No. 21-241

IN THE

Supreme Court of the United States

MONSANTO COMPANY,

Petitioner,

v.

EDWIN HARDEMAN,

Respondent.

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

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

CORY L. ANDREWS
JOHN M. MASSLON II
WASHINGTON LEGAL FOUNDATION
2009 Mass. Ave., NW
Washington, DC 20036

MATTHEW P. STEINBERG
DECHERT LLP
1095 Ave. of the Americas
New York, NY 10036

JONATHAN S. TAM
Counsel of Record
DECHERT LLP
1 Bush St #1600
San Francisco, CA 94104
(646) 731-6172
jonathan.tam@dechert.com

QUESTION PRESENTED

Amicus curiae addresses the second question presented by the Petitioner:

> Whether the Ninth Circuit's standard for admitting expert testimony—which departs from other circuits' standards—is inconsistent with this Court's precedent and Federal Rule of Evidence 702.

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INTEREST OF *AMICUS CURIAE*[*]

Washington Legal Foundation is a nonprofit, public-interest law firm and policy center with supporters nationwide. WLF promotes free enterprise, individual rights, limited government, and the rule of law. To that end, WLF often appears as *amicus curiae* in critical cases to argue that courts should exclude any expert opinion that lacks reliability. *See, e.g.*, *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999); *Gen. Elec. Co. v. Joiner*, 522 U.S. 136 (1997); *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993).

WLF's Legal Studies Division, the publishing arm of WLF, regularly produces articles by outside experts on the need to ensure reliable expert testimony in federal court. *See, e.g.*, Lee Mickus & Abigail Dodd, *Stop Calling Them "*Daubert *Motions": Federal Rule of Evidence 702 and Why Words Matter*, WLF Working Paper (Aug. 2021); Kirby T. Griffis, *The Role of Statistical Significance in* Daubert*/Rule 702 Hearings*, WLF Working Paper (Mar. 2017).

WLF believes that scientifically unreliable evidence is akin to no evidence at all. The quality of decision-making in federal court thus hinges on the ability and willingness of federal judges to prevent unreliable "scientific" expert evidence from ever

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[*] No counsel for any party has authored this brief in whole or in part. No person, other than *amicus* or its counsel, made a monetary contribution to the preparation or submission of this brief. All parties received timely notice of *amicus*'s intent to file this brief under Rule 37.2(a) and have consented to the filing of this brief.

reaching the factfinder. Unless this Court intervenes to arrest the Ninth Circuit's pattern of excusing trial court judges from their gatekeeping duty under Federal Rule of Evidence 702, the judiciary's ability to produce fair and just results will be eroded.

SUMMARY OF ARGUMENT

The Petition raises a recurring issue of exceptional importance: the Ninth Circuit's longstanding and erroneous permissiveness in admitting unreliable expert testimony on causation. In this case and many others, the Ninth Circuit has allowed or even compelled district courts to abdicate their gatekeeping duty that requires them to ensure unreliable expert evidence never reaches the jury. The Ninth Circuit has, time and again, allowed experts to pay mere lip service to a reliable methodology for assessing causation in products liability cases. But an expert's appeal to "clinical experience" and invocation of a reliable causation methodology is not enough.

The expert below employed a differential diagnosis (or rather, a differential etiology), a generally accepted method for assessing causation in an individual. Rule 702 requires not only that an expert employ a reliable method, but also that it be "*reliably applied* . . . to the facts of the case." Fed. R. Evid. 702(d) (emphasis added). At least six circuits rigorously evaluate the application of that method; simply invoking it "is not some incantation that opens the *Daubert* gate." *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 674 (6th Cir. 2010).

Not so in the Ninth Circuit. The decision below is the most recent in a long line of Ninth Circuit opinions that give wide berth to medical causation experts who say they have performed a differential etiology but have failed to do so reliably. These decisions continue to invite speculation cloaked in science into the thousands of product liability cases in the Ninth Circuit, including those in the *Roundup* Multi-District Litigation. The split on this question is now both well-developed and lopsided. This Court should grant review to enforce the reliable application requirement of Rule 702 and to bring the Ninth Circuit in line with its sister circuits.

REASONS FOR GRANTING CERTIORARI

The Petition ably details how the Ninth Circuit's standard for admitting expert testimony departs from the standards of its sister circuits; WLF agrees that this issue warrants this Court's review. *See* Pet. 28–32. In this brief, WLF focuses on the specific application of that standard to products liability cases, where specific causation—whether the product caused the alleged harm in a given invididual—is an essential element of the plaintiffs' claims. In such cases, plaintiffs' experts commonly employ a differential etiology as evidence of specific causation. The decision below allowed expert testimony that invoked differential etiology, but it failed to scrutinize whether that method was reliably applied by the experts. And on that narrow question, Ninth Circuit law is in even more striking conflict with its sister circuits, at least six of which have insisted on the reliable application requirement for differential etiology. This conflict is well-established: the Ninth Circuit has staked out its

outlier position over the course of four decisions, in sharp contrast to other circuits that have considered the question. This Court should grant review to resolve that conflict.

