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

RESPONDENTS' BRIEF IN OPPOSITION

ESTHER BEREZOFSKY
MICHAEL QUIRK
BEREZOFSKY LAW GROUP, LLC
Woodland Falls Corporate Ctr.
210 Lake Drive East
Suite 101
Cherry Hill, NJ 08002
(856) 667-0500

MATTHEW W.H. WESSLER
Counsel of Record
RACHEL BLOOMEKATZ
GUPTA WESSLER PLLC
1900 L Street, NW
Suite 312
Washington, DC 20036
(202) 888-1741
matt@guptawessler.com
rachel@guptawessler.com

Counsel for Respondents

February 2, 2018

QUESTIONS PRESENTED

1. Whether the Ninth Circuit, consistent with all other circuits, reviews a district court's expert-admissibility ruling for an abuse of discretion, but underlying questions of law *de novo*.

2. Whether in evaluating the admissibility of expert testimony under Rule 702, the Ninth Circuit, consistent with all other circuits, requires every expert to reliably apply her methodology to the facts of a case.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Other authorities

INTRODUCTION

In this case, the Ninth Circuit did something unremarkable: it recited the familiar standard of review that admissibility determinations are reviewed for an abuse of discretion while legal questions are reviewed *de novo*, and then applied that standard to the district court's *Daubert* determination. In this, Teva sees a case worthy of review. Seizing upon the panel's reference to *de novo* review, Teva asserts that the Ninth Circuit's approach here is part of a broad split among the circuits, with some using (in Teva's words) a "two tiered" standard of review when it comes to *Daubert* and others applying a "pure" or "uniform" standard. Pet. 17–18. But there is no split—circuit courts use various articulations of the abuse-of-discretion standard interchangeably. And the Ninth Circuit's review here faithfully applied that standard—it did not even invoke *de novo* review in reversing the district court for abusing its discretion.

Conceptually, even the idea of a split here does not make sense. "A district court by definition abuses its discretion when it makes an error of law." *Koon v. United States*, 518 U.S. 81, 100 (1996). So whether described as a single abuse-of-discretion standard or as two parts (with legal questions subject to plenary review), the substance is the same. That is why courts even within the same circuit articulate the standard using both formulations. *See infra* 13–16. No wonder Teva (and its codefendant GlaxoSmithKline) failed to raise any specter of this split in their en banc petitions—it does not exist.

Nor is there merit to Teva's argument that the Third, Seventh, and Ninth Circuits use the standard of review to silently subvert deference to district courts and reverse when they "simply disagree." Pet. 3. There is nothing in the language of these circuits' standards that

"improperly empowers" an appellate court to reverse based on "mere disagreement." *Id.* 16. To the contrary, Teva's three so-called "representative" cases (including this one) show only that appellate courts reverse sometimes, even when reviewing for abuse of discretion, and even when a party (like Teva here) might disagree. That, too, is unremarkable.

Teva's second attempt at a split is an even further stretch. Teva contends that the Ninth Circuit—in conflict with all other circuits—requires admissibility of scientific testimony from "highly qualified" experts who merely invoke a scientific methodology, regardless of whether they have reliably applied it. But that is not the law in the Ninth Circuit or in any other circuit, and it is not the rule that was applied in this case.

Ultimately, Teva's challenge here involves little more than a fact-bound appeal of a decision with which it disagrees. Not only is that quarrel wrong, but it affords no basis for this Court's review. The petition should be denied.

STATEMENT

A. Maxx's illness and death

In 1998, when he was 12 years old, Maxx Wendell was diagnosed with inflammatory bowel disease (IBD), an autoimmune condition characterized by chronic inflammation. Pet. App. 3a. His doctor began treating Maxx's IBD by prescribing Purinethol, a mercaptopurine (6-MP) drug manufactured by defendant GlaxoSmithKline. 6-MP is in a class of drugs called thiopurines. *Id.* They work by interfering with DNA synthesis. Because they damage DNA, they are carcinogenic. *Id.* 12a. But they are also immunosuppressant, so have long been used to treat IBD. *Id.* 3a. In July 2002, Maxx's doctor added a second

immunosuppressant drug, Remicade, manufactured by Centocor. *Id.* 3a–4a. Remicade is in a class of drugs known as tumor necrosis factor inhibitors (anti-TNFs), which are used to treat various autoimmune disorders. *Id.* Four years after starting this two-drug protocol, Maxx's IBD went into remission. *Id.* 3a.

In May 2006—two months after Maxx received his last dose—the Food and Drug Administration required a new black-box label on Remicade warning about Hepatosplenic T-cell lymphoma (HSTCL). *Id.* HSTCL is a non-Hodgkin's lymphoma that is "exceedingly rare and aggressive." *Id.* 1a. It is almost always fatal, and most die within the first year after diagnosis. *Id.* 1a, 17a. In reviewing Centocor's application for a new use of Remicade, the agency learned about increased instances of HSTCL in young, male patients who were taking a combination of Remicade and a thiopurine (like 6-MP) for the treatment of IBD. RE219.[1] As a result, it told Centocor that it must add a warning stating:

> Rare postmarketing cases of Hepatosplenic T-Cell Lymphoma have been reported in adolescent and young male patients with Crohns disease [a form of IBD] treated with Remicade. This rare type of t-cell lymphoma has a very aggressive disease course and is usually fatal. All of these Hepatosplenic T-Cell Lymphomas have occurred in patients on concomitant treatment with Azathioprine or 6-Mercaptopurine.

[1] References to "RE" refer to the Plaintiffs-Appellants' Record Excerpts filed in the Ninth Circuit as Doc. Nos. 12-1 to 12-4.

RE160; Pet. App. 3a, 48a. In addition to changing the label, Centocor also sent a "Dear Health Care Provider" letter alerting prescribers to the HSTCL cases. Pet. App. 4a. Because of this warning, when Maxx's IBD symptoms returned in November 2006, his doctor prescribed him Humira, a different anti-TNF drug that carried no similar warning. *Id.* 22a.

