

No. 17-747

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In the  
**Supreme Court of the United States**

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TEVA PHARMACEUTICALS USA, INC.,

*Petitioner,*

v.

STEPHEN WENDELL, ET UX.,

*Respondents.*

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**On Petition for a Writ of Certiorari  
to the United States Court of Appeals for the  
Ninth Circuit**

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**BRIEF OF DRI—THE VOICE OF THE  
DEFENSE BAR AS *AMICUS CURIAE*  
SUPPORTING PETITIONER**

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**STATEMENT OF INTEREST  
AND SUMMARY OF ARGUMENT<sup>1</sup>**

*Amici curiae* DRI—The Voice of the Defense Bar (www.dri.org) is an international organization of more than 22,000 attorneys who defend the interests of industries, businesses, and individuals in civil litigation. DRI’s mission includes enhancing the skills, effectiveness, and professionalism of the civil defense bar; promoting appreciation of the role of defense lawyers in the civil justice system; anticipating and addressing substantive and procedural issues germane to defense lawyers and fairness in the civil justice system; and preserving the civil jury. To help foster these objectives, DRI participates as *amicus curiae* at both the certiorari and merits stages in carefully selected cases in which this Court is presented with questions that are exceptionally important to civil defense attorneys, their clients, and the conduct of civil litigation.

In this case, the Ninth Circuit decided issues that significantly affect DRI and its members. As this Court has repeatedly recognized, expert testimony is often critical in cases involving complex or highly technical subject matter. The standards for assessing the admissibility of expert testimony play an

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<sup>1</sup> As set forth in Supreme Court Rule 37.2(a), counsel of record for all parties received timely notice of *amicus curiae*’s intent to file this brief and consented to this filing. In accordance with Supreme Court Rule 37.6, *amicus curiae* states that no counsel for any party authored this brief in whole or in part and that no entity or person, aside from *amicus curiae*, its members, and its counsel, made a monetary contribution intended to fund the preparation or submission of this brief.

increasingly pivotal role in the outcome. Yet, since the decisions in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993); *GE v. Joiner*, 522 U.S. 136 (1997); and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999), and the amendment of Federal Rule 702 in 2000, this Court has not provided guidance on the crucial gatekeeping and review responsibilities with which the lower courts are charged. Such guidance is warranted so that trial courts — and trial lawyers — can minimize the uncertainty and confusion generated by conflicting decisions of the courts of appeals on both questions raised in the petition.

The need for this Court's resolution of the entrenched circuit conflicts is all the more pressing because of the immense practical consequences for litigation in the federal courts and in the many state courts that follow the federal rules and federal precedent. The first question presented addresses the standard for appellate review of Rule 702 expert-admissibility rulings. At the core of this issue is a foundational principle governing the relationship between trial and appellate courts: the abuse-of-discretion standard. On a threshold issue of such practical importance nationwide uniformity is not merely desirable, it is essential. But, as the decision below exemplifies, uniformity is unachievable without this Court's further instruction.

The second question in the petition — the standard for evaluating the admissibility of expert testimony — has a similarly far-reaching impact. In conflict with other circuits, the decision below turns more on the general professional credentials of the expert than on the reliability and application of the

expert's methodology to the record presented. That shift in focus is incompatible with this Court's decisions and, accordingly, merits review for that reason alone.

Additional factors make this case an even more compelling candidate for certiorari. By redefining the gatekeeping function that this Court articulated in *Daubert*, *Joiner*, and *Kumho Tire*, the decision below incorrectly elevates the prior professional experience of the expert over the scientific bona fides of the methodology on which the expert seeks to opine. The balance this Court struck in its prior decisions has been knocked off kilter. Given the large (and growing) number of cases in which federal courts face expert-admissibility rulings — and the undeniable impact those rulings have on the outcome of important litigation — the need for this Court's review could scarcely be more obvious or compelling.

Day after day, DRI's members litigate these issues in the federal courts. Their collective experience offers an informed, practical perspective on how parties, counsel, and judges (trial and appellate) can effectively navigate the course this Court's prior decisions charted.

