No.

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

The admissibility of expert testimony is governed by Rule 702 of the Federal Rules of Evidence. Rule 702 provides that "[a] witness who is qualified as an expert . . . may testify in the form of an opinion or otherwise *if*," among other things, "the testimony is the product of reliable principles and methods" *and* "the testimony has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(c), (d) (emphasis added).

This Court has held that a district court's application of Rule 702 is reviewed for abuse of discretion. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 143 (1997).

The questions presented are as follows:

1. Whether the two-part standard of reviewing expert-admissibility rulings employed by the Ninth Circuit, along with the Third and Seventh Circuits, improperly empowers these courts to reverse district court decisions to exclude evidence without "the deference that is the hallmark of abuse-of-discretion review." *Joiner*, 522 U.S. at 143.

2. Whether an expert's qualifications and mere invocation of a scientific methodology can be sufficient to require admission of his testimony, as the Ninth Circuit concluded, or whether Rule 702 requires that a witness, no matter how qualified, must also satisfy the court that his methodology was "reliably applied to the facts of the case," as several other circuits have held.

PARTIES TO THE PROCEEDING

Petitioner is Teva Pharmaceuticals USA, Inc., which was a defendant-appellee below.

Respondents are Stephen Wendell and Lisa Wendell, who were plaintiffs-appellants below, and GlaxoSmithKline LLC, which was a defendant-appellee below.

RULE 29.6 STATEMENT

The parent companies of Teva Pharmaceuticals USA, Inc. are: Orvet UK, Teva Pharmaceutical Holdings Coöperatieve U.A., IVAX LLC (f/k/a IVAX Corporation), Teva Pharmaceuticals Europe B.V., and Teva Pharmaceutical Industries Ltd. Teva Pharmaceutical Industries Ltd. is the only publicly traded company that owns 10% or more of Teva Pharmaceuticals USA, Inc.

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PETITION FOR A WRIT OF CERTIORARI

Teva Pharmaceuticals USA, Inc. respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Ninth Circuit.

OPINIONS BELOW

The decision of the court of appeals (Pet. App. 1a-25a) is reported at 858 F.3d 1227. The decision of the district court (Pet. App. 26a-43a) is not published in the *Federal Supplement* but is available at 2014 WL 2943572.

JURISDICTION

The judgment of the court of appeals was entered on June 2, 2017. A petition for rehearing was denied on July 21, 2017 (Pet. App. 44a-45a). On October 5, 2017, Justice Kennedy extended the time within which to file a petition to and including November 20, 2017. No. 17A376. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

RULE INVOLVED

Rule 702 of the Federal Rules of Evidence provides:

Testimony by Expert Witnesses

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

(b) the testimony is based on sufficient facts or data;

(c) the testimony is the product of reliable principles and methods; and

(d) the expert has reliably applied the principles and methods to the facts of the case.

INTRODUCTION

Expert testimony must be backed by more than just the expert's credentials and say-so. Under the Federal Rules of Evidence, district courts are responsible for ensuring that expert witnesses—no matter how qualified on paper—base their testimony on "reliable principles and methods," "reliably applied." Fed. R. Evid. 702. And under this Court's cases, because district courts' gatekeeping judgments are fact-sensitive and case-specific, appellate courts must review them deferentially. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 143 (1997). In this case the Ninth Circuit violated both principles and deepened an existing circuit split about the scope of district courts' gatekeeping authority.

First, the Ninth Circuit joined two other circuits in improperly recharacterizing a district court's evidentiary ruling as a question of law that receives no deference on appeal. The Ninth Circuit, along with the Third and Seventh Circuits, adopted a two-part standard of review under which such fact-specific matters as the district court's "application" of the *Daubert* factors and "whether particular evidence falls within the scope of" Rule 702 are treated as legal and reviewed *de novo*. *See, e.g.*, Pet. App. 6a; *Schultz v. Akzo Nobel Paints, LLC*, 721 F.3d 426, 430-431 (7th Cir. 2013). By aggressively expanding

what counts as a legal ruling, these circuits have also expanded their own power to reverse Rule 702 rulings with which they simply disagree. As several other circuits have recognized, that is not how abuse-of-discretion review is supposed to work, and it is not consistent with this Court's directives.

Second, having seized the role of the district court, the Ninth Circuit proceeded to misapply it. Again setting itself apart from its sister circuits, the Ninth Circuit held that some experts are so highly "experienced and credentialed" that they need not demonstrate that they reliably applied their methodologies to the facts of the case. Pet. App. 15a. For these experts, "*Daubert* poses no bar based on their principles and methodology." *Id.* at 20a. No other circuit uses such an overly broad standard of expert admissibility: outside the Ninth Circuit, qualifications and reliability remain separate concepts.

The Ninth Circuit's methodological errors were dispositive here. The court of appeals disagreed with the "weight" and "[]emphasi[s]" the district court applied to certain facts and factors in excluding two experts, Pet. App. 10a, 15a; the court of appeals thought that the experts' qualifications were enough protection against unreliably applied methodology. *Id.* at 20a. It acknowledged that the issue presented a "close question," and it identified an "err[or]" rather than an abuse of discretion. *Id.* at 10a.

This case thus provides an ideal vehicle for this Court to resolve the disagreement among the circuits on these important and fundamental issues of expert admissibility.

STATEMENT

A. Plaintiffs File Suit Contending That A Combination Of Prescription Medications Caused A Rare Cancer.

This case arose from the untimely death of Maxx Wendell from a rare form of cancer, hepatosplenic T-cell lymphoma (HSTCL). Mr. Wendell's death followed a nearly decade-long battle with a severe gastrointestinal condition, inflammatory bowel disease (IBD), and Plaintiffs contend that some combination of different medications prescribed to treat Mr. Wendell's IBD caused the cancer.

In 1998, when Mr. Wendell was 12 years old, he was diagnosed with IBD. Pet. App. 3a. His pediatric gastroenterologist, Dr. Edward Rich, prescribed 6-mercaptopurine (6-MP), a thiopurine drug marketed as Purinethol®. *Id.* The FDA had not approved 6-MP to treat IBD,[1] so Dr. Rich's prescription was for an off-label use of the drug.

When Mr. Wendell began taking Purinethol, the drug was both manufactured and marketed by GlaxoSmithKline (GSK). Pet. App. 3a. In July 2003, Teva acquired from GSK the rights to market and distribute Purinethol. *Id.* at 4a. Mr. Wendell first filled his prescription with a Teva-distributed product in December 2003. Teva C.A. S.E.R. 109, 113-114. Eight months later, in July 2004, Mr. Wendell switched to a generic form sold by Par Pharmaceutical. Pet. App. 28a.

