No. 17-747

IN THE
Supreme Court of the United States

TEVA PHARMACEUTICALS USA, INC.,
Petitioner,

v.

STEPHEN WENDELL, ET UX.,
Respondents.

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

REPLY BRIEF FOR PETITIONER

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RULE 29.6 STATEMENT

The Rule 29.6 statement included in the petition for a writ of certiorari remains accurate.

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As the petition demonstrated, some circuits review expert-admissibility decisions deferentially, with appropriate solicitude for the district court's gatekeeping role. Others do not, as the Ninth Circuit here did not. Plaintiffs seek to bridge the divide by asserting that legal error is always an abuse of discretion. That is beside the point: the circuit split is over what standard of review applies *when no legal error is alleged*, just the application of Rule 702 to particular facts. In several circuits, including the Ninth Circuit in cases like this one, deference has in substance been replaced with *de novo* review of "whether particular evidence falls within" Rule 702. Pet. App. 6a. That conflict warrants review.

This Court should also grant review to bring the Ninth Circuit back into step with the other circuits, all of which require, as a condition of admissibility, an expert to demonstrate that her testimony is based on "reliable principles and methods" "reliably applied." Fed. R. Evid. 702(c)-(d). The Ninth Circuit does not, as is evident from this and other cases holding that an expert's failure to adhere to a reliable method is not grounds for exclusion, only an "issue for the jury." *City of Pomona v. SQM N. Am. Corp.*, 750 F.3d 1036, 1047 (9th Cir. 2014) (acknowledging a split).

The correct application of Rule 702 affects a host of cases each year, both civil and criminal. This Court should take up and resolve both questions presented.

I. This Court Should Grant Certiorari To Resolve Confusion In The Circuits About *De Novo* Review Of Expert-Admissibility Decisions.

Plaintiffs do not seriously dispute the pervasive inconsistency among courts of appeals about the standard for reviewing expert-admissibility decisions. Instead, they argue that (1) there is no substantive difference between a uniform abuse-of-discretion standard and one that incorporates a hefty dollop of *de novo* review; and (2) the Third, Seventh, and Ninth Circuits' standards in substance afford the requisite deference to expert-admissibility rulings. Neither argument dispels the conflict.

A. The Circuits Are Applying Substantively Different Standards of Review.

Plaintiffs argue there is no conflict because the distinction between uniform abuse-of-discretion review and a multi-part standard "is just labels," as both articulations permit reversal for legal error. Opp. 14. That argument attacks a straw man rather than engage with the conflict. No one disputes that legal error is an abuse of discretion. But that rule does not authorize appellate courts to review an exercise of discretion as though it were a legal error. That is just what several circuits have done—review *de novo* even when there is no legal question.

Most expert-admissibility appeals involve no questions of law, which is no surprise: Rule 702 and this Court's cases (*Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), *General Electric Co. v. Joiner*, 522 U.S. 136 (1997), and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999)) have set the legal

standard for the admission of expert evidence. District courts need only apply the framework set by those authorities. As a result, there is no role for *de novo* review in most appeals, and district court decisions should not be overturned absent a determination that they were "manifestly erroneous," *Joiner*, 522 U.S. at 142.

Some circuits nevertheless assert that *de novo* review applies to *some* aspect of an expert-admissibility decision, and then reverse without identifying any manifest error, or even identifying which aspects of the decision they reviewed deferentially and which aspects they did not. Pet. 20-25. In short, although *de novo* review should play no role in the vast majority of expert-admissibility appeals, some circuits use the mere existence of a legal component to justify reversing expert-admissibility rulings without "the deference that is the hallmark of abuse-of-discretion review." *Joiner*, 522 U.S. at 143.

As the Court has held in other contexts, abuse-of-discretion review is not to be picked apart to circumvent the deference due the trial judge. Deference "streamline[s] the litigation process by freeing appellate courts from the duty of reweighing evidence and reconsidering facts already weighed and considered by the district court." *Cooter & Gell v. Hartmarx Corp.*, 496 U.S. 384, 404 (1990). For that reason, this Court has adhered to a "unitary" abuse-of-discretion standard even in contexts like Rule 11 sanctions and fee-shifting: deference is mandatory, even for decisions that are more plausibly called "legal" than anything here. *See id.* at 403. While appellate courts will correct *true* legal errors, *id.* at 403, the abuse-of-discretion standard is a "unitary" one, *id.*, that im-

presses upon appellate judges the extraordinary deference owed to trial judges "on the front lines of litigation." *Id.* at 404.