Six months into his second round of two-drug therapy, Maxx was reading an issue of *Men's Health* magazine when an article or advertisement caught his eye. *Id.* 48a; RE384–85. He read that the combination of Remicade and other immunosuppressive medication was shown to cause a certain type of cancer in young male patients. RE385; Pet. App. 4a. So Maxx went to his doctor with concerns. After discussing with his doctor, Maxx's 6-MP treatment was discontinued. RE387–89; Pet. App. 4a.

Not three months later, in July 2007, Maxx checked into the emergency room with fevers, fatigue, and malaise. He was diagnosed with the exact condition he had read about: HSTCL. *Id.* As Maxx's case exemplified, HSTCL often does not respond to chemotherapy and most patients, like Maxx, are too weak to undergo bone marrow transplantation. *Id.*

Maxx sought specialized treatment at Stanford and then Columbia. At Columbia, the specialist noted that Maxx "was treated with the unfortunate combination of Remicade and 6[-MP]. It is now known that this combination can lead to the development of a primary splenic lymphoma . . . also known as [HSTCL]." *Id.* 58a. Maxx died early in the morning on December 6, 2007—less than 6 months after he first checked into the hospital. He was 21 years old. *Id.* 4a.

B. The Case

After Maxx's death, his parents brought this wrongful death action against Teva (and other drug manufacturers and distributors, some of which have settled). Maxx's parents alleged that 6-MP, alone or in combination with anti-TNF drugs, caused Maxx to develop HSTCL and that Teva failed to provide adequate warnings about this harm. Pet. App. 2a. In support of causation, the plaintiffs produced expert reports and testimony from two doctors who specialize in diagnosing and treating lymphomas. Both experts testified based on their education, training, and experience, knowledge of the pertinent medical literature, and careful review of Maxx's medical records. *Id.* 11a–12a. And both concluded to a reasonable degree of medical certainty that extended use of thiopurines, including 6-MP, either alone or in combination with anti-TNFs, such as Remicade and Humira, can cause HSTCL and was a substantial cause of Maxx's HSTCL and death. *Id.*

1. The plaintiffs' first expert, the clinical oncologist Dr. Andrei Shustov, estimated that he has seen more cases of HSTCL than 99% of oncologists in the country. *Id.* 11a. A physician and Associate Professor of Medicine at the University of Washington Medical Center, Dr. Shustov specializes in the diagnosis and treatment of lymphomas, with a clinical research focus on T-cell leukemia and lymphomas, including the exceedingly rare disease Maxx suffered from. *Id.*

Addressing general causation, Dr. Shustov concluded to a reasonable degree of medical certainty that 6-MP alone or in combination with anti-TNFs causes HSTCL; indeed, he concluded that patients with IBD who are treated with thiopurines have an almost 300-fold increase in the risk of developing HSTCL. RE309.

Dr. Shustov began his analysis by emphasizing that HSTCL is an exceedingly rare subtype of T-cell lymphoma that comprises less than 0.1% of all non-Hodgkin's lymphoma diagnoses. Pet. App. 59a. Only approximately 200 cases have been reported in the worldwide medical literature since it was first recognized in the early 1990s. *Id.* 60a. And, drawing on the medical literature, Dr. Shustov testified that "a remarkable cluster of cases has emerged among young, predominantly male patients with a history of IBD treated with the combination" of drugs Maxx received. *Id.* As Dr. Shustov described, one peer-reviewed article examined 36 HSTCL patients—all 36 had been treated with a thiopurine (like 6-MP), and 20 had also received an anti-TNF. They were overwhelmingly male, and the median age was 23. The median time for the onset of HSTCL was approximately six years after beginning these medications. *Id.* (citing David S. Kotlyar, MD, et al., *A Systematic Review of Factors That Contribute to Hepatosplenic T-Cell Lymphoma in Patients with Inflamatory Bowel Disease*, 9 Clinical Gatroenterology & Hepatology 36 (2011)). As Dr. Shustov concluded, "[t]his high an incidence of an exceedingly rare cancer in this distinct cohort is compelling evidence" that 6-MP, alone or in combination with an anti-TNF, causes HSTCL. *Id.* 62a. He emphasized: "Given the absolute rarity of this disease generally, a cluster of 36 cases arising in young, predominantly male patients treated for IBD with thiopurines and TNF antagonists stands as almost a signature of the disease." *Id.*

Dr. Shustov further supported his conclusions with statistical analysis. *Id.* 18a. Based on the available data, Dr. Shustov calculated that among IBD patients treated with thiopurines, there is a 1 in 22,000 risk of developing HSTCL. He compared that figure with the 1 in 6,000,000

risk among the general population, based on the number of HSTCL cases reported worldwide in the national and international T-cell lymphoma registries. *Id.* 13a.; RE309–12. Dr. Shustov thus concluded that there was a 300-fold increase in the risk of HSTCL for patients like Maxx.

With respect to Maxx specifically, Dr. Shustov conducted a differential diagnosis to conclude that Maxx's drug regiment was a substantial cause of his death. Pet. App. 12a. Differential diagnosis is a "scientifically-sound" method that doctors use to diagnose patients. *Id.* Per this method, he first assumed the pertinence of all potential causes. Because "6-MP is a well-known mutagen and carcinogen and puts every person who takes it at risk"—Maxx's actual drug regimen was one such cause. *Id.* Next, Dr. Shustov "rule[d] out ones as to which there is no plausible evidence of causation" and then determined the "most likely" cause. *Id.* Dr. Shustov specifically ruled out Maxx's IBD as a cause of HSTCL, citing to published studies demonstrating that IBD alone is not associated with any increased risk of lymphoma. RE253, RE278, RE295, RE299 (citing Lisa J. Herrinton, PhD, et al., *Role of Thiopurine and Anti-TNF Therapy in Lymphoma in Inflammatory Bowel Disease*, 106 Am. J. of Gastroenterology 2146 (Dec. 2011)). The most likely cause of Maxx's HSTCL, in Dr. Shustov's expert opinion, was Maxx's drug regimen; indeed, he could not "identify anything else in the patient's history or medical records" that could have caused it. Pet. App. 12a-13a.

