No. 09-1123

In The

# Supreme Court of the United States

WYETH LLC, et al.,

*Petitioners,*

v.

DONNA SCROGGIN,

*Respondent.*

**On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Eighth Circuit**

## BRIEF IN OPPOSITION

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## QUESTIONS PRESENTED

1. Whether the grant of a retrial to determine a plaintiff's entitlement to punitive damages automatically necessitates a retrial of defendant's liability on the underlying substantive claim.

2. Whether review of Wyeth's challenges to the Eighth Circuit's judgment ordering a retrial limited to punitive damages should occur, if at all, only after that retrial has taken place, allowing those challenges to be evaluated based on a concrete record rather than speculation and conjecture.

3. Whether this Court should promulgate, in its adjudicatory capacity, a particular level of specificity that trial and appellate court decisions must exhibit when resolving *Daubert* challenges to expert testimony.

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## STATEMENT

Donna Scroggin sued Wyeth and Upjohn[1] for failing to warn adequately of the risk of combination hormone therapy ("E+P"),[2] causing her to lose her breasts to cancer. Despite countless signals over two decades of the need to study the breast cancer risk, including repeated admonitions by the FDA, neither company performed studies (Petitioners' Appendix (hereafter "Pet. App.") at 9a-12a (Wyeth); 15a-16a (Upjohn)). Wyeth actually turned down offers to participate in studies based on a company policy not to support breast cancer research (Pet. App. at 9a-10a). When adverse breast cancer data was publicized by others, Wyeth sought to discredit and divert attention from the findings, refusing to incorporate the results into its product warnings (Pet. App. at 7a-13a). This lack of study resulted in warnings that failed to convey the real risk of breast cancer (Pet. App. at 19a-21a).

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[1] "Wyeth" refers to Wyeth and Wyeth Pharmaceuticals Inc., both now succeeded by Wyeth LLC. "Upjohn" refers to Pharmacia & Upjohn Company LLC. Wyeth and Upjohn were the defendants at trial and the appellees/cross-appellants on appeal. They are the petitioners here, collectively referred to herein as "defendants." Wyeth and Upjohn are now wholly owned by Pfizer Inc.

[2] "E+P" refers to the combination of estrogen (E) with synthetic progestin (P). Ms. Scroggin originally took Wyeth's E (Premarin) and Upjohn's P (Provera). She later took Wyeth's single pill, Prempro, which contained both E and P. Ms. Scroggin took E+P from 1989 until her breast cancer diagnosis in 2000 (Pet. App. at 3a).

After the first phase of trial, the jury found both defendants liable for compensatory damages for failing to warn of the risks they knew or should have known (Pet. App. at 2a; Jury Verdict, compensatory phase, Trial Court Docket, Document 552 (Feb. 25, 2008), Respondent's Appendix (hereafter "Resp. App.") at 3a-4a). After the second phase, the jury (a) found both defendants liable for reckless disregard from which malice may be inferred and (b) awarded punitive damages against both (Pet. App. at 2a; Jury Verdict, punitive phase, Trial Court Docket, Document 616 (Mar. 6, 2008), Resp. App. at 5a-6a). The district court denied defendants' motions for judgment as a matter of law on liability and compensatory damages, but granted the motions with respect to punitive damages. The court held that testimony by plaintiff's liability expert in the punitive phase was inadmissible and found the documentary evidence insufficient to warrant a punitive award. In the alternative, the court granted a new trial limited to punitive damages (Pet. App. at 2a, 38a-39a, 109a-110a).

The United States Court of Appeals for the Eighth Circuit affirmed judgment on the compensatory award for plaintiff, affirmed judgment as a matter of law on punitive damages for Upjohn, but reversed judgment as a matter of law on punitive damages for Wyeth. In adopting the alternative relief of a new trial limited to punitive damages, Judge Wollman, writing for a unanimous court, found the documentary evidence sufficient to sustain a punitive award against Wyeth. Nevertheless, the court

determined that a new trial was required in light of inadmissible testimony by plaintiff's expert (Pet. App. at 39a-43a). The court concluded that the new trial could be limited to punitive damages without injustice (Pet. App. at 43a-44a). Defendants ask this Court to grant review of the new trial order and the *Daubert* evaluations by the courts below.

1) Hormone therapy treats the vasomotor and urogenital symptoms of menopause. At menopause, a woman's ovaries shut down, significantly reducing her natural ("endogenous") estrogen production. Most women continue to make tangible levels of estrogen in other organs of the body. A minority do not. The latter are estrogen-deficient and suffer from symptoms such as hot flashes and vaginal atrophy/dryness. The hormones in defendants' pills ("exogenous" hormones) reduce these symptoms by increasing the supply of estrogen in the woman's body (Pet. App. at 3a, 29a & n. 12) even beyond the levels she experienced before menopause.

The danger of manipulating hormone levels post-menopause was first discovered in the mid-'70s when the nation experienced an epidemic of endometrial cancer. This cancer surge coincided almost in lock-step with a dramatic increase in the sale of Premarin, Wyeth's estrogen-only product. Several case control studies established that unopposed estrogen promotes the growth of estrogen receptor-positive cancer in the endometrial lining of the uterus. An FDA advisory committee concluded that Premarin was responsible for the endometrial cancer crisis.

Despite attending the FDA committee meeting, Wyeth sent a "Dear Doctor" letter to all physicians, reassuring doctors that endometrial cancer was too complicated to implicate estrogen as the culprit. According to Wyeth, so long as women took the drug as indicated, their risk would be minimal (Pet. App. at 4a-6a).[3]

Wyeth's letter "in[c]ensed the FDA at all levels, including the Commissioner." FDA officials, including the Director of the Bureau of Drugs, immediately met with Wyeth, explaining that the company was expected to react to scientific findings with sound scientific information. The company had not engaged in any study that would justify disputing the cancer link (Pet. App. 6a-7a).

The following year, scientists speculated that adding progesterone (commercially sold as synthetic progestin) ("P") to estrogen ("E") would reduce the endometrial cancer risk. Prescribing E+P to all women with intact uteri quickly became standard for menopausal symptoms, despite the fact that there had been no studies on the long-term risks of E+P (Pet. App. at 4a-5a, 8a).