Thus, the difference between a uniform or "unitary" standard of review and a multi-part standard is far from semantic. Under true abuse-of-discretion review, overriding a trial court's "broad latitude" requires the appellate court to specifically identify legal error or a manifest error of judgment that justifies reversal. *Kumho*, 526 U.S. at 142, 152-153.[1] Where the Ninth Circuit and other circuits have gone wrong is in adopting a standard that allows them to reverse expert-admissibility decisions without identifying *either* a legal error or a manifest error of judgment. And while Plaintiffs spend many pages arguing that *de novo* review is appropriate for legal errors, they never defend the application of *de novo* review without legal error.

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[1] *United States v. Frazier*, 387 F.3d 1244 (11th Cir. 2004) (en banc), is a good example. Plaintiffs cite *Frazier* (at 15) in arguing that the Eleventh Circuit uses a two-tier review standard. But they cite the *dissent*, which, without any mention of the deference owed to trial judges, would have overturned the exclusion of expert testimony. The majority, however, invoked a unitary standard, emphasizing its deferential review and "the range of possible conclusions the trial judge may reach," and concluded that the district court did not commit manifest error in excluding testimony of an expert offering only his "experience," rather than "a sufficiently verifiable, quantitative basis for [his] opinion." *Id.* at 1259, 1265-1266.

B. The Third, Seventh, And Ninth Circuits Do Not "Faithfully Apply" Deferential Review To Expert-Admissibility Decisions.

Next, Plaintiffs argue that the Third, Seventh, and Ninth Circuits all *in fact* "faithfully apply" deferential review to expert-admissibility determinations. Opp. 18. They contend that these courts apply *de novo* review only to purely legal issues, such as the interpretation of Rule 702 or whether a *Daubert* analysis was performed. Opp. 19, 22. That is demonstrably incorrect: these circuits invoke *de novo* review in cases that involve *no legal component*, like this one. Pet. 23-25. Plaintiffs discuss *none* of the cases cited in the petition for that point, except for this case. And their retelling of this case is inaccurate. Indeed, *Plaintiffs themselves specifically asked for de novo review*. Pet. 12-13. They never acknowledge that the standard they now disavow is the standard they advocated below.

1. Plaintiffs contend that the Ninth Circuit applies *de novo* review only to whether Rule 702 applies at all. Opp. 20. But the Ninth Circuit invokes this standard even when there is *no dispute* that Rule 702 applies. In this case, for example, the court qualified the abuse-of-discretion standard: "*However*, we review *de novo* the construction or interpretation of … the Federal Rules of Evidence, including whether particular evidence falls within the scope of a given rule." Pet. App. 6a (emphasis added; ellipses in original; quotation marks omitted).

Plaintiffs contend that *de novo* review played no role—that the court simply "held that the district court exceeded its broad latitude in evaluating the expert testimony" even with the "great deference af-

forded district courts." Opp. 25. The Ninth Circuit mentioned no such latitude, and Plaintiffs' attempted rehabilitation depends on disregarding large swathes of the court's opinion, which contain all the hallmarks of *de novo* review. The court recited its own assessment of admissibility first and then explained that the district court's decision did not measure up (Pet. App. 11a-19a); identified no "manifest error" and instead focused on its disagreement with the "weight" or "[]emphasi[s]" the trial court placed on certain facts (*id.* at 10a, 15a); expressed disagreement with the *Daubert* factors that the trial court found probative (*id.* at 15a-16a); and ultimately determined that although "it [was] a close question," the trial court "erred" (*id.* at 10a).

Indeed, the court's use of circuit precedent is telling. It treated prior Ninth Circuit decisions *affirming the admission* of expert evidence that lacked certain indicia of reliability as if they created a legal rule that similar evidence should have been admitted here. *See* Pet. App. 15a, 20a. But "[w]hen applying Rule 702, different [district] courts relying on essentially the same science may reach different results, but [the court of appeals] could still affirm both decisions due to [the] deferential standard of review." *Etherton v. Owners Ins. Co.*, 829 F.3d 1209, 1217 (10th Cir. 2016) (quotation marks omitted).

2. Plaintiffs similarly contend that the Seventh Circuit applies *de novo* review only to whether the district court used the *Daubert* framework. Opp. 21. But again they ignore that the Seventh Circuit invokes plenary review even when a *Daubert* inquiry indisputably was undertaken—and then reverses expert-admissibility decisions based on mere disagree-

ment, without identifying any manifest error or acknowledging the deference owed to the trial court. That is exactly what happened in *Schultz v. Akzo Nobel Paints, LLC*, 721 F.3d 426 (7th Cir. 2013), Pet. 24-25—a case Plaintiffs conspicuously do not address.

