liability and punitive damages are "inextricably intertwined," a partial retrial on damages is nevertheless permissible. *Olsen*, 1995 WL 62101, at *5. Reasoning that a full retrial would "would waste valuable resources (both public and private)," the court held that a partial retrial was permissible as long as "the parties are free to produce all relevant evidence within the framework of a partial trial in damages." *Id.* at *4-*5.

which the issues are interwoven (as *Gasoline Products* requires) but rather on the extent to which the error at the initial trial actually affected other portions of the verdict. For example, the Second Circuit has developed a standard that, in the context of an error affecting damages, considers whether "there is reason to think that the verdict may represent a compromise among jurors with different views on whether defendant was liable or if for some other reason it appears that the error on the damage issue may have affected the determination of liability." *Diamond D Enters. USA, Inc.* v. *Steinsvaag*, 979 F.2d 14, 17 (1992) (internal quotation marks and citation omitted), cert. denied, 508 U.S. 951 (1993); see *Ajax Hardware Mfg. Corp.* v. *Industrial Plants Corp.*, 569 F.2d 181, 185 (2d Cir. 1977) (noting that a partial retrial on damages is proper "only if the district court had been satisfied that the jury properly determined the issue of liability").[3] Under that standard, the Second Circuit has ordered a full retrial in a case involving punitive damages where it could be inferred that "a verdict [was] a compromise" because "damages [were] awarded in an amount inconsistent with the theory of liability offered at trial" and there was "a close question of liability." *Atkins* v. *New York City*, 143 F.3d 100, 104 (1998).

Similarly, the Fifth Circuit has stated that "a court may properly award a partial new trial only when the issue affected by the error could have in no way influenced the verdict on those issues which will not be included in the new trial." *Williams* v. *Slade*, 431 F.2d

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[3] That standard, in turn, appears to have originated in the leading treatise on civil procedure. See 11 Charles Alan Wright, Arthur R. Miller & Mary K. Kane, *Federal Practice and Procedure* § 2814, at 155-156 (2d ed. 1995).

605, 608 (1970). Conversely, where "the decision on the other issues could in any way have been infected by the error," "a new trial must be had on all issues." *Ibid.* Applying that standard, the Fifth Circuit has gone so far as to hold that a defendant who was not liable in the initial trial should be retried together with another defendant in whose favor a directed verdict was improperly granted. *Id.* at 609. And like the Second Circuit, the Fifth Circuit has ordered a full retrial in a case involving punitive damages where it concluded that "the jury's verdict on damages at the first trial suggests some rather fundamental confusion, the source of which is impossible to trace." *Fury Imports, Inc.* v. *Shakespeare Co.*, 554 F.2d 1376, 1388 (1977).

Finally, the Fourth Circuit, while initially focusing on the extent to which the issues are interwoven, see, *e.g.*, *Atlantic Coast Line R.R.* v. *Bennett*, 251 F.2d 934, 938-939 (1958), has more recently gravitated toward the Second Circuit's approach. In one case, the Fourth Circuit, in permitting a partial retrial on punitive damages, rejected the argument that "the district court's decision to set aside the first jury's punitive damage award necessitated a full retrial on all issues because the jury's 'prejudice' may have infected its rulings on [the plaintiff's] substantive claims." *Atlas Food Sys. & Servs.* v. *Crane Nat'l Vendors*, 99 F.3d 587, 599-600 (1996). The court acknowledged that "[a] finding of liability and compensatory damage is not only a prerequisite to finding punitive damages, it provide[s] the jury with important background information." *Id.* at 600. While thus seemingly recognizing that liability and punitive damages were interwoven issues, the Fourth Circuit nevertheless held that a partial retrial on punitive damages was consistent with the Seventh Amendment. This Court should grant review in order to resolve the inconsistency

in the courts of appeals' divergent and irreconcilable approaches.[4]

2. *The Court Of Appeals' Decision To Grant A Partial Retrial Limited To Punitive Damages Is Erroneous*

The court of appeals in this case held that a partial retrial on punitive damages did not violate the Seventh Amendment. App., *infra*, 43a-44a. That holding is incorrect.