2. The plaintiffs' second expert, Dr. Dennis D. Weinsenburger, was an expert hematopathologist with more than thirty years' experience in the diagnosis of non-Hodgkin's lymphoma, with particular expertise in T-cell lymphomas. *Id.* 11a. A professor and Chair of the De-

partment of Pathology at the City of Hope Medical Center, a National Cancer Institute-designated Comprehensive Cancer Center, Dr. Weinsenburger used the Bradford-Hill methodology—"a set of criteria that are well accepted in the medical field for making causal judgments"—to conclude that 6-MP drugs cause HSTCL. *Id.*, 11a, 14a n.4; RE346. He then used a differential diagnosis to conclude that "the combination of anti-TNF agents and 6-MP used in the treatment of [Maxx] caused or substantially contributed to the development of HSTCL." Pet. App. 66a; RE344–45.

In his report, Dr. Weisenburger explained that it is "well known" that "patients with IBD who are treated with thiopurines (6-MP) and anti-tumor necrosis factor (anti-TNF) agents (Remicade, Humira)" have an "increased risk" of developing HSTCL. RE224 (citing Laurent Beaugerie, *Immunosuppression-related lymphomas and cancers in IBD: how can they be prevented?*, 30 Digestive Diseases 415 (2012); and Kavitha Subramanian, et al, *Lymphoma and other lymphoproliferative disorders in inflammatory bowel disease: a review*, 28 J. of Gastroenterology & Hepatology 24 (Jan. 2013)). Pet. App. 66a. And it "typically occurs in young men (<35 years) who have been treated for prolonged periods with thiopurines alone or in combination with anti-TNF agents." *Id.*

In his view, the scientific literature demonstrates that these drugs increase the risk of HSTCL in a statistically significant manner. RE341 (discussing Parakkal Deepak, MD, et al., *T-Cell Non-Hodgkin's Lymphomas Reported to the FDA AERS with Tumor Necrosis Factor- Alpha (TNF-α) Inhibitors: Results of the REFURBISH Study*, 108 Am. J. of Gastroenterology 99 (Jan. 2013)). According to the published studies, the risk of HSTCL increases

anywhere from 6.9- to 3045.2-fold when taking thiopurine alone for the treatment of IBD. RE243, 349. Because HSTCL is rare, Dr. Weisenburger explained that it was normal for the confidence interval of a statistical study to be that wide. But a wide confidence interval did not undermine his conclusion; even the lowest-end ratio showed a markedly increased risk of HSTCL. RE350.

Like Dr. Shustov, Dr. Weisenburger also explained why factors other than Maxx's drug regimen were not likely the cause of his HSTCL. For instance, he echoed Dr. Shustov in ruling out IBD based on prior studies. Pet. App. 14a n.5. And he ruled out Maxx's age, sex, and race as biologically implausible explanations for his developing HSTCL. *Id.* 14a; RE344. Dr. Weisenburger further considered that Maxx's HSTCL might have been idiopathic (i.e., without a known cause). Although he was not entirely able to rule out that possibility, he explained given the science, his experience, and the medical literature, that the "obvious and known risk factor[],"—the drug regimen—caused or substantially contributed to Maxx's HSTCL. *Id.* 14a, 66a.

C. The Lower Court Decisions

1. The district court excluded both experts' testimony, concluding that they did not meet the *Daubert* standard of reliability, and therefore granted Teva's motion for summary judgment. Pet. App. 5a.

In assessing reliability, the district court first focused on the fact that neither doctor had conducted independent research or published on the relationship between 6-MP/anti-TNF drugs and HSTCL, but had instead developed their opinions for the litigation. *Id.* 35a. Neither expert had conducted independent research, gathered new data, or otherwise made a new contribution to the scientific literature, *id.* 16a, and so "their opinions would

not satisfy the standards required for publication in peer-reviewed medical journals," *id.* 35a. For the district court, that undermined the experts' "methodologies." *Id.*

Next, the district court emphasized that the experts failed to cite animal or epidemiological studies conclusively demonstrating that 6-MP, alone or in combination with anti-TNF drugs, causes HSTCL. *Id.* 36a. The court recognized that such studies would be difficult to conduct given the rarity of HSTCL, but it still found them "especially important" because most cases of HSTCL are idiopathic. *Id.* And although the studies the experts relied upon did contain statistical analysis about the incidence of HSTCL in different patient populations, the district court concluded that the experts had not shown that these observed differences "were statistically significant or that they account for plausible alternative causes of HSTCL, such as IBD itself." *Id.* 38a–39a.

2. The Ninth Circuit reversed. It unanimously concluded that the district court "abused its discretion," *id.* 19a, in determining that the experts' opinions were the "'junk science' Rule 702 was meant to exclude," *id.* At the outset of its decision, in a separate section (part II), the Ninth Circuit recited the standard of review for *Daubert* determinations: "We review the district court's ruling on the admissibility of expert testimony for an abuse of discretion. 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.* 6a (internal quotation marks and citations omitted). Turning to the merits, the panel conducted a comprehensive and detailed review and concluded that "the district court erred by excluding the experts' testimony." *Id.* 10a.

In reaching this result, the circuit court explained that requiring the existence of independent research and "animal or epidemiological studies" to demonstrate causation in this context—where no such studies could realistically be conducted—was unreasonably stringent. *Id.* 17a. Under the district court's approach, testimony regarding the causation of rare diseases like HSTCL might never pass muster, no matter how reliable or well-accepted within the medical community. *Id.* 19a. As the Ninth Circuit noted, "with only 100 to 200 cases reported since it was first recognized," it was "not surprising" that there may not be published studies that specifically show causation. *Id.* 17a. But that does not mean the testimony should be excluded: "That there is no study that definitively states HSTCL is caused by the ingestion of 6-MP and anti-TNF drugs does not prevent the admission of Plaintiffs' expert testimony." *Id.* 18a. Were it otherwise, any testimony regarding a newly discovered or rare disease would face the same problem—but "'[t]he first several victims of a new toxic tort should not be barred from having their day in court simply because the medical literature, which will eventually show the connection between the victims' condition and the toxic substance, has not yet been completed.'" *Id.* 19a (quoting *Clausen v. M/V New Carissa*, 339 F.3d 1049, 1060 (9th Cir. 2003)).