The endometrial cancer crisis and the FDA's reaction to Wyeth's Dear Doctor letter put Wyeth on notice of the need to study potential cancer risks of

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[3] All of the facts stated in this section, and all citations herein, are from the Eighth Circuit opinion.

E+P. An internal Wyeth memo from 1976 acknowledged that the company's own doctors had real concerns about whether hormones increase the risk of breast cancer (Pet. App. at 7a). A memo from the next year acknowledged that there were no well-designed or controlled studies on E+P (Pet. App. at 8a).

Nevertheless, Wyeth failed to study the breast cancer risk of E+P. The result was a lack of adequate safety information on the regimen. An FDA advisory committee meeting in 1990 concluded that data on the breast cancer risk of E+P was insufficient. Rather than see this finding as a red flag of the need for study, Wyeth viewed the committee's announcement as a success for Wyeth (Pet. App. at 12a). In 1992, the Degge Group, a consulting company, reviewed all available studies and concluded there was insufficient information on the breast cancer risk (Pet. App. at 14a-51a).

Wyeth not only failed to conduct its own study, it refused to assist others conducting breast cancer studies. In 1993, for instance, Wyeth refused to provide Premarin for a study by the Eastern Cooperative Oncology Group based on Wyeth's policy not to contribute drugs to studies on breast cancer (Pet. App. at 10a). Two years later, Wyeth refused to provide mammograms for a British study on E+P and breast density (a risk factor for breast cancer) unless the authors agreed not to look at breast cancer risk and ceded editorial control over any study articles to Wyeth (Pet. App. at 10a).

Wyeth's failure to study was part of a deliberate attempt to conceal the breast cancer risk of E+P. Wyeth took active steps to quell adverse breast cancer findings. When studies like those by Drs. Robert Hoover and Graham Colditz reported high breast cancer risks, Wyeth hired public relations firms to undermine the findings and positioned press liaisons at conferences to distract from study results (Pet. App. at 7a-11a). For instance, in 1996, Dr. Steven Cummings sent Wyeth an abstract of a study sponsored by the National Institutes of Health which revealed that the long-term breast cancer risk for E+P may have been substantially underestimated. Wyeth responded by creating an internal task force to discredit the study. The group's mission was to "Dismiss/Distract" and "[k]eep [the] U.S. press busy" by shifting attention away from the study while simultaneously attacking the study's validity (Pet. App. at 10a-11a). Wyeth had created a similar task force six years earlier to prevent the International Agency for Research on Cancer (IARC), a branch of the World Health Organization charged with identifying carcinogens, from developing a definitive position on hormone therapy (Pet. App. at 9a & n. 6).

Wyeth also ghostwrote articles rejecting the breast cancer link (Pet. App. at 11a) and refused to allow respected oncologists to chair consultant meetings (Pet. App. at 10a). Wyeth even created a magazine promoting E+P to its customers, while seeking to mislead them into believing the magazine had been provided by the pharmacy filling their prescriptions.

The FDA found this "campaign in its entirety to be a form of extremely insidious hidden persuasion" and nothing more than a "marketing ploy masquerading as concern for the health of postmenopausal women." Wyeth was forced to revamp the campaign (Pet. App. at 12a-13a).

2) During both the '80s and early '90s, Wyeth repeatedly sought FDA approval to sell combination hormone therapy. The FDA rejected Wyeth's applications, each time informing the company that there was insufficient science on the safety and efficacy of E+P (Pet. App. at 11a-12a). Finally, in 1993, Wyeth applied for approval of a single pill that combined estrogen and progestin. The FDA was faced with a Hobson's choice. Prescriptions of E+P were rampant. For over a decade, the agency had informed Wyeth that there was not enough breast cancer data on the combination product. Yet, Wyeth refused to perform studies. The FDA could not force study because Premarin, Wyeth's E product, had been approved many years earlier. The only way the FDA could compel a study on the breast cancer risk of E+P was to approve the application on the condition that Wyeth perform a comprehensive breast cancer study (a "Phase IV" commitment). The FDA did precisely that (Pet. App. at 13a). Wyeth later convinced the agency to allow its support for the government-run Women's Health Initiative Study ("WHI"), *infra*, to satisfy its Phase IV commitment (Pet. App. at 13a). But this study came too late for Donna Scroggin.

Wyeth's failure to study resulted in product warnings that were milquetoast. They reassured physicians and women alike that there was no real breast cancer risk. While Wyeth's Premarin and Prempro labels mentioned that some studies had suggested a risk from estrogen, the label said the risk, if any, was limited to high dose or long duration use. The labels negated even that lukewarm warning by saying the majority of studies showed *no* risk from *any* use. The Prempro labels indicated the effect of adding progestins was "unknown." More significantly, the labels stated that Wyeth's clinical trial established that the breast cancer rate among E+P users was no different than the breast cancer rate in the general population.[4] Expert testimony established that these labels did not convey the true risk of breast cancer. Ms. Scroggin's prescribing physician testified the labels reassured him there was no tangible risk (Pet. App. at 19a-20a).

Around the time Wyeth filed its application for Prempro, the National Institutes of Health had begun a large-scale, randomized, placebo-controlled clinical trial on E+P to determine whether hormone therapy had the cardiovascular benefits long touted. The WHI was halted in July, 2002, three years before its scheduled completion, because breast cancer rates among study group participants reached unacceptable

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[4] The label failed to mention that this trial, called the Pivotal Trial, was neither designed nor powerful enough to detect a breast cancer risk.

levels. WHI researcher Garnet Anderson calculated that use of E+P for more than five years resulted in more than a tripling of the risk of breast cancer (a 3.56 relative risk) (Pet. App. at 18a-19a).

Ecological data reveals that breast cancer rates, particularly for hormone receptor-positive tumors, *infra*, have increased in lock-step with increased prescriptions of E+P. And significantly, the year after prescriptions for E+P plummeted when the WHI results were announced, breast cancer rates nosedived (Pet. App. at 21a). Experts now describe E+P's relationship to breast cancer as causal (Pet. App. at 19a). The IARC now classifies E+P as a known carcinogen of the breast (Pet App. at 19a). Consequently, neither defendant even challenged general causation in the *Daubert* hearing or on appeal.