a. There can be no serious dispute in this case that the issues of liability and punitive damages are intertwined. In the first phase of the initial trial, the jury was asked to determine whether petitioners failed to warn about the risk of breast cancer associated with their medicines and whether any failure to warn proximately caused respondent's breast cancer; in the second phase, the jury was asked to determine whether, in failing to warn, petitioners acted with malice or in reckless disregard of the consequences. Compare D. Ct. Verdict Form

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[4] The court of appeals' decision in this case is irreconcilable not only with the decisions of other circuits applying *Gasoline Products* in the same or similar circumstances, but also with its own decisions in earlier cases, which had repeatedly "refused to grant a new trial solely on punitive damages" on the ground that "the issue of punitive damages was so interwoven with the substantive merits." *McDonald* v. *Johnson & Johnson*, 722 F.2d 1370, 1388 (8th Cir.), cert. denied, 469 U.S. 870 (1984); see, *e.g.*, *Burke* v. *Deere & Co.*, 6 F.3d 497, 513-514 (8th Cir. 1993), cert. denied, 510 U.S. 1115 (1994); *Slater* v. *KFC Corp.*, 621 F.2d 932, 938 (8th Cir. 1980); *Nodak Oil Co.* v. *Mobil Oil Corp.*, 533 F.2d 401, 411 (8th Cir. 1976). Although such an intracircuit conflict does not independently warrant this Court's review, it further illustrates the disarray in the lower courts concerning the correct application of the *Gasoline Products* standard.

1 (Feb. 25, 2008) with D. Ct. Verdict Form 1 (Mar. 6, 2008).

Given the overlap in the issues, in the second phase of the initial trial, the district court instructed the jury that it "should consider the evidence presented in the first phase of the trial as well as in the second phase." Tr. 2917, 2978. Counsel for respondent similarly invited the jury to consider that evidence in the second phase, Tr. 2646-2649, and both sides repeatedly referred to that evidence in their closing arguments, Tr. 2646-2652, 2661, 2663, 2668, 2670-2671. And for its part, the court of appeals heavily relied on that evidence in concluding that there was sufficient evidence of the requisite state of mind to warrant a new trial on punitive damages for the Wyeth petitioners. See App., *infra*, 4a-22a, 41a-43a.

b. The court of appeals nevertheless summarily held that a partial retrial was consistent with the Seventh Amendment on the ground that "a new trial may be had on punitive damages alone without injustice to the parties." App., *infra*, 43a-44a. Although the court of appeals cited *Gasoline Products*, it made no effort whatsoever to analyze whether the issues of liability and punitive damages are "distinct and separable," as *Gasoline Products* requires. See 283 U.S. at 500. In fact, the overlap between liability and punitive damages in this case is at least as substantial as the overlap between liability and the amount of damages that the Court found to be sufficient to preclude a partial retrial in *Gasoline Products*. See *id.* at 500-501.

In a partial retrial limited to punitive damages, a second jury would necessarily revisit issues related to those decided by the first jury without having the opportunity to see and hear the evidence as it was actually presented to that jury (regardless of whether testimony from the initial trial is read into the record or witnesses

instead testify live for a second time). The second jury would also be deprived of the opportunity to draw all permissible inferences from that evidence, in the event it were instructed to assume that the evidence establishes liability even if the second jury would independently draw the contrary conclusion. Given the overlap in the issues, a partial retrial limited to punitive damages would lead to "confusion and uncertainty" that "would amount to a denial of a fair trial," in contravention of the Seventh Amendment and associated principles of due process. *Gasoline Products*, 283 U.S. at 500.

This Court's decisions defining the constitutional bounds on punitive-damage awards confirm that the issue of punitive damages is not "distinct and separable" from the issue of liability. Since *Gasoline Products*, the Court has explained that the amount of punitive damages must bear a "reasonable relationship" to the amount of compensatory damages. *BMW of North America* v. *Gore*, 517 U.S. 559, 580 (1996). The Court has also made clear that punitive damages may be awarded only for "the conduct that harmed the plaintiff," *State Farm Mut. Auto. Ins. Co.* v. *Campbell*, 538 U.S. 408, 423 (2003), and not for "[the] injury that [the defendant] inflicts upon nonparties," *Philip Morris USA* v. *Williams*, 549 U.S. 346, 353 (2007). In determining whether to award punitive damages, therefore, a jury is required to focus on the defendant's conduct vis-à-vis the plaintiff: specifically, whether, "in committing the wrong complained of, [the defendant] acted recklessly, or willfully and maliciously, with a design to oppress and injure the plaintiff." 1 J.G. Sutherland, *Law of Damages* 720 (1883); see, *e.g.*, *Day* v. *Woodworth*, 54 U.S. (13 How.) 363, 371 (1852). The evidence that is admitted to make that showing, moreover, "must have a nexus to the specific harm suffered by the plaintiff." *State Farm*, 538 U.S. at 422.