The frequency with which courts face *Daubert* challenges, the increasing complexity of technology issues being litigated, and the practical ramifications for the disposition of cases involving expert testimony all weigh strongly in favor of this Court's review. The issues affect counsel for plaintiffs and defendants (whether they support or oppose an expert in a particular case). The issues affect the fair, orderly administration of justice. The courts of appeals are in

conflict. And the inconsistent application and review of expert-admissibility standards across the country reveal a pressing need for this Court's direction.

### **REASONS FOR GRANTING THE PETITION**

Expert testimony often plays a pivotal role in determining a case's outcome. Especially when litigation turns on facts that are highly technical, the impact of expert testimony can be magnified to an extraordinary degree. Because expert witnesses address matters beyond the realm of the typical juror's knowledge, their opinions can have an outsized effect on the factfinding process. For precisely that reason, courts have been vigilant in charting guidelines for educating jurors when common sense and shared life experiences must be supplemented by arcane technical knowledge.

This Court has been in the forefront of that judicial effort. But further guidance is necessary. As the petition explains, circuit conflicts on key aspects of assessing the reliability, admissibility, and scope of expert testimony require this Court's resolution. The need for review is particularly acute in light of the practical impact of the judicial gatekeeping role described in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Several developments have heightened that practical impact:

- In *GE v. Joiner*, 522 U.S. 136 (1997), the holding that *Daubert* decisions are subject to appellate review under the deferential abuse-of-discretion standard made it even more important that district courts have clear rules to guide the performance of their gatekeeper

responsibilities and that appellate courts employ the correct standard of review;

- In *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999), this Court held that the gatekeeping function applies to all expert testimony;

- In 2000, Federal Rule of Evidence 702 was amended to codify and define the gatekeeping role;

- The *Daubert* standard expanded beyond the federal courts to become the governing standard in most state courts as well.

Today, *Daubert* poses case-dispositive issues in broad categories of litigation nationwide. *See, e.g.*, Kenneth R. Foster & Peter W. Huber, *Judging Science: Scientific Knowledge and the Federal Courts*, 1 (1997) (“the outcomes of criminal, paternity, first amendment, and civil liability cases ... often turn on scientific evidence”); Edward K. Cheng, *Independent Judicial Research in the Daubert Age*, 56 *Duke L.J.* 1263, 1265 (2007) (“the scientific admissibility decision can be incredibly influential, if not outcome-determinative”).

Although Rule 702 recites the requirements for admissibility simply and clearly, the circuit courts have encountered difficulty with core underlying issues, *viz.*, how to articulate and apply — and review on appeal — the governing standards for admissibility of expert testimony. Having struggled with those standards for years, the circuits now find themselves in conflict, posing real-world dilemmas for counsel and litigants.

To understand why no additional “percolation” of these issues is necessary, one need go no further than the lower court decisions in this case. The stated basis for the Ninth Circuit’s reversal was *not* that it perceived any legal error in the district court’s articulation of the standard for admissibility of expert testimony. Indeed, had the court of appeals found such an error the appropriate disposition would have been a remand for the district court to exercise its discretion guided by the correct legal standard. But the Ninth Circuit left no discretionary role open for the district court, holding that “*Daubert* poses no bar” and the testimony “should have been admitted as expert testimony under Rules of Evidence 702.” Pet. App. 20a.

Rather than appreciate the discretion inherent in the district court’s gatekeeper role, the Ninth Circuit applied *de novo* review to the question “whether particular evidence falls within the scope of [Rule 702].” Pet. App. 6a. And it did so on a question it regarded as “close.” *Id.* at 10a. The Ninth Circuit thus was expressly applying *de novo* review to a ruling within the district court’s discretionary authority. As the petition explains, other circuits apply a different standard of review.

That conflict warrants certiorari. Nationwide uniformity is imperative on the correct standard for review of expert-admissibility rulings. On a practical level, those rulings often involve case-dispositive issues in major complex litigation. And the need for this Court’s review is even greater in this case because, aside from the standard of review, the Ninth Circuit’s Rule 702 analysis also conflicts with

decisions of other circuits. Since national uniformity is now lacking, litigants and their counsel — whether plaintiffs or defendants, whether proffering or opposing expert testimony — are left to litigate in an environment of pervasive unpredictability. The resulting uncertainty imposes heavy costs on the fair, effective and efficient administration of justice.

