No. 17-747

IN THE
Supreme Court of the United States

TEVA PHARMACEUTICALS USA, INC.,
Petitioner,

v.

STEPHEN WENDELL, ET UX.,
Respondents.

On Petition For A Writ Of Certiorari To The United States Court of Appeals for the Ninth Circuit

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS AMICUS CURIAE IN SUPPORT OF PETITIONER

WARREN POSTMAN
MICHAEL B. SCHON
U.S. CHAMBER LITIGATION CENTER
1615 H Street, NW
Washington, DC 20062
(202) 463-5337

JOHN H. BEISNER
Counsel of Record
JESSICA D. MILLER
GEOFFREY M. WYATT
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
1440 New York Avenue, NW
Washington, DC 20005
(202) 371-7000
john.beisner@skadden.com

Attorneys for Amicus Curiae

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BRIEF BY THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS AMICUS CURIAE IN SUPPORT OF PETITIONER

The Chamber of Commerce of the United States of America ("Chamber") respectfully submits this brief as *amicus curiae* in support of petitioner Teva Pharmaceuticals USA, Inc.[1]

STATEMENT OF INTEREST

Amicus curiae the Chamber is the world's largest business federation, representing 300,000 direct members and indirectly representing the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every geographic region of the United States. An important function of the Chamber is to represent the interests of its members by participating as amicus curiae in cases involving issues of national concern to American business, such as this one.

The Chamber's members operate in nearly every industry and business sector in the United States. These members have an interest in vindicating bedrock principles of due process and ensuring that

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[1] Pursuant to Supreme Court Rule 37.6, counsel for *amicus curiae* state that no counsel for any party authored this brief in whole or in part, and no party or counsel for a party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae*, its members, or its counsel made a monetary contribution intended to fund the preparation or submission of this brief. Counsel of record for all parties received timely notice of the intent to file this brief and have granted consent.

defendants are afforded the opportunity to present every available defense in aggregate litigation.

The Chamber has a strong interest in this case because the decision of the U.S. Court of Appeals for the Ninth Circuit misunderstands the deference due to district courts under *Daubert* and erodes the gatekeeping function of district court judges. In so doing, the ruling threatens to promote abusive litigation premised on junk science, stifling innovation and raising the costs of important, sometimes life-saving consumer products.

INTRODUCTION

The petition raises important and recurring questions concerning a district court's gatekeeping function with respect to scientific evidence and the deference due by appellate courts to the exercise of that gatekeeping function – questions that have divided the federal courts of appeals.

In this case, the district court excluded two proposed experts after applying the familiar "*Daubert* test" for admissibility under Rule 702 of the Federal Rules of Evidence. Despite a scanty scientific record, the proposed experts sought to opine that the decedent's use of a specific combination of drugs ("6-MP" and "anti-TNF" drugs) to treat his inflammatory bowel disease ("IBD") caused him to develop an aggressive and extremely rare type of cancer called hepatosplenic T-cell lymphoma ("HSTCL"). The proposed experts claimed the ability to pinpoint the decedent's drug regimen as the most likely cause of his cancer, even though there is no established cause of HSTCL – indeed, in a significant majority of cases even proposed risk factors for the disease are not present. After briefing and a hearing, the district

court excluded these opinions as speculative and unscientific.

Even though the district court's conclusion was a product of the very "gatekeeping" function this Court described in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the Ninth Circuit reversed. It did so under the rubric of reviewing for legal error rather than for an abuse of discretion, abandoning the deference that this Court has described as the "hallmark" of appellate review of rulings on the admissibility of scientific evidence. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142-43 (1997).