As a result, the issue of what is required to award punitive damages not only will, but must as a matter of due process, substantially overlap with the issue of what is required to establish liability on the underlying claim in the first place. The court of appeals' holding that punitive damages can be tried separately from liability threatens to deny petitioners a fair trial, because a jury that is told that the defendant is culpable and that its sole task is to assess the degree of culpability is hardly writing on a clean slate. The Court should grant review in this case to clarify the *Gasoline Products* standard, and hold that a partial retrial limited to punitive damages is inconsistent with the Seventh Amendment.

3. The Permissibility Of A Partial Retrial Limited To Punitive Damages Is An Important And Recurring Issue That Warrants This Court's Review In This Case

The Seventh Amendment issue raised by the court of appeals' decision is an exceptionally important one in modern civil litigation—particularly mass tort litigation of the type at issue here, in which claims for punitive damages have become commonplace. As discussed above, in the nearly eighty years since this Court's decision in *Gasoline Products*, the issue of the permissibility of a partial retrial limited to punitive damages has frequently recurred, often resulting in multiple decisions on the issue in any given court of appeals. See pp. 11-18, *supra*. This case presents an excellent vehicle for consideration of that issue, because the issue was properly preserved and passed upon below. See App., *infra*, 43a-44a; Wyeth C.A. Br. 103; Upjohn C.A. Br. 52-53.

More broadly, a decision by the Court in this case would shed light on the cryptic and confusing *Gasoline Products* standard—and therefore on its application in other contexts in which the issue of the permissibility of

a partial retrial regularly arises. To take but a few examples, lower courts have confronted that issue in cases involving partial retrials on liability, see, *e.g.*, *La Plante* v. *American Honda Motor Co.*, 27 F.3d 731, 738 (1st Cir. 1994); on the amount of compensatory damages, see, *e.g.*, *Broan Mfg. Co.* v. *Associated Distributors, Inc.*, 923 F.2d 1232, 1241 (6th Cir. 1991); on the amount of consequential damages, see, *e.g.*, *Rice* v. *Community Health Ass'n*, 203 F.3d 283, 290 (4th Cir. 2000); on a single claim, see, *e.g.*, *American Home Assurance Co.* v. *Sunshine Supermarket, Inc.*, 753 F.2d 321, 329 (3d Cir. 1985); and for a single defendant, see, *e.g.*, *Bosse* v. *Litton Unit Handling Sys.*, 646 F.2d 689, 694 (1st Cir. 1981). Because of the considerable importance and frequent recurrence of the Seventh Amendment issue both in this specific context and more generally, the Court should grant review on that issue here.

B. This Court Should Grant Review To Decide Whether A Trial Court Can Admit The Testimony Of A Scientific Expert Without Expressly Addressing The Applicability Of The 'Daubert' Factors

1. The Courts Of Appeals Are Divided On The Correct Approach To The Application Of The 'Daubert' Factors

a. The second issue that warrants this Court's review involves the application of the Court's decision in *Daubert*, *supra*. The *Daubert* Court set out four factors relevant to whether the testimony of a scientific expert is sufficiently reliable to be admissible under Federal Rule of Evidence 702. Those now-familiar factors are (1) whether the expert's theory or technique can be and has been tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether the technique has a known or potential rate of error and standards exist to control its operation; and (4)

whether the theory or technique enjoys general acceptance within a relevant scientific community. See 509 U.S. at 593-594.