Even on its own terms, though, the Ninth Circuit explained that the district court's analysis faltered because the experts here *did* rely on published studies and articles. *Id.* 17a. The district court reflexively dismissed these as mere case reports, but these studies did more: They "not only examined reported cases but also used statistical analysis to come up with risk rates." *Id.* 19a.

The Ninth Circuit further faulted the district court's decision to throw out the testimony simply because the

experts could not completely rule out an idiopathic origin. *Id.* 18a–19a. When "an expert establishes causation based on a differential diagnosis, the expert may rely on his or her extensive clinical experience as a basis for ruling out a potential cause of a disease." *Id.* 19a. Here, both experts testified in their clinical judgment that Maxx's HSTCL was much more likely caused by the drugs, given the cluster of other HSTCL cases among young men with long-term use of thioprines and anti-TNF medications. There was "a one in six million chance that Maxx would have developed HSTCL without being exposed to 6-MP"—with his exposure, his chances increased multiple fold. Thus there was no basis for the district court to doubt the experts' *methodology* underlying their conclusion that "it's much more likely that exposure to mutagen and immunosuppressants caused the lymphoma." *Id.* 13a.

In the same vein, the Ninth Circuit criticized the district court's emphasis on the fact that the experts' opinions would not be accepted for peer-review publication. *Id.* 16a. As the experts explained, "[o]pinions are not publishable," "[d]ata is publishable," and "any meta-analysis or review of the literature could only be published by invitation." *Id.* Neither expert had new data to publish, but that does not mean—as the district court found—"that their *methods* were not up to snuff." *Id.*

The upshot: the district court's decision was infected with unreasonable analysis. "It improperly ignored the experts' experience, reliance on a variety of literature and studies, and review of Maxx's medical records and history, as well as the fundamental importance of differential diagnosis by experienced doctors treating troubled patients." *Id.* 10a. The Ninth Circuit therefore held that

"all together, [the district court's] mistakes warrant reversal." *Id.* 10a.

3. Teva (along with GSK) moved for rehearing en banc. It argued that the panel failed to afford sufficient deference to the district court's determinations, and asked for error correction because, in its view, the panel "misread the record, including the district court's reasoning." GSK Pet. Reh'g En Banc 5 n.1; Teva Pet. Reh'g En Banc 12–16. The rehearing petitions raised no specter of any circuit split regarding the Ninth Circuit's standard of review. The Ninth Circuit unanimously denied rehearing en banc. Pet. App. 44a–45a.

REASONS FOR DENYING THE PETITION

I. There is no split of authority on the appropriate standard for reviewing a district court's *Daubert* determination.

Although it failed to even mention a disagreement among the circuits when it sought the full Ninth Circuit's review, Teva now claims a "deepen[ing]" split in authority over the standard of review for *Daubert* determinations. Pet. 2. On one side, Teva says, the Third, Seventh, and Ninth Circuits use a "two-part standard of review," while other circuits employ a "uniform abuse-of-discretion standard." *Id.* 17. That is wrong. No court has ever recognized such a split because, labels aside, every circuit applies the same approach. For this reason alone, the Court should deny the petition.

Whether phrased as a one-part or two-part standard, *every circuit* adheres to the same standard when reviewing a district court's decision to admit or exclude expert testimony under *Daubert* (or Rule 702). And that universal standard is a familiar one: *de novo* review for questions of law and abuse of discretion for questions requir-

ing an application of that law in a given case. *See* Harry T. Edwards & Linda A. Elliott, *Federal Courts Standards of Review* 67–68 (2007). At most, then, Teva's allegation of a split boils down to a concern that some circuits are *silently* using the settled two-tiered review standard to reverse "based on mere disagreement." Pet. 16. But there is no evidence of this at all, and regardless, it affords no basis for this Court's review.

A. The circuits all apply the same familiar standard of review for *Daubert* determinations.

Teva's bid for certiorari begins with a false premise. It suggests that "most" circuits apply a "pure" or "uniform" abuse-of-discretion standard when reviewing *Daubert* determinations, while others have "unwound it into two parts" with a "legal strand" that receives no deference. Pet. 17–18. This distinction is just labels. It is textbook law that *legal* errors—which are reviewed without deference to the district court—*always* constitute an abuse of discretion. *Koon*, 518 U.S. at 100. The Supreme Court put it plainly: "A district court by definition abuses its discretion when it makes an error of law" and "the court of appeals need not defer to the district court's resolution of the point." *Id.*; *see Cameron v. Otto Bock Orthopedic Indus., Inc.*, 43 F.3d 14, 16 (1st Cir. 1994) ("We commonly say that we review [evidentiary] determinations solely for an abuse of discretion. This may be a mild overstatement since evidentiary rulings can sometimes contain buried rulings of law reviewable *de novo*." (footnote omitted)).

So although courts may articulate either a single "abuse-of-discretion" test or a "two part[]" standard (to use Teva's label) in which legal questions are reviewed *de novo* and application of the law to the facts is reviewed for abuse of discretion, the substance of the appellate

review is the same. Given this, it is wholly unsurprising that appellate decisions—even those within the same circuit—often refer interchangeably to *both* a single-abuse-of discretion standard and a two-tiered standard. They are, in other words, different ways of saying the same thing.