The Ninth Circuit's decision should be reviewed and reversed for several reasons. For starters, the Ninth Circuit's decision to review the admissibility rulings without deference contradicted this Court's repeated statements that district courts' expert witness admissibility decisions are reviewed for an abuse of discretion. The Ninth Circuit's approach and the similar approaches taken by the Third and Seventh Circuits nominally apply abuse-of-discretion review to the ultimate decision whether to admit or exclude scientific evidence.[2] But as a practical matter, these frameworks leave no room for deference to district courts' admissibility decisions because the underlying reasoning is subjected to unrestrained de novo review. Such plenary review cannot be squared with this Court's central holding in *Joiner* and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999), which expressly called for deference not only to the

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[2] The petition describes in detail the Third and Seventh Circuit approaches and the broader conflict among the circuits on this issue. (See Pet. at 17-26.)

district court's ultimate conclusion but also to the reasoning it used to get there.

Moreover, the Ninth Circuit's decision is especially problematic because it essentially gave two expert witnesses a free pass to admissibility merely because it viewed them as highly qualified and they claimed to be applying recognized methodologies – i.e., the Bradford Hill criteria (used to assess whether a statistical association signifies a general causal relationship between an exposure and a disease) and differential diagnosis (used to assess whether a particular patient's illness was caused by an exposure with an established propensity to cause that illness). As explained below, these methodologies are notoriously prone to manipulation, underscoring the need for rigorous scrutiny by district courts exercising their gatekeeping function. But here, the Ninth Circuit did the opposite, essentially ordering the district court to give "experienced and credentialed doctors" a free pass when they invoke such methodologies and barring those courts from verifying that the experts have in fact faithfully applied them. That conclusion again squarely contradicts this Court's warning that expert testimony cannot be admitted based on the witness's "ipse dixit." *Joiner*, 522 U.S. at 146-47 (affirming exclusion where experts' opinions that exposure to PCBs contributed to the plaintiff's cancer were not supported by the studies on which the experts relied). It also departs from the more rigorous approach taken by some of the other federal courts of appeals.

Review is particularly important because the Ninth Circuit's approach is likely to expand tort liability in cases where causation is not scientifically supported. Indeed, courts and commentators have

repeatedly noted the critical impact of *Daubert*-stage rulings on the likelihood of tort liability. Absent rigorous review of weak science at the gatekeeping stage and proper deference to rulings excluding speculative and unsupported causal theories like those here, companies will face greater liability and fewer incentives to innovate. Accordingly, and as elaborated below, the Court should grant review and reverse.

ARGUMENT

I. The Court Should Grant Review To Confirm That A District Court's Exclusion Of Expert Evidence Under *Daubert* Is Reviewed For An Abuse Of Discretion.

The approaches to reviewing district court expert admissibility decisions taken in decisions by the Third, Seventh and Ninth Circuits are incompatible with this Court's instruction that "abuse of discretion is the proper standard by which to review a district court's decision to admit or exclude scientific evidence," and that the "hallmark of abuse-of-discretion review" is "deference." *Joiner*, 522 U.S. at 143, 146.

This Court has explained that a "trial judge must have *considerable leeway* in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Kumho Tire*, 526 U.S. at 152 (emphasis added). Importantly, a trial court enjoys "the same kind of latitude in deciding *how* to test an expert's reliability" as it "enjoys when it decides *whether or not* that expert's relevant testimony is reliable." *Id.* In other words, the abuse-of-discretion standard "applies *as much to the trial court's decisions about how to determine reliability as to its ultimate conclusion*." *Id.* (emphasis added).

These rulings leave no room for application of de novo review of a district court's admissibility determinations. Nonetheless, the Ninth Circuit departed sharply from these precedents by crafting a two-part standard that applies de novo review not only to the district court's "construction or interpretation of . . . the Federal Rules of Evidence," but also to the question "whether particular evidence falls within the scope of a given rule." *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1231 (9th Cir. 2017) (alteration in original) (citation omitted). The problem with these concepts is that they are sufficiently malleable to be stretched by an appellate court to couch practically any determination by the district court as one "construu[ing] or interpret[ing] . . . the Federal Rules of Evidence" or determining "whether particular evidence falls within the scope" of Rule 702. As such, the Ninth Circuit has crafted a standard that effectively eviscerates the deference owed to a district court's evaluation of the evidence.