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[1] The only FDA-approved indication of 6-MP was to treat acute lymphoblastic leukemia.

In addition to 6-MP, Dr. Rich prescribed Mr. Wendell an anti-tumor necrosis factor (anti-TNF) drug marketed as Remicade® beginning in 2002. Pet. App. 3a. When Mr. Wendell's IBD symptoms subsided but then returned, Dr. Rich prescribed a different anti-TNF drug marketed as Humira®. Pet. App. 3a-4a. Teva had no role in manufacturing or distributing either anti-TNF drug.

In July 2007, after he had discontinued both 6-MP and Humira, Mr. Wendell went to the emergency room complaining of fever, fatigue, and malaise. Pet. App. 4a. He was diagnosed with HSTCL, a rare and aggressive form of cancer that is distinct from all other lymphomas and for which no cause has been identified. C.A. E.R. 490; Teva C.A. S.E.R. 10, 16, 20-21, 39. Mr. Wendell tragically passed away five months later. Pet. App. 4a.

Plaintiffs, Mr. Wendell's parents, filed this wrongful-death lawsuit. After removal to federal court and several amendments of the complaint, Plaintiffs pleaded product-liability claims against seven manufacturers of 6-MP and anti-TNF drugs, including Teva based on its eight months of marketing the Purinethol Mr. Wendell took. Plaintiffs alleged that Mr. Wendell developed HSTCL as a result of taking a combination of these medications, and that the defendants failed to provide adequate warnings about any risk of HSTCL.

B. Plaintiffs Disclose Dr. Shustov And Dr. Weisenburger As Causation Experts.

After several years of discovery and motion practice not relevant here, Plaintiffs disclosed their two causation experts.

1. Dr. Andrei Shustov is a clinician and Associate Professor of Medicine at the University of Washington Medical Center. C.A. E.R. 209. He specializes in diagnosing and treating lymphomas and lymphoid leukemias, with a focus on T-cell leukemia and lymphomas. *Id.* at 209. Dr. Shustov had not previously researched or published any scholarship about the causes of HSTCL or any other cancer; his publications focused on autoimmunity and the *treatment* of cancer. *Id.* at 253. He also had not previously studied anti-TNF drugs, nor had he performed original research into whether thiopurines or anti-TNF drugs have any effect on the development of cancer. *Id.* at 253, 258.

Dr. Shustov submitted an expert report that contained a ten-page summary of Mr. Wendell's medical history and just over two double-spaced pages of "Discussion" regarding a perceived correlation between HSTCL and drug therapy. Pet. App. 46a-63a. The report stated that approximately 200 cases of HSTCL have been reported worldwide and noted what Dr. Shustov characterized as "a remarkable cluster of [36] cases . . . among young, predominantly male patients with a history of IBD" treated with purine analogues and anti-TNF drugs. *Id.* at 60a. The report drew entirely on one source, a 2011 article (not by Dr. Shustov) that reviewed data or case reports regarding 36 patients with HSTCL who had been treated for IBD with thiopurines alone (16 patients) or in combination with anti-TNF therapies (20 patients). Pet. App. 60a. "[C]ase reports are merely accounts of medical events" that "reflect only reported data, not scientific methodology." *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1199 (11th Cir. 2002). Case reports "make little attempt to screen

out alternative causes for a patient's condition," "often omit relevant facts about the patient's condition," and therefore are "regarded with caution" as a basis for causal attribution, rather than simply temporal association. *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 989-990 (8th Cir. 2001) (quoting Fed. Judicial Ctr., *Reference Manual on Scientific Evidence* 475 (2d ed. 2000)); *see also* Pet. App. 39a (citing similar authority).

Dr. Shustov stated that "[g]iven the absolute rarity of this disease generally," he believed this "cluster" of cases was "compelling evidence of causation." Pet. App. 62a. Dr. Shustov provided no opinion as to *how* thiopurines and anti-TNF drugs could cause HSTCL, instead stating that this mechanism "is not known." *Id.* Nor did he address any other possible cause of HSTCL in any patient. For example, all the patients in the cluster had IBD, but neither Dr. Shustov nor the cited article "control[led] for IBD as a possible risk factor." *Id.* at 39a.

Dr. Shustov then addressed Mr. Wendell's case in three sentences. He opined that Mr. Wendell "was one of those patients" that falls within this "cluster," simply because Mr. Wendell had been treated with a thiopurine in combination with anti-TNF drugs and had developed HSTCL. Pet. App. 62a. Dr. Shustov then opined that "[t]o a reasonable degree of medical probability," the combination of 6-MP and anti-TNF drugs "caused, or substantially contributed, to the development of HSTCL." *Id.*

When asked about his method for forming his opinions, Dr. Shustov said he reviewed the literature (though he cited only one source in his report) and "applied general knowledge and biology and medi-

cine." C.A. E.R. 254. Preparing his causation analysis took "a couple hours." *Id.* He said that most of his report was based on "general knowledge for medical professional[s]" and some was based on "what I've read over years about [HSTCL] and its agents." *Id.*

When asked whether he reached his opinion using a differential diagnosis, which the report did not mention, Dr. Shustov said he did not "remember [his] thought process but it is a usual thought process for approaching any patient." C.A. E.R. 287.

Dr. Shustov acknowledged that his opinions were not based on animal or epidemiological studies—and, indeed, that he did not know if any relevant studies existed. C.A. E.R. 273. He also acknowledged that case reports cannot establish causation absent rare exceptions not present here, such as acute exposure. *Id.* at 263. But he contended that HSTCL's rarity justified relying on case reports. In the absence of other evidence, Dr. Shustov said, "you go to the best clinical judgment and biological plausibility," *id.* at 265, which is the conclusion he said he reached in his report, *id.* at 282-284, 294. He acknowledged, however, that biological plausibility alone cannot prove causation. *Id.* at 262.