1. Fidelity to this Court’s holding in *Daubert* compels trial courts to “ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.” 509 U.S. at 589. *Kumho Tire* expanded this imperative to cover all expert testimony. 526 U.S. at 147. And Rule 702 explains that expert testimony is admissible only if the qualified expert’s “specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue,” only if “the testimony is based on sufficient facts or data,” only if “the testimony is the product of reliable principles and methods,” *and* only if “the expert has reliably applied the principles and methods to the facts of the case.” The principal focus has always, and correctly, been on the reliability of the *testimony*, not on the credentials or general experience of the witness.

In recognition of the unique attributes of expert witnesses, the Federal Rules of Evidence and the governing cases “grant expert witnesses testimonial latitude unavailable to other witnesses.” *Kumho Tire*, 526 U.S. at 148. Accordingly, the judicial designation of “expert” status is freighted with disproportionate potential to influence jurors. *See Daubert*, 509 U.S. at 595 (the expert’s opinion “can be both powerful and quite misleading because of the difficulty in

evaluating it”) (internal quotation marks omitted); Victor E. Schwartz & Cary Silverman, *The Draining of Daubert and the Recidivism of Junk Science in Federal and State Courts*, 35 Hofstra L. Rev. 217, 220 (2006) (explaining that expert witnesses enjoy “extraordinary powers and privileges in court” not shared by lay witnesses).

The impact on jurors is amplified because experts provide testimony on matters beyond the realm of the typical juror’s knowledge. See Fed. R. Evid. 702 (defining expert testimony as conveying “scientific, technical, or other specialized knowledge”). Cf. *People v. Leahy*, 882 P.2d 321, 325 (Cal. 1994) (“Lay jurors tend to give considerable weight to “scientific” evidence when presented by “experts” with impressive credentials”); *State v. O’Key*, 899 P.2d 663, 672 (Or. 1995) (“Evidence perceived by lay jurors to be scientific in nature possesses an unusually high degree of persuasive power”); *id.* at 678 n.20 (“Evidence that purports to be based on science beyond the common knowledge of the average person that does not meet the judicial standard for scientific validity can mislead, confuse, and mystify the jury”); *E.I. du Pont de Nemours & Co. v. Robinson*, 923 S.W.2d 549, 553 (Tex. 1995) (explaining that “[a] witness who has been admitted by the trial court as an expert often appears inherently more credible to the jury than does a lay witness” and, therefore expert testimony can have an “extremely prejudicial impact on the jury, in part because of the way in which the jury perceives a witness labeled as expert”); *Cunningham v. Wong*, 704 F.3d 1143, 1167 (9th Cir. 2013) (“Scientific and expert testimony contains an ‘aura of special reliability and trustworthiness’”), *cert.*

*denied sub nom. Cunningham v. Chappell*, 134 S. Ct. 169 (2013).

Studies and scholars report “indications that cross-examination does little to affect jury appraisals of expert testimony.” Christopher B. Mueller, *Daubert Asks the Right Questions: Now Appellate Courts Should Help Find the Right Answers*, 33 *Seton Hall L. Rev.* 987, 993 (2003). A recent study confirmed the common assumption by jurors that, because the trial judge admitted the evidence, it must have passed at least a minimum level of reliability. See N.J. Schweitzer & Michael J. Saks, *The Gatekeeper Effect: The Impact of Judges’ Admissibility Decisions on the Persuasiveness of Expert Testimony*, 15 *Psychol. Pub. Pol’y & L.* 1, 7 (2009).

2. Experience with litigation since the 2000 amendment to Rule 702 bears out the increasing necessity for this Court’s guidance on the two questions presented in this case: (1) the correct standard for appellate review and (2) the correct standard for assessing the reliability of proposed expert testimony. Without further instruction from this Court, case-dispositive outcomes will continue to differ from circuit to circuit.