Dr. Elizabeth Naftalis, plaintiff's oncology expert, testified that E+P caused Donna Scroggin's breast cancer. Dr. Naftalis is a respected breast surgical oncologist and former assistant professor in the Department of Surgical Oncology at the University of Texas Southwestern Center for Breast Care. After establishing that E+P generally causes breast cancer based on substantial epidemiological and ecological data, Dr. Naftalis engaged in differential diagnosis that isolated E+P as the "but for" cause of Ms. Scroggin's cancer. Defendants concede that differential diagnosis is a generally accepted and reliable methodology (Pet. at 27 n. 5). Defendants claim only that differential diagnosis was inappropriate here because

we do not know all the causes of breast cancer (Pet. at 27-28 & n. 5).

As they have consistently done throughout the litigation, defendants ignore the difference between (a) what *initiates* cancer, that is, what creates the first abnormal cell that eventually grows into cancer and (b) what *promotes* cancer, that is, what spurs the abnormal cell to grow and proliferate into cancer. While we do not know "(a)" in a given woman, we often know "(b)," depending upon the nature of the cancer. In other words, in certain circumstances, while we do not know all the factors that might be responsible for creating the abnormal cell, we do know the factors that could be responsible for the growth of the abnormal cell into an invasive malignancy.

In performing her differential diagnosis, Dr. Naftalis first determined the sensitivity of Ms. Scroggin's tumors to hormones. Ms. Scroggin suffered from hormone-dependent breast cancer. Pathological testing revealed that each tumor tested 100 percent positive for the presence of both estrogen receptors and progesterone receptors (Pet. App. at 29a). There was no dispute in this case that hormone receptor-positive tumors must have hormones to develop and grow into cancer. Published peer-reviewed literature confirmed that is the case (Pet. App. at 29a).

Given that the abnormal cells in Ms. Scroggin's breasts (regardless of what initiated them in the first instance) could not develop into cancer "but for" the presence of hormones, the remainder of Dr. Naftalis'

differential diagnosis properly focused on the sources of hormones that could be responsible for the growth of these tumors. Ms. Scroggin had only two potential sources of hormones: the hormones in defendants' pills (exogenous hormones) and the hormones her body produced naturally (endogenous hormones). Published, peer-reviewed research suggests that menopausal symptoms such as hot flashes occur when a woman is estrogen-deficient, that is, when her body is producing insubstantial levels of estrogen (Pet. App. at 29a). Unquestionably, vaginal atrophy (including dryness) is caused exclusively by lack of estrogen (Pet. App. at 29a). Ms. Scroggin suffered from both symptoms (Pet. App. at 3a), and both were relieved when she took hormone therapy (Pet. App. at 29a). Therefore, more likely than not, her tumors were fueled by the hormones in defendants' pills rather than the negligible hormones her own body produced after menopause (Pet. App. at 29a-30a).

After the parties filed four briefs on this issue, Magistrate Judge Henry L. Jones held an oral hearing, after which he ordered two additional sets of briefing by both sides before rendering his decision. In a written opinion discussing *Daubert* and its progeny, including the four indicia upon which defendants rely (Pet. App. at 115a-118a), Judge Jones rejected defendants' attack and found Dr. Naftalis' testimony admissible, based on District Judge William R. Wilson, Jr.'s previous ruling in the first hormone therapy trial (Pet. App. at 119a-120a). In that ruling, Judge Wilson, after discussing *Daubert* and its progeny and

citing the factors at issue (Pet. App. at 125a-128a), noted that defendants' position on what "causes" (initiates) breast cancer ignores the issue of what "promotes" breast cancer. Differential diagnosis is a valid methodology for evaluating what more likely than not *promoted* the development of plaintiff's tumors (Pet. App. at 130a-131a).

The Eighth Circuit likewise discussed *Daubert* and its progeny and cited the standards at issue here (Pet. App. at 27a-28a). The court also recognized the distinction between "cause," as defendants used that term, and "but for cause," as the law recognizes causation. After noting that defendants' sole attack on differential diagnosis was based on the claim that "no one knows the cause of breast cancer," the court held the evidence established that hormones are essential to the development or growth of hormone receptor-positive tumors like Ms. Scroggin's. Thus, the court concluded, by isolating E+P as the source of the hormones fueling the tumors' growth, Dr. Naftalis was able to conclude E+P was the cause of Donna Scroggin's breast cancer (Pet. App. at 29a-30a).

## REASONS NOT TO GRANT THE PETITION

The two issues defendants raise are fact-intensive. Defendants disagree with the Eighth Circuit's application of the law to the facts. But knowing this Court is not inclined to review fact determinations, defendants have attempted to frame the issues as

questions of law involving conflicting court of appeals rulings. Defendants have erroneously characterized circuit court holdings limited to the facts of particular cases as universal pronouncements, thereby falsely suggesting the existence of conflicting rulings, given the different fact patterns of different cases. Defendants have manufactured conflicts out of whole cloth. In essence, Defendants want this Court to waste its limited *certiorari* resources reviewing the Eighth Circuit's straightforward application of garden-variety legal standards.

Review of the first issue, the alleged impropriety of a limited new trial, would be premature because the new trial has yet to occur. Rather than speculate as to whether the trial will be just, the Court should not grant review until the trial actually takes place and any appellate issues ripen, if at all. Further, the new trial in this case will involve both the determination of Wyeth's culpability and the assessment of damages. That is because the district court assigned the "malice" question to the second phase of trial. The limited trial will thus allow a full presentation of all evidence relating to the reprehensibility of Wyeth's conduct. Finally, there is no conflict among circuit court decisions addressing the propriety of limited trials. Circuit courts have alternately ordered partial retrials and denied them, based on the facts of individual cases. Wyeth's unwarranted extrapolation of case-specific rulings into universal holdings suggests a conflict where none exists.

Defendants' attempt to link this case to an alleged conflict among circuit courts as to *Daubert* holdings is equally contrived. This case involved extensive *Daubert* briefing, a full-day *Daubert* hearing and written findings of fact by the district court that were affirmed by the Eighth Circuit. Both courts' analyses include citation to the *Daubert* factors and explanations as to why defendants' arguments based on the *Daubert* factors are without merit. This case reflects appropriate adherence to and application of the *Daubert* factors and is therefore not the appropriate vehicle for revisiting how lower courts must evidence their compliance with *Daubert*.