When asked whether there was "anything about Maxx Wendell's case" that caused Dr. Shustov to believe that Mr. Wendell's HSTCL was caused by his medications as opposed to other HSTCL risk factors, Dr. Shustov said, "Well, we have no idea what the risk factors are for de novo [HSTCL]. We don't even know what to look for." C.A. E.R. 306. But based on a perceived *correlation* from case reports, Dr. Shustov opined that exposure to 6-MP and anti-TNF

drugs was much more likely to be the cause than anything else. *Id.*

2. Dr. Dennis Weisenburger is a hematopathologist and chair of the pathology department at City of Hope Medical Center. C.A. E.R. 319. He specializes in the study and diagnosis of bone marrow and immune-system diseases but does not generally offer opinions on the cause of a patient's disease. *Id.* at 319-320. Dr. Weisenburger, like Dr. Shustov, had no experience with anti-TNF drugs and had never published any papers on HSTCL or its causes. *Id.* at 320-321, 325.

Plaintiffs disclosed, as Dr. Weisenburger's expert report, a 1½-page letter to Plaintiffs' counsel. Pet. App. 64a-66a. The letter contained three sentences about causation and referenced three articles, none of which discusses HSTCL causation. *Id.* at 66a. Dr. Weisenburger asserted in the letter that IBD patients treated with thiopurines and anti-TNF drugs have an increased risk of developing a disease such as HSTCL, and that the disease typically occurs in young men treated with these drugs for long periods. *Id.* He concluded that, "[t]herefore, it is my opinion with reasonable medical certainty" that the combination of 6-MP and anti-TNF drugs "caused or substantially contributed to the development of HSTCL" in Mr. Wendell. *Id.*

Dr. Weisenburger was originally engaged as a diagnostic expert but, less than a week before the deadline for submitting his report, he offered to also provide a causation opinion. C.A. E.R. 338; *see also id.* at 321. Dr. Weisenburger testified that his 1½-page letter was based on (1) a summary of Mr. Wendell's medical records prepared by Plaintiffs' counsel,

(2) his examination of Mr. Wendell's bone marrow slides and pathology reports, (3) his "general knowledge of the disease" and what he knew "of its association with immunosuppression and various drugs that are used to treat disease" from articles he had read "over the years," and (4) three references he "had at hand that . . . specifically addressed the issue." *Id.* at 322, 323. He did not review any other literature regarding HSTCL until *after* he submitted his letter, because he "had a deadline for the report." *Id.* at 321-322.

When asked about his methodology, Dr. Weisenburger testified that had "used the Bradford Hill methodology to come to the conclusion that I did." C.A. E.R. 346.[2] Dr. Weisenburger did not mention the Bradford-Hill criteria in his letter, and he never explained at deposition how he had applied the criteria.

Dr. Weisenburger agreed that the large majority of cases (73%) of HSTCL are *de novo* (occur without any proposed risk factors), and that the disease presents exactly the same way whether it is "de novo or whether it occurs in the setting of immunosuppression or treatment." C.A. E.R. 359. And he acknowledged that no controlled studies had identified the drugs, or any of them, as causing HSTCL. *Id.* at 333, 334, 354. He nevertheless concluded that 6-MP and anti-TNF drugs caused or substantially contributed to Mr. Wendell's disease because Mr. Wendell took those drugs before developing HSTCL, though he

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[2] "The Bradford-Hill criteria are [nine] metrics that epidemiologists use to distinguish a causal connection from a mere association." *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 795 (3d Cir. 2017).

said that "when one tries to sort out exactly what was etiologic [causative] and what wasn't, it's very difficult. It was probably all these drugs together in combination that resulted in the increased risk." *Id.* at 343. When asked how these drugs might have interacted with any other proposed risk factors, such as gender or age, he said, "I don't think anybody really knows." *Id.* at 349.

C. The District Court Excludes Plaintiffs' Causation Experts Based On The Unreliability Of Their Opinions.

After holding a hearing and considering the factors set forth in Rule 702, the Rule's advisory committee notes, and this Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the district court excluded both experts' opinions. Pet. App. 26a-43a.

First, the court found that the experts' opinions were developed solely for litigation: neither doctor had "ever conducted any independent research or published any studies on the specific relationship between 6MP and anti-TNF drugs and the development of HSTCL." Pet. App. 35a. Second, the court found that, by the experts' own admission, their opinions would not "satisfy the standards required for publication," which "casts doubt [upon] the reliability of their methodologies." *Id.*

Third, the court found that the experts' opinions were not premised on reliable evidence of general causation, such as "animal studies or epidemiological studies showing a causal link." Pet. App. 36a. The court found that the lack of "reliable evidence of a positive link between the drugs at issue and the dis-

ease" was particularly problematic given the high rate of observed HSTCL cases that occur with no known cause. *Id.* The court noted that many of the studies on which the experts purported to rely were not "actually cited in Plaintiffs' expert reports," and it found that none of these studies "purports to show that the specific combination of drugs prescribed to Maxx actually causes HSTCL." *Id.* at 38a. Instead, the studies merely contain statistics about occurrences of HSTCL among various patient populations, but do not show statistical significance and do not account for plausible alternative causes, such as the underlying IBD. *Id.* Finally, the court found that while the experts "both stated that they do not believe IBD is a risk factor for HSTCL," they provided no scientific evidence to account for this obvious alternative explanation—the third factor discussed in Rule 702's advisory committee notes. *Id.* at 39a.

Because Plaintiffs had not adduced admissible evidence on the element of causation, the district court granted summary judgment in Teva's favor. Pet. App. 39a-40a.[3]

D. Using A Two-Part Standard Of Review That Afforded No Deference To the District Court, The Ninth Circuit Reverses.

On appeal, Plaintiffs asked the Ninth Circuit to exercise plenary review over the district court's exclusion of the experts' opinions "*despite the abuse of discretion standard* under Rule 702." Pls.' C.A. Br. 31 (emphasis added). They argued that the district

[3] Three of the other defendants had settled with Plaintiffs, and the district court had granted summary judgment for GSK and Par Pharmaceutical on unrelated grounds.

court's application of Rule 702 amounted to an erroneous "legal interpretation[] of the Rule's requirements." *Id.*[4]

The Ninth Circuit reversed, using exactly the standard of review advocated by Plaintiffs. The court of appeals first stated that it reviewed "the district court's ruling on the admissibility of expert testimony for an abuse of discretion." Pet. App. 6a. Then, though the case involved no question about the meaning of Rule 702, the court qualified its abuse-of-discretion standard by stating, "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*." *Id.* (emphasis added) (quotation marks omitted).

This two-part standard of review enabled the court to review the district court's Rule 702 decision without deference. Although the court acknowledged that it was "a close question," it "conclude[d] that the district court erred by excluding the experts' testimony." Pet. App. 10a.