The Ninth Circuit's decision here is a particularly egregious example of an appellate court employing an expansive conception of de novo review to bypass the deference required by *Joiner* and *Kumho Tire* and redo a *Daubert* analysis it merely disagreed with.

Most notably, in reversing the district court's decision to exclude the plaintiffs' experts, the Ninth Circuit held that the district court placed too "much weight on the fact that the experts' opinions were not developed independently of litigation and had not been published." *Wendell*, 858 F.3d at 1235. It also held that the district court improperly "required that the experts' opinions rely on animal or epidemiological studies" rather than case reports. *Id.* at 1236.

But determining how much "weight" to place on one of the "[m]any factors" this Court identified as guideposts in *Daubert* – which expressly included both "whether the theory or technique has been subjected to peer review and publication" and whether the theory "can be (and has been) tested" – is a critical part of the "flexible" gatekeeping role this Court assigned to district courts. 509 U.S. at 593-94. And as set forth in the petition, courts have repeatedly recognized that the degree to which case studies can support a causation opinion is a fact-intensive inquiry that should be left to a district court's discretion. (See Pet. at 22-23.) If essential factors of a *Daubert* analysis can be construed as legal questions concerning the application of Rule 702 or *Daubert*, then virtually every aspect of a district court's admissibility analysis can potentially be subject to de novo review.

In short, the bifurcated approach taken by the Ninth Circuit here and in decisions by the Third and Seventh Circuits is doctrinally out of step not only with the rule applied in other circuits but also with this Court's clear holdings. Moreover, from a practical perspective, the Ninth Circuit's approach is almost invariably likely to devolve into a wholesale de novo review of any given expert admissibility decision. The Court should grant the petition to clarify that there is no room for de novo review of district court *Daubert* analyses.

II. Review Is Necessary To Clarify That Expertise Is Not A License To Offer Unreliable And Results-Oriented Opinions.

The Court also should grant review because the Ninth Circuit essentially excused plaintiffs' experts'

unreliable methods based on its conclusion that the experts were highly qualified. According to the appellate court ruling, "*Daubert* poses no bar based on . . . principles and methodology" when experts who "stand at or near the top of their field and have extensive clinical experience" proffer causation opinions. *Wendell*, 858 F.3d at 1237. That holding is unambiguously at odds with this Court's precedents.

This Court long ago made clear that "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Joiner*, 522 U.S. 136, 146. Rather, the proponents of experts of every stripe, regardless of the bases of their opinions, must establish the "reliability and relevancy" of those opinions. *Kumho Tire*, 526 U.S. at 152. This Court has also cautioned against the dangers posed by the failure to adequately scrutinize the opinions of qualified experts, calling on district courts to "make certain that an expert . . . employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Id.* Indeed, it has suggested that the need for scrutiny *increases* along with the expert's credentials in light of the recognized danger that "'[e]xpert evidence can be both powerful and quite misleading because of the difficulty in evaluating it,'" *Daubert*, 509 U.S. at 595 (citation omitted) – a risk that is especially potent where an especially accomplished expert hopes to persuade a jury to ignore the infirmities in his or her opinion through appeals to credentials.[3]

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[3] For similar reasons, Justice Breyer acknowledged in his concurrence in *Joiner* that *Daubert* often requires "judges to

The Ninth Circuit's decision essentially requires district courts in that circuit to do the opposite of what this Court's precedents require by accepting the causation opinions of experts they deem to be highly qualified without scrutinizing the reliability of their methods.