In setting out those factors, the Court explained that they do not constitute "a definitive checklist or test." *Daubert*, 509 U.S. at 593. And the Court has since made clear that, in determining how to apply those factors, trial courts have substantial discretion. See *Kumho Tire Co.* v. *Carmichael*, 526 U.S. 137, 153 (1999). At the same time, however, the Court has warned that trial courts "should consider [the *Daubert* factors] where they are reasonable measures of the reliability of expert testimony." *Id.* at 152. In addition, some members of the Court have emphasized that "trial-court discretion in choosing the manner of testing expert reliability * * * is not discretion to abandon the gatekeeping function" or "to perform the function inadequately." *Id.* at 158-159 (Scalia, J., joined by O'Connor and Thomas, JJ., concurring). Instead, "it is discretion to choose among *reasonable* means of excluding expertise that is *fausse* and science that is junky." *Id.* at 159. Thus, while "the *Daubert* factors are not holy writ," "the failure to apply one or another of them [in a particular case] may be unreasonable[] and hence an abuse of discretion." *Ibid.*

b. Since this Court's decision in *Daubert*, the courts of appeals have taken divergent approaches on the extent to which they require trial courts to address the applicability of the *Daubert* factors.

i. On the one hand, some courts of appeals have required specific analysis of the *Daubert* factors and detailed findings of facts. The Fifth Circuit has explicitly provided that, "[i]n the vast majority of cases, the district court first should decide whether the factors mentioned in *Daubert* are appropriate." *Black* v. *Food Lion, Inc.*, 171 F.3d 308, 311-312 (1999). Only then, after "con-

sider[ing] the *Daubert* factors," can the court proceed to "consider whether other factors, not mentioned in *Daubert*, are relevant to the case at hand." *Id.* at 312. In subsequent cases, the Fifth Circuit has repeatedly reaffirmed that approach. See, *e.g.*, *Paz* v. *Brush Engineered Materials, Inc.*, 555 F.3d 383, 388 (2009) (explaining that, "[a]fter the district court considers the *Daubert* factors[,] the [c]ourt then can consider whether other factors . . . are relevant to the case at hand" (internal quotation marks omitted)); *Hathaway* v. *Bazany*, 507 F.3d 312, 318 (2007) (noting that "the district court must decide whether the factors discussed in *Daubert* are appropriate, use them as a starting point, and then ascertain if other factors should be considered").

Similarly, in the Tenth Circuit, a trial court is "required to make specific, on-the-record findings that the testimony is reliable under *Daubert*" before admitting the testimony of a scientific expert. *United States* v. *Roach*, 582 F.3d 1192, 1207 (2009), cert. denied, 130 S. Ct. 1160 (2010). To be sure, the Tenth Circuit has not explicitly required a trial court to decide *first* whether the *Daubert* factors are applicable. But it has stressed that, "[w]hile the district court has discretion in the *manner* in which it conducts its *Daubert* analysis, there is no discretion regarding the actual *performance* of the gatekeeper function." *Goebel* v. *Denver & Rio Grande Western R.R.*, 215 F.3d 1083, 1087 (2000); accord, *e.g.*, *United States* v. *Zhang*, 458 F.3d 1126, 1129 (10th Cir. 2006), cert. denied, 549 U.S. 1187 (2007). Thus, in *Dodge* v. *Cotter Corp.*, 328 F.3d 1212, cert. denied, 540 U.S. 1003 (2003), the Tenth Circuit held that it was an abuse of discretion for the trial court to admit the testimony of a medical expert concerning causation despite the trial court's statements on the record that the expert was well qualified, had reviewed the medical literature, and had

relied on a well-accepted treatise for data. 328 F.3d at 1226. The Tenth Circuit stated that such comments were "insufficient by themselves to fulfill the gatekeeper function." *Id.* at 1227.

The Ninth Circuit has followed the Tenth Circuit's approach. Thus, it has "agree[d] with the Tenth Circuit that 'some * * * reliability determination must be apparent from the record' before we can uphold a district court's decision to admit expert testimony." *Mukhtar* v. *California State University*, 299 F.3d 1053, 1064-1066 (9th Cir. 2002) (quoting *United States* v. *Velarde*, 214 F.3d 1204, 1210 (10th Cir. 2000)). Although the Ninth Circuit also has not explicitly required a trial court to decide as a threshold matter whether the *Daubert* factors are applicable, it does require the trial court to make an explicit finding of reliability. See, *e.g.*, *United States* v. *Jawara*, 474 F.3d 565, 583 (2007); *Hangarter* v. *Provident Life & Accident Ins. Co.*, 373 F.3d 998, 1018 (2004).