1. Rather than begin with the district court's reasoning, the court of appeals started by explaining why, in *its* view, the experts' testimony was admissible. First, the court of appeals found that Drs. Shustov and Weisenburger were "highly qualified doctors." Pet. App. 11a. The court recited their credentials and training, noted that Dr. Shustov had treated seven HSTCL patients, and pointed to Dr. Wei-

[4] Plaintiffs consistently argued that the district court "erred" and that its decision was "legally erroneous." *See, e.g.*, Pls.' C.A. Br. 26, 38. Not once did Plaintiffs argue that the court abused its discretion in applying Rule 702.

senburger's publications on the subject of non-Hodgkin's lymphoma generally. *Id.* The court pointed to no experience investigating the *causes* of HSTCL, however, as neither doctor had any.

Second, the court of appeals opined that Drs. Shustov and Weisenburger "employed sound methodologies to reach their conclusions," at a high level of generality. Pet. App. 11a. The court noted that Dr. Shustov described a "method of conducting a differential diagnosis" he typically uses, and that such a method "is scientifically sound." *Id.* at 12a. The court accepted that Dr. Weisenburger had used Bradford-Hill criteria, which are "well accepted in the medical field for making causal judgments." Pet. App. 13a-14a & n.4.

The court of appeals stated that the experts' credentials and reference at deposition to those methodologies were enough, and that the district court "improperly required more." Pet. App. 14a. In the court's view, "Nothing in *Daubert*, or its progeny, properly understood, suggests that the most experienced and credentialed doctors in a given field should be barred from testifying based on a differential diagnosis." *Id.* at 15a. The court did not address the distinct roles of qualifications and reliability under Rule 702.[5]

2. The court of appeals then pointed to a number of "mistakes" that caused the district court to reach its contrary conclusion. Pet. App. 10a; *see id.* at 15a-19a. First, the court of appeals stated that the dis-

[5] While the court block-quoted Rule 702 at the beginning of its discussion, Pet. App. 7a, it never returned to the Rule's requirements or cited or quoted any subdivision of the Rule.

trict court put too "much weight on the fact that the experts' opinions were not developed independently of litigation and had not been published." *Id.* at 15a. Second, the court stated that "[a]lthough unwillingness to publish weighs against admissibility," the district court "wrongly" used Dr. Shustov's and Dr. Weisenburger's reticence to publish their opinions "as evidence that their *methods* were not up to snuff." *Id.* at 16a.

Third, the court stated that the district court "overemphasized" the fact that the experts' opinions were not based on epidemiological studies showing a causal relationship between the drugs at issue and HSTCL. Pet. App. 10a. The court acknowledged the district court's point about the weaknesses of non-controlled case reports, but thought that here the "statistical analysis" of case reports could combine with the experts' "own wealth of experience and additional literature." *Id.* at 18a.

Fourth, it stated that the district court "erred" when it relied upon the experts' inability to rule out alternative causes of Mr. Wendell's HSTCL (such as an idiopathic origin, or IBD itself). Pet. App. 18a.[6] Finally, the court again emphasized its high opinion of the experts' credentials and experience, which it stated that the district court "improperly ignored." Pet. App. 10a. The court concluded that when "two doctors who stand at or near the top of their field and

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[6] The court of appeals made only one reference to any "abuse of discretion"—when it discussed the experts' failure to rule out alternative possible causes of Mr. Wendell's HSTCL, and only *after* concluding that the district court "erred" by relying on the experts' inability to rule out IBD or an idiopathic origin. Pet. App. 18a-19a.

have extensive clinical experience with the rare disease or class of disease at issue, are prepared to give expert opinions supporting causation, . . . *Daubert* poses no bar based upon their principles and methodology." *Id.* at 20a.

The Ninth Circuit denied rehearing en banc. Pet. App. 44a-45a.

REASONS FOR GRANTING THE WRIT

Trial courts have "broad latitude" to determine whether the expert's methodology, supporting data, and application of that methodology are sufficiently reliable to reach the jury—latitude that is to be reviewed only for an abuse of discretion. *Joiner*, 522 U.S. at 143. Most courts of appeals read this Court's precedent to guarantee "the trial court the deference that is the hallmark of abuse-of-discretion review." *Id.* But the Ninth Circuit, along with the Third and Seventh Circuits, has reformulated the standard of review, identifying a *legal* component of reliability determinations that allows them to exercise plenary appellate review and to reverse *Daubert* decisions based on mere disagreement, not abuse of discretion.

Compounding the error, where an expert appears "highly qualified" and refers generally to a scientific methodology, the Ninth Circuit now does not require any showing that the expert *reliably applied* the methodology—a holding that conflicts not only with Rule 702(d) but with every other circuit to have considered this issue. This court should grant certiorari to resolve the conflicts on these recurring and important evidentiary questions.

I. The Two-Part Standard Of Review Employed By The Third, Seventh, And Ninth Circuits Conflicts With The Deferential Standard Applied By The Other Circuits.

Trial courts, not appellate judges, have the gatekeeping responsibility to determine whether expert evidence is sufficiently reliable to reach the jury, "particularly when a case arises in an area where the science itself is tentative or uncertain, or where testimony about general risk levels in human beings or animals is offered to prove individual causation." *Joiner*, 522 U.S. at 147-148 (Breyer, J., concurring). The role of appellate courts is cabined: they can reverse expert-admissibility decisions only for an abuse of discretion, with deference to the trial court being the "hallmark" of this standard of review. *Joiner*, 522 U.S. at 143 (majority opinion).

Over the 20 years since this Court's decision in *Joiner*, the circuits have come into conflict about how to conduct appellate review. While most appellate courts have strictly adhered to *Joiner*'s abuse-of-discretion standard, the Third Circuit, the Seventh Circuit, and now the Ninth Circuit have unwound it into two parts. Those circuits have incorrectly identified a "legal" strand of the analysis, which they employ to review expert-admissibility rulings without deference, and to reverse where they simply disagree with the trial court's on-the-ground judgment.

A. Most Circuits Use A Uniform Abuse-Of-Discretion Standard And Reverse Only "Manifestly Erroneous" Rule 702 Rulings.

Most circuits have adhered to the deferential review framework set by this Court in *Joiner*. These

circuits apply a pure abuse-of-discretion standard in reviewing district court Rule 702 rulings.