Plaintiffs likewise ignore the Third Circuit's application of its multi-part standard, failing to even mention *Pineda v. Ford Motor Co.*, 520 F.3d 237 (3d Cir. 2008), in which the court thought there was no dispute about Rule 702's meaning, yet reversed the exclusion of expert testimony because it simply "disagree[d]" with the trial court's conclusion. Pet. 23-24.

3. For Plaintiffs to be right that the Third, Seventh, and Ninth Circuits "faithfully apply" deferential review in expert-admissibility appeals, those circuits would have had to invoke the *de novo* standard of review completely gratuitously. But their decisions—holding that the district court "erred," with no mention of the deference due the trial judge—show that they meant what they wrote.

Furthermore, if these circuits were in fact affording deference to the trial court, then reversals should be rare. *See, e.g.*, *United States v. Ala. Power Co.*, 730 F.3d 1278, 1289 (11th Cir. 2013) (only three out of 54 expert-admissibility decisions reversed in preceding five years, which "signif[ies] an awareness that ... both this court and the Supreme Court have consistently emphasized the need to defer to the district court's discretionary gatekeeping decisions"). But in the Ninth Circuit, for example, decisions on expert testimony (particularly decisions *excluding* it) are frequently reversed with no mention of the deference owed under *Joiner* and without identifying any manifestly erroneous judgment call by the district

court. *See, e.g.*, *Messick v. Novartis Pharm. Corp.*, 747 F.3d 1193, 1196-1199 (9th Cir. 2014); *Ramirez v. ITW Food Equip. Grp., LLC*, 686 F. App'x 435, 440-441 (9th Cir. 2017); *Scantlin v. Gen. Elec. Co.*, 510 F. App'x 543, 545 (9th Cir. 2013). What makes that string of reversals possible is a standard of review that permits the court of appeals to substitute its own judgment for the district court's—contrary to the law in other circuits as well as to this Court's cases. This Court should resolve that conflict now.

II. The Ninth Circuit Has Broken With Other Circuits By Allowing "Highly Qualified" Experts To Testify Without Establishing That They Reliably Applied Accepted Methodologies.

The Ninth Circuit allowed experts it thought "highly qualified" to testify without demonstrating that they applied any scientific methodology in a reliable manner. The decision below deepens a conflict and worsens the impact of prior circuit precedent instructing trial courts not to scrutinize the *application* of accepted methods.

1. Plaintiffs' primary argument regarding the second question presented is that this case is an outlier. Opp. 26-28. But the Ninth Circuit's decision is consistent with earlier precedent holding that if a method is reliable, "adherence to [the method's] protocol … typically is an issue for the jury." *SQM*, 750 F.3d at 1047 (acknowledging split with Third Circuit).

Furthermore, this wrongheaded circuit precedent is already affecting trial courts. Reading the decision below and *SQM*, district judges conclude that they cannot demand more of highly qualified experts than

reference to an accepted scientific method, irrespective of how it was applied. *See, e.g.*, *Romero ex rel. Ramos v. S. Schwab Co.,* No. 15-CV-815-GPC-MDD, 2017 WL 5885543, at *5 (S.D. Cal. Nov. 29, 2017) (citing *Wendell* and concluding that a distinguished scientist's failure "to adhere to the accepted standards of measurement" were irrelevant because "how [an expert] performed a particular methodology ... goes to the weight of [his] testimony and not its admissibility"); *Somerlott v. McNeilus Truck & Mfg. Inc.*, No. C16-789-MJP, 2017 WL 6459039, at *2 (W.D. Wash. Dec. 18, 2017) (citing *Wendell* and holding that an expert "should be permitted to testify" because of his "expertise in mechanical engineering" even though his opinion was "neither precise nor well-articulated in his expert report or deposition"); *Corning Optical Commc'ns RF LLC v. PPC Broadband Inc.*, No. CV-12-02208-PHX-SMM, 2015 WL 11718120, at *4-*5 (D. Ariz. Sept. 18, 2015) (holding that expert's "execution" of an accepted methodology "raises concerns" but, citing *SQM*, could not be a ground for exclusion).