ii. On the other hand, some courts of appeals have held that trial courts need not specifically address the applicability of the *Daubert* factors or make detailed findings of fact. The Seventh Circuit has explicitly held that "there is no requirement that the district judge consider each one of [the *Daubert*] 'guideposts' when making an admissibility ruling." *Ancho* v. *Pentek Corp.*, 157 F.3d 512, 515-516 (1998). Other Seventh Circuit decisions are to the same effect. See, *e.g.*, *Walker* v. *Soo Line R.R.*, 208 F.3d 581, 590 (noting, in a case in which "the district court did not articulate explicitly [the expert's] experience in terms of the *Daubert* factors," that "the district court's consideration of the question was not so inadequate as to render it faulty as a matter of law"), cert. denied, 531 U.S. 930 (2000).

The Fourth Circuit has also rejected the proposition that a trial court must specifically analyze the *Daubert* factors in order to comply with *Daubert*'s requirements. See, *e.g.*, *Maryland Casualty Co.* v. *Therm-O-Disc, Inc.*, 137 F.3d 780, 785 (per curiam) (refusing to hold that a trial court must evaluate the *Daubert* factors in considering the admissibility of testimony of scientific expert), cert. denied, 525 U.S. 827 (1998). And the Eleventh Circuit has made clear that, while it "encourage[s] district courts to make specific fact findings concerning their application of Rule 702 and *Daubert* in each case where the question arises," such factfinding is not required. *United States* v. *Lee*, 25 F.3d 997, 999 (1994) (per curiam).

2. The Correct Approach To The Application Of The 'Daubert' Factors Is An Important And Recurring Issue That Warrants This Court's Review In This Case

a. This case constitutes an ideal vehicle for the Court to clarify the correct approach to the application of the *Daubert* factors. It is clear that, if the trial court had addressed the applicability of those factors, it would have determined both that the factors were applicable and that they compelled the exclusion of the expert testimony at issue. That testimony—which was essential to respondent's case—was classic junk science, because it sought to use differential diagnosis to determine the cause of a disease where the cause is unknown in the vast majority of cases.

To begin with, the magistrate judge admitted the testimony of respondent's expert, Dr. Naftalis, without *any* analysis of the *Daubert* factors (or any explanation as to why those factors were inapplicable). See App., *infra*, 119a-120a. Although the magistrate judge cited the district court's ruling admitting the testimony of a different expert in a different trial involving a plaintiff with a dif-

ferent medical history, that ruling likewise did not address the applicability of the *Daubert* factors. See *id.* at 124a-144a. In that ruling, the district court made no finding that using differential diagnosis to determine the cause of breast cancer in an individual woman was a technique that can be or has been tested for accuracy. Rather, the court stated that "reliance on differential [diagnosis] is not fatal when epidemiological studies also support the expert's conclusions," *id.* at 130a—hardly a determination that differential diagnosis was a reliable methodology *in the absence of* those studies. That earlier ruling also did not find that differential diagnosis, as applied to determine the cause of breast cancer in an individual, had been subjected to peer review and publication.[5] And it did not cite any evidence that the use of differential diagnosis to determine the cause of breast can-

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[5] There is no dispute that differential diagnosis is an accepted methodology when the potential causes of a disease are known. But the use of that methodology in other contexts no more proves its reliability here than the general acceptance of diagnosing a fever by use of a thermometer means that using a thermometer is a reliable method for diagnosing breast cancer. When assessing reliability of an expert's method, the issue is not the abstract reasonableness of the method, but rather "the reasonableness of using such an approach * * * to draw a conclusion regarding *the particular matter to which the expert testimony was directly relevant.*" *Kumho Tire*, 526 U.S. at 154. Accordingly, lower courts have frequently concluded that differential diagnosis is inappropriate where, as here, most of the causes of a disease are unknown. See, *e.g.*, *Henricksen* v. *Conoco Phillips Co.*, 605 F. Supp. 2d 1142, 1162 (E.D. Wash. 2009); *Perry* v. *Novartis Pharms. Corp.*, 564 F. Supp. 2d 452, 469 (E.D. Pa. 2008); *Doe* v. *Ortho-Clinical Diagnostics, Inc.*, 440 F. Supp. 2d 465, 478 (M.D.N.C. 2006).