The Eleventh Circuit, after being reversed in *Joiner* and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999), for affording inadequate deference to the district court's gatekeeping role, got the message that deference means deference. The Eleventh Circuit now makes clear that district courts have a "range of possible conclusions" on the admissibility of expert testimony, which means that "there will be occasions in which we affirm the district court even though we would have gone the other way had it been our call. This is how an abuse of discretion standard differs from a *de novo* standard of review." *Cook ex rel. Estate of Tessier v. Sheriff of Monroe Cty., Fla.*, 402 F.3d 1092, 1103 (11th Cir. 2005) (citation omitted) (affirming exclusion of expert testimony). The Eleventh Circuit reverses only if the district court's decision is "manifestly erroneous," *id.* (citation omitted), and places a "heavy thumb—really a thumb and a finger or two—. . . on the district court's side of the scale." *Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1344 (11th Cir. 2010) (citation omitted).

In *Kilpatrick*, for example, the Eleventh Circuit affirmed the exclusion of an expert's differential-diagnosis testimony even though other courts had admitted such testimony "in similar situations." 613 F.3d at 1343. The district court had excluded the testimony because it found that the literature upon which the expert based his causation analysis "was insufficient to create a reliable methodology which passes *Daubert* muster." *Id.* at 1341. Reviewing deferentially, the Eleventh Circuit cautioned that expert testimony need not *always* "rely on articles that

draw a direct, concrete, and absolute causal connection," but it concluded that it could not "disagree to the point of finding an abuse of discretion in the district court's conclusion." *Id.* at 1341 n.18.

The Eighth Circuit likewise affords "significant deference" to district court rulings and affirms even if it "might have come to a different conclusion as an original matter from the one that the district court did." *Grp. Health Plan, Inc. v. Philip Morris USA, Inc.*, 344 F.3d 753, 760 (8th Cir. 2003). In *Group Health Plan*, the district court excluded as overly speculative the opinion of the plaintiffs' causation expert, Dr. Harris, who was highly qualified, who had an extensive publication record, and whose opinion had been admitted by every other court to consider it. *Id.* at 759. The Eighth Circuit affirmed. It made clear that, in its view, "the issue is closer than the district court thought, for Dr. Harris's work is thorough, sophisticated, and often well-grounded in the relevant scientific literature." *Id.* at 760. Nevertheless, because of the "significant deference" owed to the district court, it was "unable to conclude that the district court committed a clear error of judgment in excluding the testimony." *Id.*

Other circuits likewise apply a uniform abuse-of-discretion standard, affording great deference and reversing only when the district court's decision was manifestly erroneous. *See, e.g.*, *United States v. Jordan*, 813 F.3d 442, 447 (1st Cir.) (affirming exclusion of one expert and admission of another, noting that "an appellate court must defer in large measure to the trial court's superior point of vantage"), *cert. denied,* 136 S. Ct. 2528 (2016); *Currier v. United Techs. Corp.*, 393 F.3d 246, 250, 253 (1st Cir. 2004) (stating

that "[a] judge reasonably could resolve many admissibility questions either way, and rampant second-guessing by appeals courts would paralyze the judicial process" and concluding that there was no abuse of discretion in admitting expert testimony even though it "skittered near the line of inadmissibility"); *Olin Corp. v. Certain Underwriters at Lloyd's London*, 468 F.3d 120, 133 (2d Cir. 2006) (affording "great latitude" to the district court's admission of expert opinion and affirming even though expert opinions were not all "particularly well-supported"); *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 528 (6th Cir. 2008) (stating that "we will not substitute our own judgment for that of the district court" and affirming admission of expert testimony).

B. Three Circuits Employ A Two-Part Standard Of Review That Substantially Diminishes Deference By Treating Discretionary Judgments As Legal Ones.

In contrast with most other circuits, the Third, Seventh, and Ninth Circuits use a two-part standard that allows them to mask their impermissible plenary review of Rule 702 decisions and to reverse when they simply would have reached a different result.

1. The Seventh Circuit applies the following two-part standard of review: it reviews *de novo* the district court's *application* of Rule 702, and then reviews the ultimate "decision to admit or exclude expert testimony . . . for an abuse of discretion." *Schultz*, 721 F.3d at 430-431; *accord Gayton v. McCoy*, 593 F.3d 610, 616 (7th Cir. 2010) ("We review de novo whether the court correctly applied *Daubert*'s framework, and we review the court's

decision to admit or exclude expert testimony for abuse of discretion.").

The Third Circuit applies a similar two-part standard: it reviews the decision to admit or exclude expert testimony for an abuse of discretion, but it applies "plenary review" to the district court's "interpretation of the requirements of Rule 702." *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 151 (3d Cir. 1999). Similarly, here, the Ninth Circuit paid lip service to the abuse-of-discretion standard, stating that it reviews "the district court's ruling on the admissibility of expert testimony for an abuse of discretion," but applies *de novo* review to "whether particular evidence falls within the scope of a given rule." Pet. App. 6a (citation omitted).

If matters such as the "application" of Rule 702 or "whether particular evidence falls within" Rule 702 receive plenary review, one might wonder what is left for these courts to review for abuse of discretion. In many instances, the answer is not much: these courts often undertake an exhaustive review that fails to mention (much less afford) deference to the district court and reverses where these courts simply would have decided the issue differently, without identifying any manifest error.

2. This case is a perfect example. The Ninth Circuit used its two-part standard to mask what was effectively plenary review, as is evident from the court's repeated statements about its disagreement with the "weight" and "[]emphasi[s]" the district court applied to certain "facts" and *Daubert* factors, Pet. App. 10a, 15a—aspects over which a trial court enjoys "broad latitude" under true abuse-of-discretion review. *Kumho*, 526 U.S. at 153.

The court of appeals afforded no deference whatsoever to the district court's assessment that the experts' analyses were insufficiently rigorous, or that their opinions were based on only "a handful of studies and case reports" that the district court found did not "purport[] to show that the specific combination of drugs prescribed to [Mr. Wendell] actually causes HSTCL." Pet. App. 38a. Instead, the Ninth Circuit simply disagreed that the case reports were inadequate in this case. *Id.* at 17a-18a.

Circuits that apply uniform abuse-of-discretion review afford substantial deference to exactly this type of case-specific determination. *See, e.g.*, *Glastetter*, 252 F.3d at 990 (no abuse of discretion in excluding differential diagnosis based on studies that "were largely grounded upon case reports and other anecdotal information"); *Meister v. Med. Eng'g Corp.*, 267 F.3d 1123, 1131-1132 (D.C. Cir. 2001) (no abuse of discretion where differential analysis was premised on "heavy reliance on case reports" and none of the literature reviewed purported to establish causal nexus as opposed to mere "[t]emporal methodology"); *see also Hollander v. Sandoz Pharm. Corp.*, 289 F.3d 1193, 1211 (10th Cir. 2002) ("it was not unreasonable" for district court to characterize "case reports regarding other women suffering various injuries after taking Parlodel . . . as unreliable evidence of causation").