### A. The Court Should Not Grant Review Here to Determine Whether New Trials Limited to Punitive Damages Should Be Prohibited.

#### 1. Review of the new trial order in this case would be premature because the lawsuit remains in an interlocutory posture.

The new trial on punitive damages has yet to occur. While, technically, the mandate of the Eighth Circuit is a final order, the lawsuit remains ongoing. A jury trial on (a) Wyeth's culpability for punitive damages and (b) the amount of punitive damages, if any, to be awarded has yet to occur.

This is significant for at least two reasons. First, Wyeth's arguments would be better evaluated, if at

all, after the new trial has occurred. Wyeth has speculated that evidence in the new trial may be introduced in ways that would be unjust (Pet. at 19-20). Plaintiff disagrees. But whether the presentation of evidence is fair is a question better evaluated after the presentation occurs.

Undertaking review now would undermine judicial efficiency and unnecessarily burden the Court. Were this Court to affirm, Wyeth would undoubtedly appeal on the same issue again after the new trial, if the jury finds for the plaintiff. If the jury finds for Wyeth, the company will not seek review. The Court would thus be better served by allowing the new trial to occur before contemplating review.

**2. In contrast to the new trials in various cases Wyeth cites, the new trial here will involve both Wyeth's culpability and the amount of damages and is therefore just.**

This case did not involve ordinary bifurcation. Rather, the MDL court determined that both the question of culpability for punitive damages and the amount thereof, if any, should be determined in the second phase of trial. Thus, in the punitive phase, the jury determined (a) whether Wyeth's conduct constituted reckless disregard from which malice may be inferred and, given its affirmative answer, (b) the amount of punitive damages to be awarded (Resp. App. at 5a-6a). The new trial will focus on the same

issues. The jury will decide culpability first and award damages only if it determines Wyeth's conduct reflected malice. That distinguishes this case from those cited by Wyeth in which a new trial limited to punitive damages was deemed unjust because the trial would not involve evaluation of the defendant's culpability. *See, e.g., Smyth Sales v. Petroleum Heat & Power Co.*, 141 F.2d 41, 44-45 (3d Cir. 1944) (trial on amount of punitive damages cannot be separated from evaluation of evidence of wanton and malicious conduct) (*cited in* Pet. at 13-14); *but cf. Atlas Food Systems and Services, Inc. v. Crane National Vendors, Inc.*, 99 F.3d 587, 599-600 (4th Cir. 1996) (finding limited new trial on punitive damages appropriate when new trial would include evidence of willful and wanton conduct) (*cited in* Pet. at 17).

This is significant for two reasons. First, it establishes that the new trial can be limited to punitive damages without creating confusion and uncertainty. All evidence relating to whether Wyeth's conduct was malicious, including evidence that was previously introduced in the first phase of trial, will be admissible in the new trial. This includes exonerating evidence. Wyeth claims that the evidence may not be introduced exactly the same way it was in the first trial, pointing out that a document may be read into evidence rather than being the subject of testimony, or vice versa (Pet. at 19-20). But that is true of any new trial, whether limited or not. Both sides hone and adjust their presentations based on what they learned from the first experience. The fact that new trials

inevitably do not mirror the initial trials hardly renders new trials inherently unfair.

Wyeth and the Washington Legal Foundation claim that the jury would not be free to draw all permissible inferences from the evidence (Pet. at 20; Brief of Washington Legal Foundation as Amicus Curiae in Support of Petitioners (hereafter "WLF Brf") at 12 n. 5). But that is false. The jury can make any inferences it chooses. The jury can even infer no wrongdoing at all from the evidence and, if so, would answer "no" to the reckless disregard question and decline to award any punitive damages.

Wyeth claims that punitive damages cannot be tried separately because punitive awards must bear a reasonable relationship to the compensatory damages awarded (Pet. at 20). But that is a standard by which appellate courts review the reasonableness of a punitive award. It is not the standard guiding the jury's evaluation. Typically, the jury is not even instructed in this regard because no bright line test exists for whether the ratio of punitive to compensatory damages is reasonable. Courts consider a number of factors that would only confuse a jury if it had to wade through them. *BMW of North America, Inc. v. Gore*, 517 U.S. 559, 580-83 (1996) (discussing factors courts consider in examining ratio). Further, nothing prohibits the district court in the new trial from informing the jury of the amount of compensatory damages awarded in the first trial.

Wyeth notes that juries must base their punitive awards solely on the conduct that harmed the plaintiff and not on conduct that harmed others (Pet. at 20). But this is accomplished, first, with instructions telling the jury it may consider harm to others solely in evaluating the reprehensibility of the conduct, but it must not award damages for harm to others. *Philip Morris USA v. Williams*, 549 U.S. 346, 355 (2007). The jury can be instructed in precisely that manner here. Second, the district court is obliged to exclude evidence involving conduct with no nexus to the plaintiff. That can occur in a limited new trial just as it did in the original trial. In this case, the district court – the court charged with evaluating the facts – determined that the new trial could permissibly be limited to the punitive damages issue (Pet. App. at 109a-110a).

The second reason the procedural posture of this case is important is that it means this case would not be the appropriate avenue for revisiting *Gasoline Products Co. v. Champlin Refining Co.*, 283 U.S. 494 (1931), even if the Court were inclined to reconsider that holding. In the vast majority of courts, when trials are bifurcated, the jury decides liability, compensatory damages and entitlement to punitive damages in the first phase of trial. The jury decides only the amount of punitive damages to be awarded in the second phase. *See, e.g., Transportation Insurance Co. v. Moriel*, 879 S.W.2d 10, 30 (Tex. 1994) (surveying state court bifurcation). Thus, the evidence in the second phase is generally limited to the financial status

(typically net worth) of the defendant. Under those circumstances, where the jury is not considering culpability, a partial retrial may be unjust. A case involving the ordinary bifurcation of compensatory and punitive damages would offer a more comprehensive review of this issue than this case would.