The decision below thus sends a clear message to lower courts, which will be even more reticent to exclude testimony from credentialed experts as long as they recite a recognized scientific method. Not only will this result in expensive and time-consuming trials where summary judgment should instead be granted, it will also allow juries to be misled by "powerful" but shoddily-performed expert evidence that they are unable to properly evaluate. *Daubert*, 509 U.S. at 595; *see also* Pet. 33.

2. Plaintiffs also make a brief, half-hearted attempt to argue that the decision below did not really

rest on the experts' qualifications. In a single paragraph, they argue that the Ninth Circuit's reversal was actually based on the experts' methodical application of the differential diagnosis and Bradford-Hill methodologies. Opp. 5, 28-29.

Plaintiffs' brief completely rewrites the history of the case. Dr. Shustov's statement that he "[didn't] remember [his] thought process" when asked whether he had used a differential diagnosis (C.A. E.R. 287) becomes, in Plaintiffs' brief, testimony that he "conducted a differential diagnosis to conclude that Maxx's drug regiment [sic] was a substantial cause of his death," Opp. 7. Dr. Weisenburger's testimony that he did not examine Mr. Wendell's medical records until the night before his deposition and instead formed his opinion based on an attorney "summary" (C.A. E.R. 322-323) turns into, in Plaintiffs' retelling, a "careful review of Maxx's medical records," Opp. 5. Dr. Weisenburger's testimony that he did not conduct a literature review until *after* he submitted his 1½-page expert "report" and Dr. Shustov's testimony that his causation opinion took "a couple hours" (C.A. E.R. 254, 321-322) transforms into opinions developed in reliance on scientific literature, Opp. 28.

Notably missing from Plaintiffs' brief is any argument that the Ninth Circuit concluded that the experts' scientific methods—differential diagnosis and Bradford-Hill criteria—were reliably applied, as required by Rule 702(d). Nor could it have. Dr. Weisenburger provided no explanation for how he applied, or could have applied (Pet. 27 n.9), the Bradford-Hill methodology besides his unsupported and implausible statement, "And then I used the Bradford Hill methodology to come to the conclusion that

I did." Pet. App. 13a-14a. And as just noted, Dr. Shustov did not even "remember" performing a differential diagnosis. C.A. E.R. 287. All that mattered to the Ninth Circuit was, as the court emphasized repeatedly, that it viewed the experts as "highly qualified." Pet. App. 11a, *accord* 15a, 20a. As other circuits have explained, "if the reliability of an expert's methodology is at issue, it's not good enough ... to stress the expert's qualifications." *Storagecraft Tech. Corp. v. Kirby*, 744 F.3d 1183, 1190 (10th Cir. 2014) (Gorsuch, J.).

This dilution of Rule 702 is particularly problematic where a party proffers a subjective methodology (like Bradford-Hill or differential diagnosis) as proof of causation. Chamber Br. 9-10. Allowing expert testimony to reach the jury irrespective of how these methodologies were applied to the facts means that an expert's bare assertion can improperly substitute for *proof* of causation—which is precisely what happened here. *See, e.g.*, C.A. E.R. 344 (Weisenburger's testimony that "[w]hen you have a patient with obvious and known risk factors, you tend to *assume* that those risk factors were the cause" (emphasis added)). As other circuits have held (Pet. 29-31), to be reliably applied, these methods must be supported by studies that are evidence of *causation*, which the district court found did not exist here. Instead, Plaintiffs' experts offered only case reports that note correlations in individual cases but offer no proof of causation. Pet. App. 38a. It is precisely this type of "unscientific speculation offered by a genuine scientist," *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 318 (7th Cir. 1996) (Posner, J.), that Rule 702 expects trial courts to screen out.

III. The Questions Presented Are Important And Should Be Addressed Now.

Plaintiffs do not dispute that these issues are important and recur frequently. As *amici* explain, non-deferential decisions that dilute the district court's gatekeeping function have an extraordinary impact on toxic-tort and products-liability cases, which often turn on causation.

Plaintiffs contend that the Ninth Circuit's forgiving and non-deferential standards are appropriate because plaintiffs should not be barred from recovery "simply because the medical literature, which will eventually show the connection between the victims' condition and the toxic substance, has not yet been completed." Opp. 11 (quoting Pet. App. 19a). But Rule 702 exists precisely to avoid this question-begging result. "Law lags science; it does not lead it." *Rosen*, 78 F.3d at 319. Defendants should not be held liable for harm they did not cause, and history shows that *assuming* that science "will eventually show the [causal] connection" can negatively affect consumers. Chamber Br. 19-20; DRI Br. 14.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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