The Ninth Circuit similarly disagreed with the district court's determination (Pet. App. 36a-37a) that Drs. Shustov and Weisenburger failed to account for plausible alternative causes of HSTCL, such as Mr. Wendell's underlying IBD. Pet. App. 18a-19a, 37a-39a. Not only is this one of the factors expressly dis-

cussed in the Rule 702 advisory committee notes, it also falls within the district court's discretion to determine based on the facts of the case. *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 265 (4th Cir. 1999) ("A differential diagnosis that fails to take serious account of other potential causes *may be so lacking* that it cannot provide a reliable basis for an opinion on causation." (emphasis added)).

The same is true of the Ninth Circuit's disagreement that a lack of epidemiological studies supporting general causation rendered the expert opinions unreliable in this case. Pet. App. 17a-18a. This, too, is precisely the type of fact-bound determination that falls squarely within the wide latitude of the district court to determine based on the facts of each case—at least in circuits that exercise uniform *abuse-of-discretion* review. *See, e.g.*, *Meister*, 267 F.3d at 1131-1132; *Glastetter*, 252 F.3d at 992 (noting that "epidemiological evidence might have assisted Glastetter in establishing causation" and concluding district court did not abuse its discretion in excluding expert opinion based on a lack of epidemiological evidence in combination with the absence of other reliable evidence).

The two-part standard of review was critical to the outcome here: only by characterizing "whether particular evidence falls within the scope of" Rule 702 as a legal issue warranting *de novo* review was the Ninth Circuit able to reverse because "the district court erred." Pet. App. 10a, 18a, 20a.

3. The same phenomenon occurs under the Third Circuit's nearly identical two-part standard. In one representative case, the district court excluded testimony of a proffered warnings expert because the

expert was not qualified to opine on automobile warnings and employed an unreliable methodology. *Pineda v. Ford Motor Co.*, No. 04-3359, 2006 WL 3337488, at *4-*6 (E.D. Pa. Nov. 15, 2006). The Third Circuit reversed without making any mention of the deference the district court is owed and without identifying any abuses of discretion. *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008) (identifying "the only issue" as "whether the District Court erred in its decision to exclude [the] expert testimony"). Instead, it reversed because it simply "disagree[d]" with the district court's conclusions. *Id.* at 244 (concluding that the expert was qualified, relying heavily on the expert's engineering credentials); *see also id.* at 249 & n.16 (district court "erred" in concluding that expert testimony was unreliable because the deficiency the district court identified—failure to conduct a comparative analysis of warnings—was not fatal).[7]

4. This plenary-review masking also occurs under the Seventh Circuit's two-part standard, which reviews *de novo* the district court's "application" of Rule 702.

In one recent case, the district court excluded an expert opinion that linked the decedent's leukemia to benzene exposure by relying on a "no-threshold" theory of causation that had "been roundly rejected by courts across the country." *Schultz v. Glidden Co.*, No. 08–C–919, 2012 WL 968005, at *3 (E.D. Wis.

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[7] *See also Pure Earth, Inc. v. Call*, 531 F. App'x 256, 261-262 (3d Cir. 2013) (Sloviter, J., dissenting) (admonishing majority for undertaking plenary review of the district court's *Daubert* decision and stating that excluding causation testimony based only on evidence of *correlation* was not an abuse of discretion).

Mar. 21, 2012). Although the plaintiff argued that the testimony should nonetheless be admissible because the expert cited a study that could support a different theory—that higher levels of exposure could create a statistically significant increased risk of cancer—the district court excluded the testimony because "the basic thrust" of the expert's testimony was "that the amount of benzene exposure is irrelevant, so long as it is 'nontrivial,'" and because the expert failed to rule out or even explain why the decedent's habit of smoking more than a pack of cigarettes a day for more than three decades was not the sole cause of his disease. *Id.* at *4.

The Seventh Circuit reversed in relevant part, holding that the district court "erred by excluding" this testimony. *Schultz*, 721 F.3d at 434. The Seventh Circuit did not point to any manifest error, describe any way in which the district court abused its wide discretion, or acknowledge the deference due the district court. Instead, it simply disagreed with the district court's conclusion and the weight the district court gave to particular facts. *See id.* at 432-434. A standard of review that allows a court of appeals to reverse the exclusion of testimony where the "basic thrust" of the expert's causation theory "has been rejected by the overwhelming majority of the scientific community," *Schultz*, 2012 WL 968005, at *3-*4 (citation omitted), cannot be reconciled with the wide latitude that characterizes the uniform abuse-of-discretion standard required by *Kumho* and *Joiner*.

* * * * *

The two-part standard of review employed by the Third, Seventh, and Ninth Circuits drain much, if

not all, of the discretion out of the abuse-of-discretion standard. This Court should grant review to resolve the conflict among the circuits and make clear that district courts have discretion in applying *Daubert* principles to experts' proposed methodology.

II. The Ninth Circuit Conflicts With Its Sister Circuits By Allowing "Highly Qualified" Experts To Testify Irrespective Of Whether Their Methods Were Reliably Applied.

The court of appeals placed seemingly dispositive weight on its view that "the experts were highly qualified doctors," brushing off the district court's concerns about their unreliable methodology as matters for the jury to weigh. Pet. App. 11a, 15a, 20a. But Rule 702 provides not only that an expert must be qualified, but also that expert *testimony* must be reliable. That means the testimony must be "the product of reliable principles and methods," *and* those principles and methods must be "reliably applied . . . to the facts of the case." Fed. R. Evid. 702(c), (d). The Ninth Circuit stands alone in collapsing these requirements for an undefined set of highly-credentialed experts.

In other circuits, an expert's bare reference to a scientific methodology will not do—no matter how sterling the expert's credentials. The Ninth Circuit treated "differential diagnosis" and "Bradford Hill" essentially as magic words that open the gate. As other circuits correctly recognize, *invoking* those methodologies may be easy, but reliably *applying* them is harder.