Review of this erroneous approach is especially important because the particular expert methodologies at issue in this case – the Bradford Hill criteria and differential diagnosis – are frequently used in toxic tort cases to attempt to prove causation and are particularly prone to manipulation by savvy experts who seek to dress up a desired but unsubstantiated conclusion in the garb of scientific reasoning. See generally Joe G. Hollingsworth & Eric G. Lasker, *The Case Against Differential Diagnosis:* Daubert*, Medical Causation Testimony, and the Scientific Method*, 37 J. Health L. 85, 86 (2004) (explaining that "[t]oxic tort litigation . . . is the one area that has been most affected by" the introduction of the *Daubert* standard and describing the common use of differential diagnosis to prove causation in such cases).

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make subtle and sophisticated determinations about scientific methodology," but pointed out that district courts have a wealth of discretionary tools available to assist in such inquiries, including conducting *Daubert* hearings and enlisting the help of independent scientists. 522 U.S. at 147-50 (Breyer, J., concurring). He also made clear that the cases presenting the most complex science issues are those that most require rigorous *Daubert* inquiries, explaining that "neither the difficulty of the task nor any comparative lack of expertise can excuse the judge from exercising the 'gatekeeper' duties that the Federal Rules of Evidence impose," which "must be exercised with special care" in such cases. *Id.* at 148.

The reason these methods are prone to abuse is that they require expert assessment of multiple factors that can easily disguise subjective and speculative guesswork. Specifically, "[t]he Bradford Hill criteria are metrics that epidemiologists use to distinguish a causal connection from a mere association," *In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig.*, 858 F.3d 787, 795 (3d Cir. 2017) – and are often employed in the litigation context in attempts to prove general causation. These criteria "include strength of the association, consistency, specificity, temporality, coherence, biological gradient, plausibility, experimental evidence, and analogy."[4]

Scientists recognize that "[t]here is no formula or algorithm that can be used to assess whether a causal inference is appropriate based on these guidelines" and that applying them to infer causation from an association "requires judgment and searching analysis, based on biology, of why a factor or factors may be absent despite a causal relationship, and vice versa." *Reference Manual* at 600. As a result, an expert witness applying the Bradford Hill criteria "can theoretically assign the most weight to only a few factors, or draw conclusions about one factor based on a par-

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[4] "[S]trength of association" is a calculation of the increase (or decrease) in risk between exposure and disease as reported across epidemiological studies; "consistency" assesses whether different studies show an increased risk; "biological gradient" (or "dose-response relationship") assesses whether greater exposure to an agent increases risk; and "biological plausibility" examines whether there is a plausible biological mechanism through which the agent can cause the disease. See*, e.g.*, *Reference Manual on Scientific Evidence* ("*Reference Manual*") at 601-06 (3d ed. 2011); *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 592-93 (D.N.J. 2002), *aff'd*, 68 F. App'x 356 (3d Cir. 2003).

ticular combination of evidence." *Zoloft*, 858 F.3d at 796.

Differential diagnosis (or "differential etiology") is a distinct method that is often employed in the litigation context to try to prove specific causation. "A differential diagnosis seeks to identify the disease causing a patient's symptoms by ruling in all possible diseases and ruling out alternative diseases until (if all goes well) one arrives at the most likely cause." *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 674 (6th Cir. 2010). Like the Bradford Hill criteria, conducting a differential diagnosis involves scientific judgjudgment, and unless rigorously scrutinized, "expert witnesses can cross what is sometimes a fine line between differential diagnosis and pure guesswork" when ruling in or out potential causes as part of their analysis. 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, 250 (2006).[5]

The multifactorial and judgment-driven nature of the Bradford Hill and differential diagnosis method-

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[5] In many cases (like this one), the particular disease has no known cause or is "idiopathic," rendering the selection of potential causes inherently speculative and reliant on potentially irrelevant causal factors such as the mere fact that the plaintiff was exposed to the agent prior to developing the disease. See Schwartz & Silverman, *supra*, at 251 (explaining that many differential diagnoses performed in litigation "overemphasize temporal relationships, rather than focusing on causation established through the scientific method"); see also, *e.g.*, *Tamraz*, 620 F.3d at 670-71 (rejecting causation opinion of expert who opined via differential diagnosis that manganese exposure caused the plaintiff's idiopathic Parkinson's disease by making multiple analytical "leap[s] of faith" that ultimately resulted in a merely "plausible" causation "hypothesis").