A decade-long study of cases involving financial experts showed “[t]he success rate of challenges varied widely by jurisdiction” ranging from the Tenth and Eleventh Circuits (where 63% of financial expert testimony challenged under *Daubert* was excluded in whole or in part), to the Third Circuit (where the exclusion rate was a national low of 33%). PriceWaterhouse Coopers, *Daubert Challenges to Financial Experts: An 11-year Study of Trends and*

*Outcomes 2000-2010* at 12 (2011). A recent update to that study analyzed appellate review of trial court rulings on *Daubert* challenges to financial experts: while the majority of appeals upheld the lower court rulings, the affirmance rate was 50% higher when the expert testimony was admitted than when it was excluded. PriceWaterhouse Coopers, *Daubert Challenges to Financial Experts: A Yearly Study of Trends and Outcomes 2000-2015* at 35 (May 2016) available at <https://www.pwc.com/us/en/forensic-services/publications/assets/pwc-daubert-study-whitepaper.pdf>. (between 2011 and 2015, 89% of decisions admitting financial expert testimony were upheld; only 58% of decisions excluding financial expert testimony were upheld).

A national survey of state court trial judges reported general disarray on the simple threshold question of which *Daubert* factor, if any, should be given the most weight. Sophia I. Gatowski, *et al.*, *Asking the Gatekeepers: A National Survey of Judges on Judging Expert Evidence in a Post-Daubert World*, 25 *Law & Hum. Behav.* 433, 448 (2001) (half of the judges willing to weigh factors gave the most weight to general scientific acceptance, with the remaining *Daubert* factors divided about equally in the percentage of judges weighing them as “most important”). More than 20% of the 400 surveyed judges reported they were unsure how to combine the *Daubert* guidelines. *Id.* If, as the Ninth Circuit held in this case, *de novo* review applies to whether particular proffered testimony is within the scope of Rule 702, then the uncertainty that is already manifest at both trial and appellate levels will be even more widespread.

This entrenched confusion is not a fleeting, recent development: “at the time *Daubert* was handed down, all parties and amici claimed victory and satisfaction with the decision.” Note, *Flexible Standards, Deferential Review: Daubert’s Legacy of Confusion*, 29 Harv. J. Law & Pub. Policy 1085, 1091 (2006) (citing Paul C. Giannelli, *The Supreme Court’s “Criminal” Daubert Cases*, 33 Seton Hall L. Rev. 1071, 1077 (2003) (all parties were pleased with the decision and noting, “This alone should have raised red flags”)). Early commentary on *Daubert* reported that “no one is exactly sure what the new standard is.” David O. Stewart, *Decision Creates Uncertain Future for Admissibility of Expert Testimony*, A.B.A. J., Nov. 1993 at 48.

In the two decades that followed, uncertainty and inconsistency went unabated. See, e.g., Victor G. Rosenblum, *On Law’s Responsiveness to Social Scientists’ Findings: An Intelligible Nexus?*, 2 Psychol. Pub. Pol’y & L. 620, 631 (1996) (“[U]ncertainty and confusion—fueled unintentionally in *Daubert*—prevail in the legal system”); Victor E. Schwartz & Cary Silverman, *supra*, 35 Hofstra L. Rev. at 218 (“five general areas of inconsistency in the application of expert testimony standards”); Margaret A. Berger, *The Admissibility of Expert Testimony*, Fed. Judicial Ctr., *Reference Manual on Scientific Evidence* 11, 19 (3d ed. 2011) (“Although almost 20 years have passed since *Daubert* was decided, a number of basic interpretive issues remain”).

Pervasive confusion was predictable and perhaps inevitable. The scientific method and the judicial craft employ different standards and serve different

purposes. No matter how learned and knowledgeable they are in their own profession, judges and lawyers are not scientists. There is, accordingly, an inherent tension in fashioning rules for the admissibility of expert testimony. As this Court observed in *Daubert*, “there are important differences between the quest for truth in the courtroom and the quest for truth in the laboratory.” 509 U.S. at 596–97. *Daubert*, *Joiner* and *Kumho Tire* are important steps in an ongoing process. Additional steps are required. Disparate, conflicting decisions on the admissibility of expert testimony — as well as on the standards for making and reviewing those decisions — highlight the continuing need to fine-tune and direct the trial courts in discharging their gatekeeping responsibilities and the appellate courts in fulfilling their review functions.