1. Consider the Eleventh Circuit—Teva's model for the "pure" abuse-of-discretion standard. It routinely recites its standard of review in *Daubert* cases using a two-tier formulation, such as: "We review a district court's exclusion of expert testimony under the federal rules of evidence for an abuse of discretion. As for the district court's interpretation of Federal Rule of Evidence 702, our review is plenary." *United States v. Frazier*, 387 F.3d 1244, 1293 (11th Cir. 2004) (internal citations omitted). And here is another one: "This court reviews the district court's decision to exclude expert testimony under Federal Rule of Evidence 702 for abuse of discretion. To the extent that a ruling of the district court turns on an interpretation of a Federal Rule of Evidence, our review is plenary." *United States v. Paul*, 175 F.3d 906, 909 (11th Cir. 1999) (internal citations omitted); *see also City of Tuscaloosa v. Harcros Chems., Inc.*, 158 F.3d 548, 556 (11th Cir. 1998) (same); *Witt v. Stryker Corp. of Mich.*, 648 F. App'x 867, 872 (11th Cir. 2016) (same); *Long v. Raymond Corp.*, 245 F. App'x 912, 913–14 (11th Cir. 2007) (same).

The same is true in the Eighth Circuit. *See United States v. Montgomery*, 635 F.3d 1074, 1089 (8th Cir. 2011) ("We review the district court's interpretation and application of the Federal Rules of Evidence *de novo* and its evidentiary rulings for abuse of discretion."); *United States v. Purkey*, 428 F.3d 738, 752 (8th Cir. 2005) ("We review de novo the district court's interpretation and

application of the rules of evidence, and review for an abuse of discretion the factual findings supporting its evidentiary ruling.") (quoting *United States v. Smith*, 383 F.3d 700, 706 (8th Cir. 2004)).

And all the other circuits that allegedly embrace Teva's "uniform" abuse-of-discretion review follow the same approach. Pet. 19–20 (citing cases from the First, Second, and Sixth Circuits). A few years ago, the First Circuit made this point explicitly. It reversed a district court's *Daubert* determination and pointedly explained that its abuse-of-discretion review "is not monolithic: within it, embedded findings of fact are reviewed for clear error, questions of law are reviewed de novo, and judgment calls are subjected to classic abuse-of-discretion review." *Milward v. Acuity Specialty Prods. Grp., Inc.*, 639 F.3d 11, 13–14 (1st Cir. 2011) (quoting *Ungar v. Palestine Liberation Org.*, 599 F.3d 79, 83 (1st Cir. 2010)). *See also Borawick v. Shay*, 68 F.3d 597, 601 (2d Cir. 1995) ("Our review must be de novo on the question whether, in exercising its discretion to admit evidence, the district court applied the proper legal test."); *Best v. Lowe's Home Centers, Inc.*, 563 F.3d 171, 178–79 (6th Cir. 2009) (applying two-tier standard of review).

There is, accordingly, no divergence among the circuits—they all employ two-tiered standards. Indeed, compared to the Eleventh, Eighth, and other circuits Teva relies upon, the allegedly contrary Third Circuit standard for reviewing *Daubert* determinations is practically indistinguishable: "On appeal, we review a District Court's decision to exclude expert testimony for abuse of discretion. The District Court's interpretation of the requirements of Rule 702, however, is subject to plenary review." *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 151

(3d Cir. 1999) (internal citation omitted). So too is the Seventh Circuit's: "We review de novo whether the court applied the legal framework required under Rule 702 and *Daubert*, and we review the court's decision to admit or exclude expert testimony for abuse of discretion." *United States v. Pansier*, 576 F.3d 726, 737–38 (7th Cir. 2009). And this case, like the rest of the Ninth Circuit, follows in tow. Pet. App. 6a; *United States v. Och*, 16 F. App'x 666, 670 (9th Cir. 2001) ("We review the district court's interpretations of the Federal Rules of Evidence de novo . . . [and] its rulings on the admissibility of expert testimony for an abuse of discretion.") (citing *United States v. Bensimon*, 172 F.3d 1121, 1125 (9th Cir. 1999)).

2. If this standard-of-review framework sounds familiar that's because it is. Appellate review for *Daubert* issues involves one of the most commonplace—and common sense—types of review known to the law. *See* Edwards & Elliott, *Standards of Review*, at 67–68; *Highmark Inc. v. Allcare Health Mgmt. Sys., Inc.*, 134 S. Ct. 1744, 1748 (2014) ("Traditionally, decisions on questions of law are reviewable *de novo*, . . . and decisions on matters of discretion are reviewable for 'abuse of discretion.'" (quoting *Pierce v. Underwood*, 487 U.S. 552, 558 (1988)) (internal quotation marks omitted)).

Whether deemed a single abuse-of-discretion standard, or a two-tiered standard, this form of appellate review applies in so many areas of law that it almost defies categorization. It includes review of basic evidentiary determinations, sentencing decisions, class certification orders, attorneys fee awards, and preliminary injunctions, just to name a few. And for all of these sorts of routine matters, a reviewing court reviews a district court's interpretation of the underlying legal issue *de novo* but its application in a given context with deference

to the district court. *See*, *e.g.*, *Montgomery*, 635 F.3d at 1089 (interpretation of Federal Rules of Evidence reviewed *de novo*, evidentiary determination reviewed for abuse of discretion); *United States v. Staten*, 466 F.3d 708, 713 (9th Cir. 2006) (interpretation of sentencing guidelines reviewed *de novo*, application in a given case reviewed for abuse of discretion); *Pickett v. Iowa Beef Processors*, 209 F.3d 1276, 1279 (11th Cir. 2000) (interpretation of Rule 23's requirements reviewed *de novo*; class certification decision reviewed for abuse of discretion); *I.B. v. New York City Dep't of Educ.*, 336 F.3d 79, 80 (2d Cir. 2003) (interpretation of relevant fee statute reviewed *de novo*, but resulting award reviewed for abuse of discretion); *Platt v. Bd. of Comm'rs on Grievances & Discipline of Ohio Sup. Ct.*, 769 F.3d 447, 454 (6th Cir. 2014) (district court's decision as to preliminary injunction reviewed for abuse of discretion, except underlying constitutional questions reviewed *de novo*).

Not only does Teva have no circuit split, it doesn't even have a controversial or unsettled question. To the contrary, the issue it asks this Court to review is one of the most conventional and well understood in the law.