ologies provides expert witnesses ample means to mask the precise sort of results-oriented causation opinions that *Daubert* is intended to exclude.[6] Experienced counsel are well aware that these methodologies sound impressive but are easily manipulated, and they often try "to take advantage of" courts' hesitancy to delve into the scientific weeds "by arguing that . . . courts should defer to the judgment of medical experts" who purport to apply such methods. Hollingsworth & Lasker, *supra*, at 86 (referring to differential diagnosis specifically). And because these experts almost invariably have "a preconceived assumption of causality" when they are retained to

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[6] The "weight of the evidence" methodology, discussed further below, is also sometimes used to attempt to prove general causation in toxic tort cases and is even less structured than the Bradford Hill criteria. It involves the assignment of different weights to different pieces of causation evidence. As one plaintiff's expert described it: "[T]he weight-of-the-evidence is sort of what it sounds like. . . . You have evidence and you need to weigh that evidence. Or give different weights to the various pieces of evidence. So, you know, you may count the animal studies for something, you may count this epi[demiological] study for something else, and this one for something else, and essentially what you're doing is you're putting together, you're trying to put together a picture of what you think is happening. It's like a jigsaw puzzle . . . . *People select different things in different ways, they put more weight on some, and they don't pay attention to other things and they come up with different pictures*." *Magistrini*, 180 F. Supp. 2d at 606. As the *Magistrini* court explained in excluding that expert's opinion for failing to explain why he relied on certain studies but ignored those that contradicted his opinion, "[i]n order to ensure that the 'weight-of-the-evidence' methodology is truly a methodology, rather than a mere conclusion-oriented selection process that weighs more heavily those studies that supported an outcome, there must be a scientific method of weighting that is used and explained." *Id.* at 607.

offer litigation opinions, allowing their analyses to escape real scrutiny by deferring to their qualifications results in biased and unreliable causation opinions reaching the jury. *Id.* at 99-100 (explaining that "differential diagnosis in a litigation context is often conducted in support of an already asserted legal claim of causation" with the result of the differential diagnosis "effectively preordained," and that "the plaintiff will not ordinarily present with obvious alternative causes of injury sufficient to shake the expert from" that assumption); see also Schwartz & Silverman, *supra*, at 251 (observing that causation opinions developed for trial by treating physicians "are likely to come 'more as an afterthought, in an ad hoc manner' and may fail to systematically consider and rule out alternative potential causes") (quoting *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1208 (8th Cir. 2000)).

Many courts have recognized these dangers and appropriately acknowledged that merely claiming to have applied an established framework such as the Bradford Hill criteria or differential diagnosis is not an "'incantation that opens the *Daubert* gate.'" *Tamraz*, 620 F.3d at 674 (citation omitted); see also, *e.g.*, *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1253 (11th Cir. 2005) ("[A]n expert does not establish the reliability of his techniques or the validity of his conclusions simply by claiming that he performed a differential diagnosis on a patient.").

For example, in *Zoloft*, the Third Circuit emphasized that "[f]lexible methodologies" such as Bradford Hill can be implemented in multiple ways" despite being "generally reliable" techniques in the abstract. 858 F.3d at 795. As a result, a district court's gatekeeping responsibility requires the court to ensure

"that the Bradford Hill/weight of the evidence criteria 'is truly a methodology, rather than a mere conclusion-oriented selection process'" by scrutinizing the expert's "specific techniques" under *Daubert* and requiring experts applying these methodologies to "explain 1) how conclusions are drawn for each Bradford Hill criterion and 2) how the criteria are weighed relative to one another." *Id.* at 796 (citation omitted).