A. The Ninth Circuit Permits Experts' Qualifications To Substitute For Reliable Application Of Scientific Methodology.

Credentials alone are not a license to opine. Rule 702 requires more than just qualifications—once an expert is found qualified, she may offer opinion testimony *only* if it is "the product of reliable principles and methods," *and* those principles and methods are "reliably applied . . . to the facts of the case." Fed. R. Evid. 702(c), (d). The Rule makes no exceptions for experts found *highly* qualified. But the Ninth Circuit did. The court of appeals considered Drs. Shustov and Weisenburger to be at the "top of their field," and it therefore applied a different standard: it was enough that their deposition testimony (though not their expert reports) referenced two scientific methodologies—differential diagnosis and the Bradford-Hill criteria. Pet. App. 15a, 20a.[8]

That credentials-focused analysis brushed aside the district court's conclusion that the doctors did not reliably apply those methodologies—or any other. Dr. Shustov described how he *generally* conducts a differential diagnosis, but when asked about having done so in Mr. Wendell's case, he said that he "d[idn't] remember [his] thought process." C.A. E.R. 287. Similarly, Dr. Weisenburger never explained how he applied the Bradford-Hill criteria or, indeed, how he *could* apply them here,[9] and his relevant lit-

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[8] The Ninth Circuit also provided no objective guideposts for what separates the "highly qualified" (who may opine at will) from the merely "qualified" (who must follow the ordinary rules).

[9] Bradford-Hill criteria can be applied only after a statistically significant association has been demonstrated by appropriate

erature review did not occur until *after* he submitted his letter report.

B. The Other Circuits Require All Experts To Show That Their Methodology Was Reliably Applied.

Allowing an expert's résumé to substitute for a reliable methodology defeats the purpose of Rule 702: to ensure that an expert's impressive resume does not lead juries astray. Indeed, every other circuit to have considered the issue has concluded that even "[a] supremely qualified expert cannot waltz into the courtroom and render opinions unless those opinions are based upon some recognized scientific method and are reliable and relevant under the test set forth by the Supreme Court in *Daubert*." *Clark v. Takata Corp.*, 192 F.3d 750, 759 n.5 (7th Cir. 1999); *accord, e.g.*, *McDowell v. Brown*, 392 F.3d 1283, 1298 (11th Cir. 2004). Unlike the court below, the other circuits do not hesitate to uphold decisions excluding the unreliable opinions of distinguished doctors and scholars. *See, e.g.*, *Oddi v. Ford Motor Co.*, 234 F.3d 136, 156 (3d Cir. 2000) (affirming exclusion of unreliable testimony by expert who "clearly meets *Daubert*'s qualifications requirement"); *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1316–17 (11th Cir. 1999) (no abuse of discretion in excluding testimony from "a prolific scientific author" who "has published nu-

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epidemiologic studies. Fed. Judicial Ctr., *Reference Manual on Scientific Evidence* 598-599 & n. 141 (3d. ed. 2011). No such studies existed here.

merous articles in peer reviewed journals" and had impressive "scientific expertise").[10]

The other circuits also recognize, unlike the Ninth Circuit, that merely invoking the name of a scientific method "does not by itself answer the reliability question." *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 674 (6th Cir. 2010). Instead, an expert must also demonstrate that she actually *applied* an established methodology *in a reliable manner*. *See Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd.*, 326 F.3d 1333, 1343 (11th Cir. 2003) ("In evaluating whether Frank's testimony was reliable, it is important to be mindful of a distinction that appears throughout the parties' arguments: the difference between the reliability of computational fluid dynamics generally and of Frank's application of CFD in this case."). Even the most qualified expert in a field must show her work.

This requirement is particularly important in the medical-causation context. Differential diagnosis can be an appropriate methodology. But in other circuits, "simply claiming that an expert used the 'differential diagnosis' method is not some incantation that opens the *Daubert* gate." *Tamraz*, 620 F.3d at 674 (citation omitted). In those circuits, for differential-diagnosis testimony to be admissible, the expert must (1) "rule in" potential causes of injury using independent reliable evidence of general causation, then (2) "rule out" potential causes using reliable methods or at least provide a reasonable explanation

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[10] *See also, e.g.*, *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996) ("the courtroom is not the place for scientific guesswork, even of the inspired sort" by "a distinguished cardiologist").

why any alternative cause was not the sole cause. *Best v. Lowe's Home Ctrs., Inc.*, 563 F.3d 171, 179-180 (6th Cir. 2009); *Hollander*, 289 F.3d at 1211; *Glastetter*, 252 F.3d at 989; *see also Chapman v. Procter & Gamble Distrib., LLC*, 766 F.3d 1296, 1308–09 (11th Cir. 2014) (no abuse of discretion in excluding differential diagnosis opinion based on a causation theory that had not been reliably established); *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 254 (2d Cir. 2005) (the district court is afforded "broad discretion in determining whether in a given case a differential diagnosis is enough by itself to support such an opinion").[11] Contrary to other circuits, the Ninth Circuit allowed the experts to skip the first step and instead "assume[] [in] the pertinence of all potential causes." Pet. App. 12a.

Similarly, although Bradford-Hill criteria may be employed as a reliable method for determining causation, other circuits recognize that "each application is distinct and should be analyzed for reliability," and the expert must "explain 1) how conclusions are drawn for each Bradford Hill criterion and 2) how the criteria are weighed relative to one another." *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 795–96 (3d Cir. 2017). In other circuits, when an expert invokes the Bradford-Hill criteria but does not demonstrate he reliably applied them or based his analysis on reliable scientific evidence, his testimony is properly excluded irrespective

[11] For example, a district court may deem unreliable a differential diagnosis based on evidence of general causation rooted in a temporal relationship because it is vulnerable to the "classic post hoc ergo propter hoc fallacy which assumes causation from temporal sequence." *Kilpatrick*, 613 F.3d at 1343 (quotation marks omitted). *Compare* Pet. App. 38a.

of his credentials. *See, e.g.*, *id.* at 800 (physician "did not consistently assess the evidence supporting each criterion or explain his method for doing so"); *Hollander*, 289 F.3d at 1204 & n.7, 1210 (expert opinion was based on case reports that contained limited information about the injured patients rather than reliable causation evidence).