### 3. In deference to *Gasoline Products*, the circuit courts have consistently determined whether justice permits partial new trials based on the facts of particular cases.

a. Wyeth concedes that the law on limited new trials is controlled by *Gasoline Products* (Pet. at 10-11). That case involved the plaintiff's allegations of breach of a gasoline royalty contract and the defendant's counterclaim for breach of a partially oral contract for erection of gasoline treating towers. The jury found breach of both contracts and awarded damages to both parties. On appeal, the First Circuit found harmful error in the jury instructions on the measure of damages for the counterclaim. The court ordered a new trial on the counterclaim only, limited to the issue of damages. This Court reversed, finding that the damages associated with the counterclaim could not be separated from the other liability issues. *Gasoline Products*, 283 U.S. at 500.

The Court initially observed that the Constitution does not require retrial of every issue in a case merely because one issue was incorrectly determined.

> Here we hold that, where the requirement of a jury trial has been satisfied by a verdict according to law upon one issue of fact, that requirement does not compel a new trial of that issue even though another and separable issue must be tried again.

*Id.* at 499. The key inquiry is whether the issues to be retried can be separated from the others without creating confusion and uncertainty, and thus injustice. *Id.* at 500.

In *Gasoline Products*, no such separation could have occurred. The second jury would lack essential contract terms necessary to calculate damages. There was dispute at trial as to when contract performance was to begin and end and even the number of treating towers to be built. It was unclear whether the contract was purely for construction of the tower(s) or whether, regardless of the number of towers built, the plaintiff was obliged to make the defendant's plant capable of treating all gasoline products produced. The verdict form did not ask the jury to delineate the contract terms it found. Without knowing these terms, the second jury could not assess damages, which were largely based on lost profits. *Id.* at 496, 500. The jury would be calculating damages in a vacuum. So, while this Court approved a partial retrial on the counterclaim, it disapproved limiting that partial retrial to damages alone.

b. The circuit courts have remained faithful to *Gasoline Products*, ordering limited new trials when the issues are separable and denying limited new

trials when the issues are not. Wyeth claims that some courts deny limited new trials on punitive damages altogether whereas others allow them under certain general conditions. Wyeth has misinterpreted the holdings it cites. Those decisions are, not surprisingly, based on the facts of the cases the courts were evaluating. They do not contain universal rules to be applied in all cases, as Wyeth suggests.

(i) Wyeth erroneously argues that the Tenth Circuit, Third Circuit and Ninth Circuit forbid new trials limited to punitive damages (Pet. at 12-14). Not one of the three circuits has so held. The principal Tenth Circuit case Wyeth cites has nothing to do with this issue. *See Mason v. Texaco, Inc.*, 948 F.2d 1546 (10th Cir. 1991), *cert. denied*, 504 U.S. 910 (1992) (*cited in* Pet. at 12). Wyeth claims the court in *Mason* upheld an order to retry punitive damages with the rest of the case. What Wyeth fails to mention is that there was never any request for, or consideration given to, retrying punitive damages separately. In fact, the jury found no punitive damages and the plaintiff did not appeal that finding. Instead, the appellate court found an error regarding the compensatory damages issues and remanded for a new trial. The trial court retried all issues, including punitive damages, over the defendant's objections, and later issued judgment on a verdict that included punitive damages. The appellate court affirmed. *Id.* at 1549-50. The Tenth Circuit said nothing about the propriety of partial retrials, much less that new trials limited to punitive damages are prohibited. Rather,

the court said that because its mandate was a new trial on all "fact bound" issues, the trial court acted correctly by including punitive damages in the retrial. *Id.* at 1552.

The decision in *Haynes Trane Service Agency v. American Standard, Inc.*, 573 F.3d 947 (10th Cir. 2009) (*cited in* Pet. at 13) does not even involve punitive damages. In that case, a jury found fraud in various transactions, but the court took the compensatory damages issue under advisement, finding that an independent accounting was required. The appellate court held that was error; the jury should have found damages. A second jury could not calculate damages without reconsidering each transaction because the first jury found fraud without identifying which transactions were fraudulent and which were not. *Id.* at 966-67. Based on the particular facts of that case, a retrial of damages alone was inappropriate.

The only other Tenth Circuit case Wyeth cites found that, under the particular facts before it, a full retrial was necessary to avoid confusion and uncertainty. *Malandris v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 703 F.2d 1152, 1178 (10th Cir. 1981) (*citing Gasoline Products*, 283 U.S. at 500), *cert. denied*, 464 U.S. 824 (1983). The court did not state that new trials limited to punitive damages are prohibited. It announced no general rule at all.

Contrary to Wyeth's claim, the Third Circuit does not forbid new trials limited to punitive damages. In

fact, in *Smyth Sales* (*cited in* Pet. at 13), the Third Circuit expressly stated that its holding was limited to the facts of the particular case and Connecticut law. The court wrote that, under different circumstances, it may well have ordered a partial retrial on damages alone. *Smyth Sales*, 141 F.2d at 45 ("It would, therefore, be inappropriate for us under these circumstances to direct what under other circumstances we might be well inclined to order, namely, a new trial of the issue of damages only."). Furthermore, the reasoning of *Smyth Sales* would uphold the mandate of a limited new trial here. The court held only that the jury's determination of the amount of punitive damages to be awarded – in that particular case – could not be separated from the jury's evaluation of the evidence of wanton and malicious conduct. *Id.* at 44-45. Here, the new trial will include both issues.

A district court sitting within the Third Circuit, after citing the *Smyth Sales* decision, held that, under the facts of the case before it, the malice question must be included in a new trial on punitive damages, but the simple negligence and compensatory damages issues need not be. *Marcone v. Penthouse Int'l, Ltd.*, 577 F. Supp. 318, 338 (E.D. Pa. 1983), *rev'd on other grounds*, 754 F.2d 1072 (3d Cir.), *cert. denied*, 474 U.S. 864 (1985). The court's holding was essentially the same as the district court and Eighth Circuit holdings here.

In *Simone v. Golden Nugget Hotel & Casino*, 844 F.2d 1031 (3d Cir. 1988) (*cited in* Pet. at 13), the jury

found for the plaintiff on a number of causes of action, awarding compensatory and punitive damages. The appellate court reversed on all causes but one: false imprisonment. There was no way to tell whether the jury award was based on the facts giving rise to the only claim the court had found valid. Thus, a new trial on the cause of action was warranted as well. The court was careful to base its decision solely "on this record." *Id.* at 1041; *see also Spence v. Board of Education of Christina School District*, 806 F.2d 1198, 1202 (3d Cir. 1986) (requiring full retrial based on facts of case) (*cited in* Pet. at 13-14). Far from adopting a general rule, the Third Circuit looks at the facts of each case in determining whether a limited new trial is warranted.