The *Zoloft* court ultimately affirmed the exclusion of an expert whose Bradford Hill analysis relied on, *inter alia*, a "conclusion-driven" re-analysis of past studies, unreliable "ad hoc adjustments" to epidemiological data and an inconsistent consideration of statistically insignificant study results. *Id.* at 798-800. Other courts embracing an appropriately rigorous approach to gatekeeping have done the same where experts failed to demonstrate that their approaches adhered to scientific standards. See, *e.g.*, *Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 514 (W.D. Pa. 2003) (excluding expert witnesses whose "efforts to apply the Bradford Hill principles to the available evidence" were "not scientifically reliable" and granting summary judgment for defendant); *Magistrini*, 180 F. Supp. 2d at 604 (excluding Bradford Hill-based causation opinion where the expert "did not adequately explain his methods for assessing the[ir] internal validity"); see also, *e.g.*, *Dunn v. Sandoz Pharm. Corp.*, 275 F. Supp. 2d 672, 679 (M.D.N.C. 2003) (excluding expert whose "application of the Bradford Hill criteria does not satisfy the reliability prong of *Daubert*"); *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1046, 1049 n.5 (S.D. Ill. 2001) (excluding causation expert whose Bradford Hill analysis consisted largely of "curt conclusions making vast assumptions" and whose analysis appeared to be

an "afterthought" designed to justify the expert's conclusions).

All too often, however, courts have thrown their hands up in the face of complex scientific causation issues and – consistent with the Ninth Circuit's approach in this case – have either improperly admitted, or reversed the exclusion of, causation opinions of experts who purported to apply Bradford Hill and similar methodologies in deference to the experts' "judgment."

For example, in *Milward v. Acuity Specialty Products Group, Inc.*, 639 F.3d 11, 21-22 (1st Cir. 2011), the First Circuit reversed the district court's exclusion of an expert who opined via a weight-of-the-evidence analysis that exposure to benzene could cause the plaintiff's rare type of leukemia, despite acknowledging that there was no direct scientific evidence supporting causation. In so doing, the First Circuit permitted the expert to amalgamate different pieces of evidence to generate a causation hypothesis through a concededly unscientific weighing process, even though the causal connection provided by each piece of evidence was tenuous at best, as the district court there perceived.

Commentators have widely recognized the *Milward* court's approach, recognizing that it is difficult to square with this Court's instruction in *Joiner* that courts should scrutinize experts' scientific evidence and not blindly accept their conclusions. See, *e.g.*, David E. Bernstein, *The Misbegotten Judicial Resistance to the* Daubert *Revolution*, 89 Notre Dame L. Rev. 27, 58 (2013) (explaining that *Joiner* scrutinized the "experts' evidence in exactly the way the *Milward* court said was forbidden, that is, by . . . looking at

each study relied on by the experts to see if it could support causation testimony," and observing that "*Milward* utterly fails to explain how its holding is consistent with *Joiner*"); David E. Bernstein & Eric G. Lasker, *Defending* Daubert*: It's Time to Amend Federal Rule of Evidence 702*, 57 Wm. & Mary L. Rev. 1, 41 (2015) ("The First Circuit's admission of this 'weight of the evidence' testimony blatantly disregarded *Daubert's* admonition that expert testimony must be derived by the scientific method . . . . Although a trial court may – as the district court did in *Milward* and the Supreme Court did in *Joiner* – review individual lines of scientific evidence to determine whether they meet this admissibility threshold, there is no way for a court to so evaluate the 'weight of the evidence' approach followed by the *Milward* expert."). The ruling in *Milward* is especially problematic because, like the Ninth Circuit's decision here, it involved the judgment of an appellate court on a cold record, overruling the carefully reasoned exclusion of a district court that had more intimate knowledge of the scientific record and the particular expert's methodology.[7]

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[7] *Milward* is just one example of a court improperly deferring to an expert's application of a subjective causation methodology. See also, *e.g.*, *McClain*, 401 F.3d at 1237, 1253 (reversing where district court permitted experts to testify that an herbal weight-loss supplement caused heart attacks and strokes in part because district court believed it "lacked sufficient knowledge on the scientific subject matter to exclude the testimony"; expert's differential diagnosis failed to satisfy *Daubert* because there was no scientific basis to rule the supplement in as a potential cause, and "[i]n the absence of such a foundation for a differential diagnosis analysis, a differential diagnosis generally may not serve as a reliable basis for an expert opinion on causation in a toxic tort case").