In other circuits, the district court's decision would have been affirmed because other circuits recognize that referencing a scientific method "is not some incantation that opens the *Daubert* gate." *Tamraz*, 620 F.3d at 674 (citation omitted). That is not just a matter of district-court discretion; *even the Third and Seventh Circuits*, which give the district court little deference, *see* Part I, *supra*, have held exclusion decisions like this one substantively *correct*. In the Ninth Circuit, however, it is enough to simply say, "And then I used the Bradford Hill methodology to come to the conclusion that I did," Pet. App. 13a-14a; a district court has no discretion to demand more from experts like these. This Court should grant review to resolve this conflict and bring the Ninth Circuit in line with its sister circuits and Rule 702.

III. The Petition Raises Questions Of Great Significance That Merit Review By This Court Now.

The deference-free standard for reviewing *Daubert* decisions has significant implications for plaintiffs, defendants, and trial courts in expert-heavy areas of law. Less deference means less finality, less predictability, more appeals, and more second-guessing. And the decision below will have a particularly profound impact on the many toxic-tort and

product-liability cases that, as here, involve causation hypotheses that have not been scientifically tested. This petition presents an ideal vehicle to address these important issues.

A. The Questions Presented Are Important and Recurring.

The practical significance and frequent recurrence of the questions presented call for this Court's review.

1. The standard of review employed by the Third, Seventh, and Ninth Circuits creates extraordinary judicial inefficiency. Because the abuse-of-discretion standard already permits reversal where a district court's Rule 702 ruling is manifestly erroneous, the only benefit that can be derived from the non-deferential standard applied by these outlier circuits would be to "contribute only negligibly" to the accuracy of *permissible* district court *Daubert* rulings "at a huge cost in diversion of judicial resources." *Anderson v. City of Bessemer City*, 470 U.S. 564, 574-575 (1985).

Furthermore, the lack of deference that the two-part standard affords to district courts "denigrate[s] the importance of the trial [court] and encourage[s] appeals of rulings relating to the testimony of expert witnesses" in these circuits. *United States v. Brown*, 415 F.3d 1257, 1266 (11th Cir. 2005). Appeals that would be frivolous under a uniform abuse-of-discretion standard become worth the cost of appeal. *Cf. Cooter & Gell v. Hartmarx Corp.*, 496 U.S. 384, 404 (1990) ("deference will . . . discourage litigants from pursuing marginal appeals, thus reducing the amount of satellite litigation").

Appellate review of expert-admissibility decisions does not exist to provide disappointed parties the opportunity to relitigate (perhaps with different arguments) evidentiary close calls that were appropriately considered by the trial court. Indeed, the deferential standard mandated by *Joiner* and *Kumho* is aimed at preventing exactly this result.

2. The Ninth Circuit's disregard of the requirement that that a scientific methodology was *reliably performed* will allow juries to be misled by "powerful" expert evidence that they are unable to properly evaluate. *Daubert*, 509 U.S. at 595 (citation omitted). Indeed, this concern is even *more* acute in the context of "highly qualified" experts: juries are more likely to erroneously believe unscientific testimony uttered by a genuine scientist than unreliable testimony offered by an obvious hack. Any plaintiff seeking to circumvent the requirement of reliably applied methodology can now seek out the Ninth Circuit.

Moreover, allowing medical product-liability cases to go to trial based on unreliable causation opinions has serious ramifications for patients. The "powerful" and potentially "misleading" nature of expert evidence greatly increases the chances that pharmaceutical and medical device companies will be held liable for injuries that their products did not cause, and thus that products that are enormously beneficial for patients will be pulled from the shelves even if all available reliable evidence indicates it is safe. 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, 224-225 (2006) (discussing the morning-sickness drug Bendectin®).

3. These issues will impact an extraordinary number of cases. Virtually every state, including California, requires expert testimony to prove causation where the causal relationship exceeds the common knowledge of jurors. *See In re Baycol Prods. Litig.*, 596 F.3d 884, 889 (8th Cir. 2010); *In re Mirena IUD Prods. Liab. Litig.*, __ F. App'x __, 2017 WL 4785947, at *3 (2d Cir. Oct. 24, 2017) (citing cases surveying States and U.S. territories). As a result, *Daubert* challenges are a common feature of product-liability and mass-tort litigation. Indeed, pharmaceutical product-liability cases often "boil[] down to a fight over causation," Bert Black, *A Unified Theory of Scientific Evidence*, 56 Fordham L. Rev. 595, 679–80 (1988) (discussing Bendectin cases that gave rise to *Daubert*), and the appeal incentives created by the Third, Seventh, and Ninth Circuits' non-deferential standard will only increase the number of appeals in which these issues arise.

B. This Petition Offers An Excellent Vehicle To Review The Questions Presented.

This case presents a clear record for reviewing the questions presented. Plaintiffs asked the Ninth Circuit to review the district court's *Daubert* decision de novo, Pls.' C.A. Br. 31, and the court obliged. Indeed, the Ninth Circuit's non-deferential standard is evident from its holding: "Although we think it a close question, . . . the district court erred by excluding the experts' testimony." Pet. App. 10a. By definition, where the admissibility of expert testimony is "a close question," its exclusion could be reversed only under *de novo* review.

The court of appeals was equally clear about its outlier reliability standard. It repeatedly emphasized the experts' credentials and unequivocally concluded that for physicians who "stand at or near the top of their field, and have extensive clinical experience with the rare disease or class of disease at issue, . . . *Daubert poses no bar* based on their principles and methodology." Pet. App. 20a (emphasis added). And here, too, the error was dispositive. If the court had required a showing that the experts had reliably applied differential diagnosis and the Bradford-Hill criteria, as the other circuits require, it could not have reached the same conclusion: these experts made no effort to explain their use of differential diagnosis or the Bradford-Hill criteria, much less demonstrate they had reliably applied these methods.

Furthermore, this Court is *less* likely to have another opportunity to review the second question presented in the future. Given the Ninth Circuit's diluted expert-admissibility standard, district courts within the Ninth Circuit will be hesitant to exclude testimony that unreliably applies scientific methodologies. Decisions *admitting* testimony are not immediately appealable as of right; are reviewable after trial only through the lens of harmless error; and often escape review altogether because the costs and risks associated with taking a battle-of-the-experts case to trial put extraordinary settlement pressure on defendants. This Court should thus grant review in this case, which offers a clean record to consider this important issue.

* * * * *

It has been two decades since this Court's decision in *Joiner*. The deep circuit conflict demonstrates that this Court's review is warranted to ensure that district courts are afforded the discretion necessary to prevent juries from being misled by "unscientific speculation offered by a genuine scientist." *Mitchell v. Gencorp Inc.*, 165 F.3d 778, 783 (10th Cir. 1999) (citation omitted).

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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