The Ninth Circuit has never held that a general rule is appropriate; rather, the determination has always been case by case. In the first case Wyeth cites, the court wrote:

> We do not say that in no circumstances can a separate jury determine the issue of damages after another jury has determined the issue of liability, for we do not reach that question in this case. . . . We do hold that *under the circumstances presented by this appeal* 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 (9th Cir.) (emphasis added), *cert. denied*, 366 U.S. 924

(1961) (*cited in* Pet. at 14). In *Wiener*, the court held only that a new trial on punitive damages must also involve the facts regarding recklessness, which is precisely what will occur here. *Id.*

In *Sears v. Southern Pacific Co.*, 313 F.2d 498 (9th Cir. 1963), the court held only that, under the particular facts of that case, the retrial, even if limited, would involve the same evidence as if all issues were retried. Thus, it made sense for the jury in the second trial to consider all issues. *Id.* at 503. That hardly constitutes a prohibition on new trials limited to punitive damages, as Wyeth claims. Furthermore, in the instant case, the jury will *not* hear all the evidence the first jury considered. In particular, the jury will not hear evidence relating to scientific causation, proximate cause/learned intermediary defense, comparative negligence or the statute of limitations, to name but a few issues.

(ii) Wyeth next claims that two circuit courts routinely order limited new trials with little analysis of the relationship between liability and punitive damages (Pet. at 15-16). In support, Wyeth cites a single Sixth Circuit decision ordering a partial new trial purportedly because the error in that case was limited to the punitive damages instruction. *See Grimm v. Leinart*, 705 F.2d 179, 183 (6th Cir. 1983), *cert. denied*, 465 U.S. 1066 (1984) (*cited in* Pet. at 14-15). But the court in that case expressly stated that errors relating to punitive damages call for new trials of either the entire case or the damages issue, depending on the facts of a case. *Citing Gasoline*

*Products*, the court wrote: "Normally, this [error] would call for a remand to the district court for a new trial *on all of the issues* or at least on the issue of *damages*." *Id.* at 182 (emphasis added).

Wyeth notes that the Seventh Circuit allows partial retrials *of damages issues generally*, so long as there are "safeguards" to protect the rights of the parties (Pet. at 15). Initially, neither of the decisions Wyeth cites involved punitive damages. Second, the court merely held that, if imposing conditions on the trial court will ensure that the jury in the second phase has all the evidence it needs to avoid injustice, such conditions are appropriate. *Watts v. Laurent*, 774 F.2d 168, 181 (7th Cir. 1985), *cert. denied*, 475 U.S. 1085 (1986); *MCI Communications Corp. v. AT&T*, 708 F.2d 1081, 1168 (7th Cir.), *cert. denied*, 464 U.S. 891 (1983). That is fully consistent with *Gasoline Products*, which requires a case by case analysis of whether a partial retrial can occur without injustice.[5]

(iii) Finally, Wyeth claims that some circuits allow partial retrials whenever the error in the first

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[5] DRI – The Voice of the Defense Bar argues that district court instructions on the varied limitations of liability findings would confuse the second jury (Brief of DRI – The Voice of the Defense Bar as *Amicus* Curiae in Support of Petitioners (hereafter "DRI Brf") at 11-13). In this case, the jury answered "yes" to a single liability question – whether Wyeth failed to warn of a known or knowable risk, and whether that failure caused Ms. Scroggin's breast cancer. (Resp. App. at 3a-4a). The straightforward nature of this finding highlights the importance of the case by case analysis mandated by *Gasoline Products*.

trial did not affect other parts of the judgment (Pet. at 15-18). Again, Wyeth has improperly extrapolated narrow, case-specific holdings into general pronouncements. For instance, Wyeth claims the Second Circuit's standard permits a limited new trial so long as there was no compromise verdict among jurors. That is false. In *Diamond D Enterprises USA, Inc. v. Steinsvaag*, 979 F.2d 14 (2d Cir. 1992), *cert. denied*, 508 U.S. 951 (1993) (*cited in* Pet. at 16), the jury returned a verdict far less than what the evidence dictated. There was thus a natural suspicion that there may have been a compromise verdict. After noting that a partial retrial is an improper response to a compromise verdict, the appellate court affirmed the district court's partial retrial order after finding no evidence of such a verdict in that case. *Id.* at 17-18. At no point did the court state, or even imply, that compromise verdicts are the only basis for denying a limited new trial.

Wyeth cites *Ajax Hardware Manufacturing Corp. v. Industrial Plants Corp.*, 569 F.2d 181 (2d Cir. 1977), as holding that a partial retrial is proper only when the error in the first trial did not affect the other issues. Wyeth suggests this is the only standard the court uses in evaluating limited new trials (Pet. at 16). To the contrary, the court stated only that a determination by the district court that the jury properly determined liability is a *prerequisite* to a limited new trial. The court certainly did not suggest that such a determination *mandates* a limited trial. In fact, the court expressly acknowledged that when

damages and liability issues cannot be considered alone fairly, a new trial on all issues is warranted. *Id.* at 185 n. 2.

Wyeth cites *Williams v. Slade*, 431 F.2d 605 (5th Cir. 1970) (*cited in* Pet. at 16-17), yet another opinion unrelated to punitive damages, as suggesting the Fifth Circuit allows retrials whenever the error in the first trial did not affect the issues not to be retried. To be sure, the court did isolate that condition as a prerequisite for a partial retrial. *Id.* at 609. But the court never suggested that was the only condition. The dispute in *Williams* was which defendant ran a red light – the driver of plaintiff's car or the other driver involved in the collision. The trial court inexplicably granted a directed verdict for the driver of plaintiff's car and the jury exonerated the other driver. The jury must have concluded the dismissed defendant ran the red light, making a new trial involving both defendants mandatory. *Id.*

Finally, Wyeth contends that the Fourth Circuit, in one case, approved a limited new trial despite acknowledging the interrelationship between liability and punitive damages (Pet. at 17). But Wyeth fails to note that the court approved of the new trial, which had already occurred, because all evidence of wanton conduct was presented to the jury in that trial, thereby ensuring a just result.