This Court should grant certiorari to make clear that the approach to admissibility of complex causation opinions taken in cases such as *Milward* and the similar one advanced by the Ninth Circuit here are impermissible under *Daubert*. In so doing, the Court should confirm the clear message of its prior cases – that courts *must* delve into the scientific weeds, *especially* when doing so is difficult. By refusing to scrutinize expert opinions when experts "stand at or near the top of their field" (or at least appear to do so based on a cold appellate record), *Wendell*, 858 F.3d at 1237, the Ninth Circuit contravened this Court's clear instructions regarding the fundamental gatekeeping responsibilities imposed by *Daubert*.

III. The Ninth Circuit's Approach Lowers The Bar To Junk Science And Invites Abusive Litigation.

Finally, the Court should grant review because of the substantial harm invited by the Ninth Circuit's decision. Left unchecked, the Ninth Circuit's approach will invite litigation based on speculative theories of liability, greatly expanding litigation costs, which in turn will stifle innovation and increase the costs of important consumer products, both in the context of potentially life-saving prescription drugs and beyond.

There is no question that the Ninth Circuit's approach will lower the bar for the admission of expert evidence. Indeed, there is evidence that this consequence has already been realized. In one post-*Wendell* case, a Ninth Circuit district court refused to scrutinize whether an expert had cherry-picked favorable studies in developing her opinion that Fitbit devices do not accurately track sleep data. See

Brickman v. Fitbit, Inc., No. 3:15-CV-02077-JD, 2017 WL 6209307, at *3-4 (N.D. Cal. Dec. 8, 2017). Despite acknowledging that the expert's "quite concise" report did not "treat the studies in detail," the court held that it was sufficient that the expert "reviewed and evaluated" the studies she cited and that her opinions had "indicia of reliability and validity." *Id.* at *4. Relying on *Wendell* – and providing little in the way of additional analysis – the court concluded that the expert's opinions were "'not the "junk science" Rule 702 was meant to exclude'" and denied the defendant's motion to strike her testimony. *Id.* (citing *Wendell*, 858 F.3d at 1237).

The implications of this development are troubling because, as a practical matter, many such cases – including those sounding in product liability, toxic tort and intellectual property, among others – "are won or lost on the strength of the scientific evidence presented to prove causation." *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1197 (11th Cir. 2002) (referring to toxic-tort cases particularly). As noted above, jurors faced with "a barrage of questionable scientific evidence" from an impressively credentialed expert are likely to "be awestruck by the expert's mystique" and to blindly accept his or her opinions. *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1310 (11th Cir. 1999); see also, *e.g.*, *Werth v. Hill-Rom, Inc.*, 856 F. Supp. 2d 1051, 1067 (D. Minn. 2012) (explaining that given the plaintiff's experts' "impressive credentials, including two with doctorate degrees from Stanford University and a third who is a former NASA scientist . . . . it is not difficult to conceive that a jury would blindly accept Plaintiffs' causation theory while overlooking the shaky foundation upon which it rests"); see also generally Joseph M. Price &

Gretchen Gates Kelly, *Junk Science in the Courtroom: Causes, Effects and Controls*, 19 Hamline L. Rev. 395, 397 (1996) (discussing the "'aura of infallibility'" that jurors often perceive experts to have and collecting cases recognizing that jurors are generally unable to evaluate whether scientific testimony is reliable, which can lead them to blindly accept dubious expert theories and be required to "decide between two equally incomprehensible scientific theories"; further noting that this circumstance can lead jurors to "simply disregard both [sides' scientific theories] and decide the case based upon other factors").