B. The Third, Seventh, and Ninth Circuits faithfully apply the settled standard for reviewing *Daubert* determinations.

In the absence of any real split, Teva is left to speculate that some circuits say they apply the established standard form of review but then do something else entirely. In Teva's view, the Third, Seventh, and Ninth Circuits *all* improperly "recharacteriz[e]" "fact-specific" matters as legal questions, and then subversively afford "no deference" with one goal in mind: To "reverse Rule 702 rulings with which they simply disagree." Pet. 2–3. Teva's attempt to second-guess these courts goes no-

where. A brief review of these circuits' decisions debunks Teva's claim.

1. First, take the Ninth Circuit's standard articulated in this case. Teva points to it as evidence that the Ninth Circuit "aggressively expand[s] what counts as a legal ruling" subject to *de novo* review. *Id.* But this is what the court said about the controlling standard:

> We review the district court's ruling on the admissibility of expert testimony for an abuse of discretion. *Messick v. Novartis Pharm. Corp.*, 747 F.3d 1193, 1196 (9th Cir. 2014). 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.* (alteration in original) (quoting *United States v. Durham*, 464 F.3d 976, 981 (9th Cir. 2006)).

Pet. App. 6a. What about this formulation is "aggressively" expansive? Certainly, there can be no issue with the Ninth Circuit's (and Third Circuit's) *de novo* review of the "construction or interpretation" of Rule 702. *See Heller*, 167 F.3d at 151 (explaining that a district court's "interpretation of the requirements of Rule 702 . . . is subject to plenary review"). Questions about what the Rule requires that are independent from the facts of any specific case are legal questions subject to plenary review. *See*, *e.g.*, *Daubert v. Merrell Dow Pharm. Inc.*,, 509 U.S. 579, 590 (1993) (Rule 702 does not require that "subject of scientific testimony must be 'known' to a certainty; arguably, there are no certainties in science."); *Lowe's Home Centers, Inc.*, 563 F.3d at 178–79 (differential diagnosis may be a reliable methodology under

Daubert in evaluating expert's testimony); *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1208–9 (8th Cir. 2000) (expert testimony need not always be based on published studies to satisfy Rule 702). Even the second question presented in this petition provides a good example of a question subject to *de novo* review—whether Rule 702 requires that a highly qualified expert also apply a reliable methodology before her testimony may be admitted. That is certainly a legal question that is properly reviewed *de novo*. *See Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1315 (9th Cir. 1995).

Teva seizes (at 21, 23) on the fact that the Ninth Circuit reviews *de novo* "whether particular evidence falls within" Rule 702. Teva takes that to mean that the Ninth Circuit treats the admissibility of every expert's proffered testimony in every case as a legal question subject to plenary review, arguing that it "drain[s] much, if not all, of the discretion out of the abuse-of-discretion standard." Pet. 25–26. That asks far too much of the quoted standard. Instead, the Ninth Circuit applies plenary review just to the question of whether a witness's testimony is the sort of evidence for which a court must apply Rule 702's analysis. And were there any doubt, the citation to *United States v. Durham* cinches it. Pet. App. 6a. In *Durham*, the court had to assess whether a woman's testimony that a substance was marijuana should be regarded as expert or lay testimony. 464 F.3d at 982 (resolving whether Rule 701 or 702 governed). This was a legal determination subject to *de novo* review. But, as the court explained, "[o]nce it has been determined that challenged evidence falls within the scope of a given rule, the District Court's decision to admit the evidence is reviewed for abuse of discretion." *Id.* at 981.

If this is Teva's main complaint, it might more appropriately be lodged against this Court, which takes the same approach. In *Kumho Tire Co. v. Carmichael*, for example, the Court considered whether Rule 702 (and the *Daubert* framework) applied "to the testimony of engineers and other experts who are not scientists." 526 U.S. 137, 141 (1999). Looking to the language and purpose of Rule 702, it concluded that the Rule applies to all specialized and technical testimony. *Id.* at 147–49. It did not defer to the district court. *Id.* at 146 (noting that the Eleventh Circuit reviewed the "district court's legal decision to apply *Daubert*" *de novo*). And to the extent there is any dispute over how a court should review a district court's decision to apply Rule 702 to particular evidence, *see United States v. Jones*, 107 F.3d 1147, 1152 (6th Cir. 1997), it is irrelevant in this case; all parties agree Rule 702 was the proper framework here.

2. Teva also challenges the Seventh Circuit's statement that it reviews "*de novo* whether the court correctly applied *Daubert*'s framework." Pet. 20 (quoting *Grayton v. McCoy*, 593 F.3d 610, 616 (7th Cir. 2010)). Taken out of context, this language might appear to suggest that the Seventh Circuit—which is not the reviewing court in this matter—applies a more stringent review to the district court's application of the *Daubert* standard to a particular expert's testimony. But in context, no such concern exists. When the Seventh Circuit reviews *de novo* whether the district court "correctly applied" or "properly followed" *Daubert*'s framework, all it is asking is if the district court analyzed whether the proposed testimony met Rule 702's requirements. *Id.*; *Schultz v. Akzo Nobel Paints, LLC*, 721 F.3d 426, 430 (7th Cir. 2013).