> We also conclude that the district court's decision to limit the second trial to punitive damage issues was not an abuse of discretion

> based on the interrelationship of punitive damage issues with other issues in the case. All of the evidence relating to National Vendors' willful or wanton conduct was before the second jury, enabling it to render a proper verdict on both the liability for and amount of punitive damages.

*Atlas Food Systems and Services*, 99 F.3d at 599-600. In this case, the jury will likewise be privy to all evidence relating to Wyeth's reckless indifference to women's health.

Circuit courts consistently apply *Gasoline Products* to the facts of particular cases and have reached different rulings only because the facts of cases are different.

### B. The Court Should Not Grant Review of this Case to Determine How District Courts Should Memorialize their *Daubert* Decisions.

Defendants' second issue is a transparent attempt to have this Court review the merits of the *Daubert* decisions made by the courts below. That is why the bulk of defendants' argument focuses on their claim that Dr. Elizabeth Naftalis' specific causation analysis constitutes "junk science" (Pet. at 26-30). Defendants have attempted to disguise their attack on the courts' application of the law to the facts as a challenge to the alleged ambiguity of the *Daubert* standard itself. In the process, defendants cite various circuit court requirements, all of which

were met here, and suggest that this case warrants review of how a district court conducts its *Daubert* inquiry.

This Court has emphasized that the *Daubert* analysis is "a flexible one" (Pet. at 21). *See Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 594-95 (1993); *accord Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 151 (1999). As defendants acknowledge, the district court has "substantial discretion" in carrying out its gatekeeper role (Pet. at 23).

### 1. The courts below fully evaluated, then rejected, defendants' arguments based on the *Daubert* factors.

The district court and the Eighth Circuit conducted specific inquiries pursuant to *Daubert*, issued written findings, cited the *Daubert* factors and explained why defendants' arguments pursuant to those factors are without merit (Pet. App. at 28a-30a, 115a-120a, 125a-131a). The claim that the courts did not explicitly apply the *Daubert* factors constitutes semantics gone awry.

This dispute does not concern whether E+P causes breast cancer. The WHI data revealed a greater than tripling of the risk (Pet. App. at 18a-19a). Over two dozen other epidemiological studies found more than a doubling of the risk (Amended and Corrected Reply/Response Brief of Plaintiff/Appellant/Cross-Appellee

Donna Scroggin (hereafter "Am. Rsp Brf"), Supplemental Appendix (hereafter "Supp. App.") at 002082-002293 & 001753 at 431:12-432:8). Experts, including the World Health Organization agency charged with identifying cancer-causing agents in the environment, agree that E+P causes breast cancer (Pet. App. at 19a). Defendants did not challenge general causation on appeal or to this Court. Thus, the only issue here is whether plaintiff presented reliable evidence that her particular case of breast cancer was caused by E+P.

Dr. Naftalis applied the methodology of differential diagnosis to determine whether E+P *promoted* the growth of Ms. Scroggin's breast cancer. Wyeth concedes that differential diagnosis, in general, is a reliable methodology (Pet. at 27 n. 5). Courts have consistently held that differential diagnosis satisfies each of the *Daubert* indicia for reliability. Differential diagnosis "has widespread acceptance in the medical community, has been subject to peer review, and does not frequently lead to incorrect results." *Westbury v. Gislaved Gummi AB*, 178 F.3d 257, 262-63 (4th Cir. 1999); *see also Glaser v. Thompson Medical Co.*, 32 F.3d 969, 978 (6th Cir. 1994) (differential diagnosis is "a standard diagnostic tool used by medical professionals to diagnose the most likely cause or causes of illness, injury and disease"); *Heller v. Shaw Industries, Inc.*, 167 F.3d 146, 154-55 (3d Cir. 1999) ("differential diagnosis consists of a testable hypothesis, has been peer reviewed, contains standards for controlling its operation, is generally accepted, and is used

outside of the judicial context"). "The overwhelming majority of the courts of appeals" concur. *Westbury*, 178 F.3d at 263 (multiple citations omitted).

Because defendants conceded the reliability of differential diagnosis, there was no need for the courts to write about each *Daubert* factor in explaining why differential diagnosis is reliable. The courts needed only address the contentions defendants advanced for differential diagnosis being inappropriate in the breast cancer context. Both courts did. Defendants' argument was that we do not know all causes of breast cancer, thus differential diagnosis cannot pinpoint any "but for" cause (Pet. at 28). The district court, ruling on the same motion in the first MDL trial, noted that defendants' argument ignores the fact that E+P was responsible for the *promotion* of plaintiff's breast cancer (Pet. App. at 130a-131a).[6] The district court adopted that ruling in this case (Pet. App. at 119a-120a).

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[6] Defendants misleadingly complain that this ruling involved a different plaintiff with a different medical history (Pet. at 26-27). But defendants' arguments are not plaintiff-specific. Defendants argue that differential diagnosis cannot be used to determine the cause of any woman's breast cancer.

Defendants also claim the district court later stated that its *Daubert* ruling had been too lax (Pet. at 28 n. 5). That statement referred globally to the court's *Daubert* rulings on six different experts (Pet. App. at 124a-125a). Thus, in this case, the court imposed new restrictions on plaintiff's liability expert (*E.g.*, District Court Docket, Document No. 389 (Nov. 21, 2007), Resp. App. at 1a-2a). There was never any suggestion that the court's ruling on specific causation had been lax.

The Eighth Circuit explained that Dr. Naftalis isolated the sole cause of the growth of Donna Scroggin's breast cancer (even though we do not know what initiated the first bad cell that eventually grew into cancer). Ms. Scroggin suffered from hormone-dependent breast cancer; that is, her cancer tested 100 percent positive for the presence of both estrogen receptors and progesterone receptors. *There was no dispute in this case that hormone receptor-positive breast cancer requires hormones to develop.* Published, peer-reviewed literature confirms such tumors' need for hormones (Pet. at 29a).

As the Eighth Circuit explained, once Dr. Naftalis established that Ms. Scroggin's breast cancer could not have developed into a malignancy without a source of hormones, her differential diagnosis focused on what sources of hormones could be responsible. The only two sources of hormones Ms. Scroggin had were the hormones in defendants' pills and the hormones her body made naturally. Ms. Scroggin is one of a minority of women who, post menopause, do not produce tangible levels of hormones, as evidenced by her menopausal symptoms (Pet. App. at 29a). Thus, E+P was, more likely than not, a "but for" cause of the development of abnormal cells into an invasive malignancy (Pet. App. at 29a-30a).