Allowing experts to press unfounded causation theories merely because they appear highly qualified accordingly presents a grave threat to product manufacturers, ultimately hurting consumers. As commentators have repeatedly observed, "[v]erdicts based upon unreliable scientific evidence ultimately limit the number of products available to the American consumer and result in safe, valuable products being pulled off the market." Price & Kelly, *supra*, at 398; Schwartz & Silverman, *supra*, at 225 (explaining that "admitting unreliable expert testimony can unjustly harm a defendant where its product or conduct was not the cause of the plaintiff's injury" and "unnecessarily raises the cost and sometimes the availability of good products and services").

Indeed, abusive mass tort litigation has caused products that were later proven safe to be withdrawn from the market and needlessly bankrupted manufacturers whose products turned out not to be dangerous. See Schwartz & Silverman, *supra*, at 225-26 (discussing the 1983 withdrawal of Bendectin resulting from litigation theories that were later "thoroughly discredited" and Dow Corning's 1995

bankruptcy following heavy litigation over silicone breast implants, when ultimately "no link was found between implants and autoimmune disorders, cancer, or any other serious disease"); Price & Kelly, *supra*, at 398-99 (discussing these and additional examples, including extensive litigation (brought by the same lawyers responsible for frivolous breast implant litigation) faced by the manufacturer of a contraceptive device that was widely approved and endorsed by medical authorities).

Perhaps most concerning, tort litigation premised on junk science stifles innovation because it disincentives manufacturers from developing new and potentially life-saving drugs and medical devices when there is a risk that such development will subject the manufacturers to backbreaking tort liability. See Price & Kelly, *supra*, at 399-400 (discussing a Health Industry Manufacturers Association survey finding "a pervasive 'fear of exposure to costly, possibly catastrophic lawsuits in an extremely litigious area' among suppliers of raw materials used in medical devices," and observing that "the foothold junk science has gained in American courtrooms[] results in a shortage of materials for use in medical implants, a potential inability to meet patient needs and a loss of global competitiveness for U.S. medical manufacturers"; further noting that fear of product liability litigation forced the manufacturer of an AIDS vaccine to cease conducting trials of the vaccine).

Justice Breyer recognized these concerns in *Joiner*, where he explained that "modern life, including good health as well as economic well-being, depends upon the use of artificial or manufactured substances, such as chemicals," and that it is thus "particularly important to see that judges fulfill their

Daubert gatekeeping function, so that they help assure that the powerful engine of tort liability, which can generate strong financial incentives to reduce, or to eliminate, production, points toward the right substances and does not destroy the wrong ones." 522 U.S. at 148-49 (Breyer, J. concurring).

The Ninth Circuit's approach raises these precise concerns. By lowering the bar to junk science (as long as it is peddled by ostensibly "top" experts), the Ninth Circuit's ruling invites an expansion of abusive litigation against manufacturers based on speculative and unsubstantiated theories. The Court should grant review to help ensure that the Ninth Circuit's decision does not lead to a proliferation of dubious causation theories that escape *Daubert* scrutiny and needlessly harm product manufacturers and consumers.

CONCLUSION

For the foregoing reasons, and those stated by Petitioners, the Court should grant the petition for a writ of certiorari.

Respectfully submitted,

WARREN POSTMAN
MICHAEL B. SCHON
U.S. CHAMBER
LITIGATION CENTER
1615 H Street, NW
Washington, DC 20062
(202) 463-5337

JOHN H. BEISNER
Counsel of Record
JESSICA D. MILLER
GEOFFREY M. WYATT
SKADDEN, ARPS,
SLATE, MEAGHER
& FLOM LLP
1440 New York
Avenue, NW
Washington, DC 20005
(202) 371-7000
john.beisner@skadden.com

Attorneys for Amicus Curiae

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