3. This case presents a fitting opportunity for the Court to address the problems that plague the lower courts. On a basic substantive level, determining whether expert testimony on medical causation is admissible is an important and recurring issue on which further guidance is needed. Medical causation is hotly contested because it is “frequently the crucial issue” in toxic-tort and product-liability cases, “which have aroused considerable controversy because they often entail enormous damage claims and huge transaction costs.” Fed. Judicial Ctr., *Reference Manual on Scientific Evidence* 32 (2d ed. 2000). These cases are often “won or lost on the strength of the scientific evidence presented to prove causation.” *Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194, 1197 (11th Cir. 2002). As typically occurs in such situations (*Joiner* and this case, for example), an order excluding

the plaintiff's causation expert is soon followed by an order granting summary judgment to the defendant because the plaintiff cannot satisfy an essential element of the claim. *See Restatement (Third) of Torts: Physical and Emotional Harm*, § 28, Reporter's Note, cmt. c (2010) ("the admissibility of an expert's opinion may be determinative as to whether the plaintiff satisfies the burden of production on agent-disease causation"). Conversely, when the trial court allows the plaintiff's expert to testify, the defendant, unable to appeal that ruling immediately, often faces immense pressure to settle. *See also PriceWaterhouse Coopers, 2000-2015 Yearly Study, supra*, at 35. Other factors that intensify the pressure — even in cases with little or no merit — are the costs of trial, the unpredictability of jury verdicts, and the ramifications of a potential adverse judgment on other pending cases. Because an erroneous decision to admit expert testimony disproportionately magnifies the risk and increases the burden of further proceedings, it weighs heavily in the settle-or-litigate risk assessment equation.

Expert-admissibility rulings in medical causation cases affect more than just the parties to the litigation and can have significant implications for the national economy. Under our system of tort law, a single jury's determination on the question of medical causation can have powerful resonance, effectively determining whether a useful product will remain on the market. It is therefore essential "that judges fulfill their *Daubert* gatekeeping function, so that they help assure that the powerful engine of tort liability, which can generate strong financial incentives to reduce, or to eliminate, production, points toward the right

substances and does not destroy the wrong ones.” *Joiner*, 522 U.S. at 148–49 (Breyer, J., concurring). Admitting speculative testimony that “allow[s] the law to get ahead of science” would “destroy jobs and stifle innovation unnecessarily.” *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 677–78 (6th Cir. 2010); *see also id.* at 678 (citing a news article “describing how scientists concluded, after years of litigation, billions in settlements and the bankruptcy of a major manufacturer, that no evidence tied breast implants to health problems”). Similarly, admitting testimony that — as the district court observed — is not appropriately tailored to the record, encourages just such deleterious speculation.

This case not only poses questions with broad potential reach, but also offers those questions in a uniquely appropriate context for resolution. Because the Ninth Circuit expressly applied *de novo* review to an aspect of the *Daubert* analysis that should fall within the trial court’s discretion, the case presents two key pieces of the expert-admissibility puzzle: the substantive elements of Rule 702 that govern the trial court’s gatekeeping function and the standard of review that governs the appellate court’s supervisory function.

Gatekeeping requires the trial court to assess the factors set out in Rule 702. In the proper exercise of that function, trial courts are necessarily afforded latitude. This Court’s holding in *Joiner* reinforced that point by directing circuit courts to apply abuse-of-discretion review. But something is wrong when an appellate court holds, as the Ninth Circuit did in this case (Pet. App. 6a), that *de novo* review applies to

“whether particular evidence falls within the scope of [Rule 702].” The process of deciding “whether particular evidence falls within the scope” *is* the exercise of discretion. As the decision below reveals, there is a pressing need for this Court to say so.

### CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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