The unknown causes of breast cancer upon which defendants rely are factors which create the first bad breast cell that may one day become cancerous. As the Eighth Circuit held, regardless of what created that cell, it would not have become a hormone

receptor-positive cancer absent hormones. And because Donna Scroggin was not producing sufficient endogenous hormones, the hormones in defendant's pills were responsible for the growth or promotion of Ms. Scroggin's cancer (Pet. App. at 28a-30a).

Defendants contend that Dr. Naftalis' own testimony at the *Daubert* hearing proved that her analysis was unreliable. In support, defendants cite several purported admissions by Dr. Naftalis with the notation "Daubert Tr.," meaning "Daubert Transcript" (Pet. at 28). Defendants have misrepresented the record. There was no testimony taken at the *Daubert* hearing. Because both sides had attached a plethora of deposition testimony, prior trial testimony and affidavits to their submissions, by agreement, neither side called a witness. The seven citations to the purported *Daubert* transcript that defendants make are actually citations to Dr. Naftalis' trial testimony. A district court cannot have erred in exercising its gatekeeping duty based on testimony that occurred after the district court exercised its gatekeeping duty.

But this is academic because the claims defendants make about Dr. Naftalis' testimony are false. As Drs. Naftalis and Suzanne Klimberg, a breast surgical oncologist and Director of the Breast Cancer Program at the University of Arkansas in Little Rock[7]

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[7] Defendants did not challenge Dr. Naftalis' credentials during the *Daubert* proceedings or on appeal (Pet. App. at 28a). Nor did they challenge Dr. Klimberg's qualifications.

testified, differential diagnosis is a standard medical technique and a generally accepted methodology for ascertaining the cause of breast cancer. Dr. Naftalis learned the technique in medical school. Drs. Naftalis and Klimberg employ differential diagnosis in their regular medical practices to diagnose the likely cause of a woman's breast cancer. Isolating causation in this fashion is critical because appropriate treatment regimens often depend upon the particular cause of breast cancer (Am. Rsp Brf, Supp. App., Vol. VI at 001571 at 2; 001590 at 57:18-59:22, 74:16-75:23, 79:3-81:8; 001669 at 1-2; Trial Transcript (hereafter "Trial Tr."), Vol. IV at 861:7-21, 961:7-963:19, *cited in* Am. Rsp Brf at 53-55).[8]

Furthermore, defendants' arguments are irrelevant because the methodology has been shown to be reliable even if its use in each individual context has not been as thoroughly examined. As the Third Circuit has held:

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[8] In a footnote, defendants contend that plaintiff's position is tantamount to claiming that post-menopausal women who suffer from the symptoms of menopause and do not take hormone therapy are immune to breast cancer (Pet. at 29 n. 7). That is false. Plaintiff argues that such women are highly unlikely to develop hormone receptor-positive breast cancer. They are still prone to developing hormone negative tumors. Furthermore, studies have confirmed that estrogen-deficient women have very low rates of breast cancer (Am. Rsp Brf, Supp. App., Vol. VII at 1865 at 440-41, 1878 at 1959 at Abstract, 1969 at Abstract, 1979, 1987 at Abstract, *cited in* Am. Rsp Brf at 45-46).

> [A]lthough differential diagnosis is a generally accepted technique, no particular combination of techniques chosen by a doctor to assess an individual patient is likely to have been generally accepted. But unlike a methodology used in conducting a scientific study, lack of general acceptance is not a sign of unreliability, it is merely a result of the fact that the medical community will rarely have considered the reliability of a particular process of differential diagnosis used in an individual case. Nor is it likely that the particular combination will have been published and subject to peer review. . . . For these reasons, we must be flexible in conducting our *Daubert* inquiry.

*In re Paoli Railroad Yard PCB Litig.*, 35 F.3d 717, 758 (3d Cir. 1994), *cert. denied*, 513 U.S. 1190 (1995).

### 2. The *Daubert* inquiry in this case is consistent with the holdings of all circuit courts.

The courts below undertook a *Daubert* analysis, issued written findings summarizing their determinations, cited the *Daubert* factors and explained why defendants' attacks based on those factors do not pass muster (Pet. App. at 28a-30a, 115a-120a, 125a-131a). The courts therefore met even the most stringent of requirements on the *Daubert* analysis imposed by circuit courts. This case is therefore not the appropriate vehicle for revisiting *Daubert*.

Defendants claim the courts below did not apply the *Daubert* factors because they did not specifically detail that they were doing so (Pet. at 26-27). Both courts cited the *Daubert* factors and evaluated and rejected defendant's arguments for why those factors favor exclusion. The Eighth Circuit, in particular, explained in great detail why defendants' attacks on Dr. Naftalis' analysis based on the *Daubert* factors were invalid (Pet. App. at 28a-31a).

But even if the courts had not applied the *Daubert* factors, their opinions nonetheless satisfy all requirements imposed by the circuit courts discussed by defendants. Those include: (1) requiring courts to consider the *Daubert* factors before contemplating other indicia of reliability (Fifth Circuit alone), (2) requiring findings of fact, whether oral or written (Tenth Circuit, Ninth Circuit), and (3) recommending but not necessarily requiring findings of fact (Eleventh Circuit) (cases *cited in* Pet. at 23-26). Because both courts here issued written findings, the second and third requirements have been satisfied. Moreover, the first requirement has also been satisfied, because the Fifth Circuit requires nothing more than consideration of the *Daubert* factors. The district court is free to adopt the standards it ultimately deems appropriate. *See, e.g., Paz v. Brush Engineered Materials, Inc.*, 555 F.3d 383, 388 (5th Cir. 2009) (*cited in* Pet. at 24). Thus, if there were a purported conflict among circuit courts, that conflict has no bearing on this lawsuit.

There are cases in which courts fail to cite the *Daubert* factors. There are cases in which courts fail to issue findings of fact. There are cases in which courts fail even to conduct a *Daubert* hearing. Any of those cases may provide a proper vehicle for revisiting the *Daubert* inquiry. This case does not.

## CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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