Any doubts are put to rest by the Seventh Circuit's recent explanation of its rule: "To apply the proper legal

standard, 'judges merely need to follow *Daubert* in making a Rule 702 determination.'" *Gopalratnam v. Hewlett-Packard Co.*, 877 F.3d 771, 782 (7th Cir. 2017) (quoting *Naeem v. McKesson Drug Co.*, 444 F.3d 593, 608 (7th Cir. 2006)). Put another way: the Seventh Circuit reviews *de novo* only whether "a *Daubert* analysis of some form in fact [was] performed." *Naeem*, 444 F.3d at 608 (internal citations omitted). That is not a high bar. It means only that a district court "must provide more than just conclusory statements of admissibility or inadmissibility to show that it adequately performed its gatekeeping function." *Gopalrantum,* 877 F.3d at 782 (quoting *Grayton*, 593 F.3d at 616). So, while a "one sentence admissibility determination that did not even reference *Daubert* by name" will fail under this standard, so long as a district court "'accurately outline[s] the *Daubert* framework' at the outset of its analysis" and reviews the relevant studies, it will suffice. *Id.* at 782—83. Ironically, this is precisely the standard the defendants advocated for at the rehearing stage in this case. GSK Pet. Reh'g En Banc 8 (quoting *Goebel v. Denver & Rio Grande W. R.R. Co.*, 346 F.3d 987, 989–90 (10th Cir. 2003) ("[W]e review de novo the question of whether the district court performed its gatekeeper role and applied the proper legal standard in admitting an expert's testimony.")).

3. Teva's theory that the Third, Seventh, and Ninth Circuits subvert *Daubert* by reversing lower court decisions based on mere "disagreement" is also contradicted by a broader canvas of the *Daubert* landscape. Just as in other circuits, courts in the Third, Seventh, and Ninth Circuits will not substitute their judgment for that of the district court when reviewing a district court's decision to admit or exclude a particular witness's testimony under *Daubert*. This is the case even if the appellate court would have come out the opposite way. *See*,

e.g., *Waldorf v. Shuta*, 142 F.3d 601, 627 (3d Cir. 1998) ("[W]hile we do not doubt that we would not have disturbed the court's ruling if it had excluded Rizzo as an expert witness, we cannot disturb the court's ruling qualifying him.")

And just last year, the Ninth Circuit—over vigorous dissent arguing that the district court should have been reversed—emphasized the deference it must afford a district court's *Daubert* rulings. *Murray v. S. Route Mar. SA*, 870 F.3d 915, 923 (9th Cir. 2017). "Because of the fluid and contextual nature of the inquiry, district courts are vested with 'broad latitude' to 'decid[e] *how* to test an expert's reliability' and '*whether or not* [an] expert's relevant testimony is reliable.'" *Id.* (alterations in original) (quoting *Kumho*, 526 U.S. at 152–53). Contrary to Teva's characterization, the Ninth Circuit reinforced the basic point: "[W]e owe the court's ruling 'the deference that is the hallmark of abuse-of-discretion review' and may not second-guess its sound judgments." *Id.* (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 141–43 (1997)).

The Seventh Circuit has said much the same thing. In a recent *Daubert* appeal, it colorfully recited its refrain that "[a]ppellants who challenge evidentiary rulings of the district court are like rich men who wish to enter the Kingdom: their prospects compare with those of camels who wish to pass through the eye of the needle." *Gopalratnam*, 877 F.3d at 782 (quoting *United States v. Walton*, 217 F.3d 443, 449 (7th Cir. 2000) and *United States v. Coleman*, 179 F.3d 1056, 1061 (7th Cir. 1999)). Teva may think that these courts reverse when they "simply disagree," but no fair reading of the decisions bears that out.

In contrast with these decisions (and there are dozens more), Teva only identifies this case, and a lone case from each of the other allegedly offending circuits that, it contends, proves that the governing standard is only "lip service." Pet. 21.[2] But these hand-picked cases do not disturb the settled approach that scores of decisions from all the circuits embrace. Teva emphasizes (at 21–25) that these panels—like the court here—concluded that the district court "erred." But that does not mean these circuits employ an improper standard. "Err" is a generic term—not a synonym for "*de novo*"—that certainly covers a district court's abuse of discretion. That Teva pins its alleged circuit split on such vague statements in a few isolated cases only underscores the weakness of its petition.

C. This case is an inappropriate vehicle because the panel did not apply a *de novo* standard.

Because Teva disagrees with the panel's assessment, it assumes the Ninth Circuit's review must have been too stringent. But the Ninth Circuit's decision here did not

---

[2] The petition also cites in a footnote Judge Sloviter's dissent in *Pure Earth, Inc. v. Call*, 531 F. App'x 256, 261–62 (3d Cir. 2013), to support its theory that the Third Circuit improperly applies *de novo* review of *Daubert* determinations. But dissenting judges across the circuits often accuse the court of applying too rigid a standard when they disagree with a decision to reverse. *See*, *e.g.*, *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 679 (6th Cir. 2010) (Martin, J. dissenting) ("Unfortunately, while paying lip service to the correct standard, the majority actually applies a de novo standard of review."); *United States v. Ala. Power Co.*, 730 F.3d 1278, 1291 (11th Cir. 2013) (Hodges, J., dissenting) ("[I]f this appeal involved error correction on *de novo* review, a reversal might well be the appropriate result."). Isolated dissents based on the individual circumstances of a given case do not demonstrate the need for certiorari review.

rest on *de novo* review, making this case a particularly inappropriate vehicle for review. In a discrete enumerated section of the opinion, the Ninth Circuit articulated the abuse-of-discretion standard, including the uncontroversial observation that such a standard includes *de novo* review for questions of legal interpretation. Pet. App. 6a. The petition seizes upon that basic recitation to argue that the panel applied a *de novo* standard to review the district court's application of the law to this particular testimony. Pet. 23. But nowhere in the panel's analysis does it purport to rely on plenary review power—or to invoke it, explain it, or otherwise give it content. Ultimately, then, Teva's request for review rests on a mischaracterization of the standard applied by the Ninth Circuit.

Rather than conduct *de novo* review, the Ninth Circuit specifically invoked the abuse-of-discretion standard in its analysis, holding that "the district court abused its discretion" by excluding the experts' testimony for failing to completely rule out the possibility that Maxx's HSTCL was idiopathic. Pet. App. 19a. It reviewed multiple facets of the district court's analysis and, given the number of serious flaws, it held that the district court exceeded its broad latitude in evaluating the expert testimony. Given the great deference afforded district courts, it may have been a "close question" whether the court abused its discretion. *Id.* 10a. But ultimately the Ninth Circuit concluded that, "all together," the "mistakes warrant reversal." *Id.* (citing to *Kennedy v. Collagen Corp.*, 161 F.3d 1226, 1228–30 (9th Cir. 1998) (applying abuse-of-discretion review)).