cer was a generally accepted method within the medical community.[6]

At a hearing before the magistrate judge, moreover, petitioners conclusively demonstrated that the *Daubert* factors supported exclusion of Dr. Naftalis's testimony as unreliable. First, differential diagnosis has never been tested as applied to breast cancer, nor is it easy to conceive of how it could be tested—but, because no doctor has ever used the method outside of the litigation context, the issue has never arisen. Second, differential diagnosis, as applied in this context, has never been peer-reviewed; at the *Daubert* hearing, Dr. Naftalis conceded that she was unable to name any book or article that described the use of differential diagnosis to determine the cause of breast cancer, and she had never presented her theory to her peers nor heard any of her peers present it. See *Daubert* Tr. 1040-1041, 1048-1049. Third, there is no evidence that differential diagnosis has any known or potential rate of error as applied to breast cancer: because scientists do not know what causes most cases of breast cancer and most women who develop breast cancer have not taken hormone therapy, the "conclusion" in litigation of an expert that a specific woman's breast cancer was caused by a specific factor is simply unverifiable. See *id.* at 1023-1024; Resp. C.A. App. 826-827. Fourth, differential diagnosis is not a generally accepted method for determining the cause of breast cancer in either the medical community or by the expert herself in her own practice. See *Daubert* Tr. 1027, 1040-1041, 1048-1049, 1080-1081.

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[6] Notably, the district court subsequently acknowledged that its *Daubert* analysis in the earlier ruling may have been "too lax." Tr. 23 (May 18, 2007).

Because the *Daubert* factors supported exclusion of Dr. Naftalis's testimony, and because respondent failed to offer (and the magistrate judge failed to identify) any plausible reason not to apply those factors in this context, a rule that required a trial court specifically to analyze the applicability of those factors would be outcome-dispositive here. And the practical consequence of the failure to apply the *Daubert* factors was to permit junk science of precisely the type *Daubert* was intended to exclude—scientific testimony relying on a theory that had never been tested, peer-reviewed, applied in practice by the expert, or used outside the context of litigation.[7]

In addition, the magistrate judge's failure to apply (or address the applicability of) the *Daubert* factors rendered his ruling on the admissibility of Dr. Naftalis's testimony virtually impossible to review on appeal. Perhaps not surprisingly, therefore, the district court and the court of appeals similarly failed to analyze and apply the *Daubert* factors. The district court summarily overruled petitioners' objections to the magistrate judge's order. App., *infra*, 111a-112a. And while the court of appeals (like the magistrate judge) cited the *Daubert* factors, it did not apply them or otherwise address petitioners' contention that differential diagnosis was an insufficiently reliable method to determine the cause of respondent's cancer. See *id.* at 27a-30a. At every stage of the judicial

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[7] The linchpin of Dr. Naftalis's theory was that, if a woman has menopausal symptoms, her body necessarily will have insufficient natural hormones to produce breast cancer, enabling Dr. Naftalis to rule out natural hormones as a cause and to identify hormone therapy as the cause instead. If that theory were valid, however, it would necessarily imply that women with menopausal symptoms who did not take hormone therapy were immune from breast cancer—which is contrary to established scientific fact.

process, therefore, the *Daubert* analysis in this case was insufficient. This Court should grant review to clarify that, at least in a case involving the testimony of a scientific expert, a trial court must address the applicability of the *Daubert* factors before discarding those factors and relying on other factors in the reliability analysis.

b. As with the Seventh Amendment issue, the *Daubert* issue is an exceptionally important one to civil litigants. It is no overstatement to say that questions concerning the applicability of the *Daubert* factors arise literally every day in courts around the Nation; in multidistrict litigation, moreover, a single *Daubert* ruling can apply to thousands of cases. Yet this Court has not provided substantial guidance concerning how trial courts should go about the process of applying *Daubert*. In fact, the Court has not addressed *any* aspect of *Daubert* since its decision in *Kumho Tire* more than a decade ago—notwithstanding the central importance of *Daubert* in cases like this one, which as a practical matter will often stand or fall based on the admissibility of expert testimony on issues such as causation. It cannot be disputed that courts around the Nation have radically different views on how they are to perform their vital gatekeeping responsibilities under *Daubert*. This Court should grant review to bring much-needed consistency on an issue of considerable practical significance.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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