II. The Ninth Circuit does not allow highly qualified experts to testify unless they have applied a reliable methodology.

Attempting to manufacture a second split, Teva next claims that the Ninth Circuit departs from all other circuits in holding 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" and they can merely invoke "differential diagnosis" without reliably applying that methodology. Pet. 3. But that is not the Ninth Circuit's rule, in this case or any other.

A. The petition mischaracterizes the Ninth Circuit's law.

1. Contrary to Teva's assertion, the Ninth Circuit, like all other circuits, follows Rule 702 in requiring that every expert apply reliable methods, no matter how highly qualified. Indeed, Teva's co-defendant GSK acknowledged as much in its en banc petition. GSK Pet. Reh'g En Banc 11–13 (arguing that "Rule 702 cannot be satisfied by a stellar resume" and citing Judge Kozinski). And Teva did not even mention a split on this issue in its en banc petition. That is because the law is clear. In *Daubert* itself, after remand by this Court, the Ninth Circuit held that the expert's testimony was inadmissible because of its unreliable methodology, notwithstanding "the impressive qualifications of plaintiffs' experts." *Daubert*, 43 F.3d at 1315. As the Ninth Circuit made clear: "We've been presented with only the expert[']s qualifications, [his] conclusions and [his] assurances of reliability. Under *Daubert*, that's not enough." *Id.* at 1319.

Accordingly, in the Ninth Circuit, "[i]t is well settled that bare qualifications alone cannot establish the admis-

sibility of scientific expert testimony." *United States v. Hermanek*, 289 F.3d 1076, 1093 (9th Cir. 2002). In *Hermanek*, for example, the Circuit reversed the district court because it "relied solely on [the expert's] general qualifications without requiring the government to explain the method [the expert] used to arrive at his interpretations." *Id.* at 1094. Likewise, it has upheld district courts that have excluded testimony from experts explicitly deemed qualified, when the district court has found their methodology unreliable. *Ollier v. Sweetwater Union High Sch. Dist.*, 768 F.3d 843, 860 (9th Cir. 2014). *See also United States v. Decoud*, 456 F.3d 996, 1013 (9th Cir. 2006); *Domingo ex rel. Domingo v. T.K.*, 289 F.3d 600, 607 (9th Cir. 2002).

2. Teva further asserts that, in the Ninth Circuit, "merely invoking the name of a scientific method"—particularly differential diagnosis—satisfies *Daubert*'s reliability inquiry. Pet. 29. But again the en banc briefs tell a different story. GSK Pet. Reh'g En Banc 15 (under Ninth Circuit precedent, "the expert's differential diagnosis analysis must be reliable"). The Ninth Circuit has recognized that "[a] doctor using a differential diagnosis grounded in significant clinical experience and examination of medical records and literature can certainly aid the trier of fact and cannot be considered to be offering 'junk science.'" *Messick*, 747 F.3d at 1199. But, just as Teva argues is required in other circuits, the Ninth Circuit requires an expert employing differential diagnosis to use reliable methods in both "ruling in" and "ruling out" potential causes of a plaintiff's injury. Specifically, "[w]hen an expert rules out a potential cause in the course of a differential diagnosis, the 'expert must provide reasons for rejecting alternative hypotheses using scientific methods and procedures and the elimination of those hypotheses must be founded on more than

subjective beliefs or unsupported speculation.'" *Id.* at 1198 (quoting *Clausen,* 339 F.3d at 1058).

Plenty of cases illustrate the Ninth Circuit's application of these principles. *See*, *e.g.*, *Nelson v. Matrixx Initiatives, Inc.*, 592 F. App'x 591, 592 (9th Cir. 2015) (excluding testimony because district court "found that neither expert was able to provide a reliable method for ruling in Zicam, or ruling out age or the cold virus as the cause of Nelson's smell loss."); *Newkirk v. ConAgra Foods Inc.,* 438 F. App'x 607, 609 (9th Cir. 2011) (expert "could not rely on a differential diagnosis" because he could not reliably "rule in" defendant's product as cause of disease); *Whisnant v. United States*, 274 F. App'x 536, 537 (9th Cir. 2008) (excluding testimony because "the expert's differential diagnosis failed to account for possible alternate causes of the plaintiff's symptoms."). The Court should deny review on Teva's second question as well.

B. Teva's petition asks for error correction.

With no split in sight, Teva is left arguing that the Ninth Circuit departed from its own rules and reversed the district court's determination based on the qualifications of the experts alone. At most, that would be a claim for error correction, but it is wrong in any case.

The court acknowledged that the "experts were highly qualified doctors." Pet. App. 11a. But its analysis did not rest on those qualifications. It also stated that the "doctors employed sound methodologies to reach their conclusions," including relying on their review of the scientific literature, knowledge of epidemiology, clinical experience, and analysis of Maxx's medical records. *Id.* And the Ninth Circuit identified numerous flaws in the district court's analysis. Specifically, it emphasized that the district court only saw what the experts did not

have—independent research and animal studies—but ignored the experience, scientific literature, statistical analysis, medical records, and well-established decision-making procedures that the experts did rely upon. *Id.* 10a. The panel's review was not focused on expert qualifications alone, far from it: "all together," the district court's pervasive errors in judgment "warrant[ed] reversal." *Id.*

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

MATTHEW W.H. WESSLER
Counsel of Record
RACHEL BLOOMEKATZ
GUPTA WESSLER PLLC
1900 L Street, NW, Suite 312
Washington, DC 20036
(202) 888-1741
matt@guptawessler.com
rachel@guptawessler.com

ESTHER BEREZOFSKY
MICHAEL QUIRK
BEREZOFSKY LAW GROUP, LLC
Woodland Falls Corporate Ctr.
210 Lake Drive East, Suite 101
Cherry Hill, NJ 08002
(856) 667-0500

Counsel for Respondents

February 2, 2018