I. THE NINTH CIRCUIT HAS LONG IGNORED RULE 702'S "RELIABLE APPLICATION" REQUIREMENT.

The Ninth Circuit decision below deferred to experts who offered causation opinions purporting to apply what they called a "differential diagnosis" but was in fact a differential etiology. Though many judicial decisions—including the decision below—use the terms "differential diagnosis" and "differential etiology" synonymously, the terms technically pertain to two distinct methodologies. A differential diagnosis identifies what a particular ailment is, while a differential etiology identifies its cause. *See* Pet. App. 80a n.2; *Myers v. Illinois Cent. R.R. Co.*, 629 F.3d 639, 644 (7th Cir. 2010). Specifically, "in a differential etiology, the doctor rules in all the potential causes of a patient's ailment and then by systematically ruling out causes that would not apply to the patient, the physician arrives at what is the likely cause of the ailment." *Myers*, 629 F.3d at 644; *accord* Michael D. Green et al., *Reference Guide on Epidemiology*, *in* Fed. Jud. Ctr., Reference Manual on Scientific Evidence 549, 617 & n.211 (3d ed. 2011).

The erroneous deference in the decision below to an expert's subjective application of the differential etiology method follows naturally from a line of Ninth Circuit precedent. In a series of decisions, the Ninth Circuit has disregarded Rule 702 by according undue deference to an expert's qualifications and clinical

experience and giving a pass on the reliability of the expert's application of their methodology. *See, e.g.*, *Primiano v. Cook*, 598 F.3d 558, 567 (9th Cir. 2010); *Hopkins v. Dow Corning Corp.*, 33 F.3d 1116, 1124–25 (9th Cir. 1994). It has extended this deference to experts who purport to apply a differential etiology. That deference gives short shrift to the judicial gatekeeping role and has allowed—or even encouraged—district courts to admit unreliable expert evidence. As the district court here observed, under Ninth Circuit precedent it "must be more tolerant of borderline expert opinions" with shaky scientific support "than [district courts] in other circuits." *See* Pet. App. 84a. This Court should grant review to correct the Ninth Circuit's persistent error.

The Ninth Circuit's decision in *Messick v. Novartis Pharms. Corp.* exemplifies its improper deference to causation experts who purport to apply a differential etiology. 747 F.3d 1193 (9th Cir. 2014). There, the district court excluded an expert who admitted there was *no* "scientifically reliable way" to rule out whether five other risk factors could have caused the plaintiff's injury. *Messick v. Novartis Pharms. Corp.*, 924 F. Supp. 2d 1099, 1105 (N.D. Cal. 2013). That concession doomed the admission of the expert's opinion. But the Ninth Circuit resurrected it, emphasizing that the expert "repeatedly referred to his own extensive clinical experience as the basis for his differential diagnosis." 747 F.3d at 1197–99 (relying in part upon *Primiano*, 598 F.3d at 567). The Ninth Circuit also gave undue deference to the expert's clinical experience and subjective judgment because "[m]edicine partakes of *art* as well as science." *Id.* at 1198 (emphasis added). An appeal to "art" invites a

standardless assessment of causation in violation of Rule 702 and invites *ipse dixit* to substitute for science. *Joiner*, 522 U.S. at 146.

A few months after *Messick*, another Ninth Circuit panel affirmed the admission of differential-etiology opinions by medical experts who found that the plaintiff's symptoms "fit with" the medical literature. *Murray v. S. Route Mar. SA*, 870 F.3d 915, 925–26 (9th Cir. 2017). The Ninth Circuit never addressed whether the medical experts reliably ruled out other potential causes, let alone analyzed the question. *See id.* Instead, citing *Messick*, it simply echoed the medical experts' finding that the plaintiff's symptoms "were not pre-existing or unrelated" to the event in question, and opened the gates. *See id.* But Rule 702 "requires more than simply 'taking the expert's word for it.'" Fed. R. Evid. 702 advisory committee's note to 2000 amendments.

And then again, in *Wendell v. GlaxoSmithKline LLC*, the Ninth Circuit reversed the exclusion of experts who claimed they performed differential etiologies. 858 F.3d 1227, 1236–37 (9th Cir. 2017). The Ninth Circuit emphasized the experts' credentials and experience throughout its analysis, repeatedly citing them in answer to any question about the reliability of the experts' findings. *See id.* at 1235–38. The Ninth Circuit acknowledged the limits of the science surrounding the plaintiff's "exceedingly rare"—and often idiopathic—injury, but it assumed that future studies would "eventually show the connection" with the defendant's product. *See id.* at 1236–37. Though expert testimony must be based on "good grounds" and "what is known," *Daubert*, 509 U.S. at 590, the Ninth

Circuit again deferred to credentials and invocation of reliable methods: "the most experienced and credentialed doctors in a given field," it said, ought not "be barred from testifying based on a differential diagnosis," *Wendell*, 858 F.3d at 1235–38. This failed "dramatically to employ scientific reasoning" as required by Rule 702 and *Daubert*. David L. Faigman & Jennifer Mnookin, *The Curious Case of* Wendell v. GlaxoSmithKline LLC, 48 Seton Hall L. Rev. 607, 608, 615–17 (2018).

II. THE DECISION BELOW PERPETUATES THE NINTH CIRCUIT'S ERRONEOUS RULE 702 PRECEDENTS.

Just as in these prior decisions, the Ninth Circuit's decision here erroneously deferred to experts invoking differential etiology and their clinical experience in lieu of evaluating whether they reliably applied this methodology. In particular, the Ninth Circuit failed to adequately analyze whether the Respondent's specific causation experts reliably ruled out other potential causes of his non-Hodgkin's lymphoma ("NHL").

The scientific reality is that "[a]pproximately 70% or more of NHL cases are idiopathic, meaning they develop for unknown reasons." Pet. App. 7a. And there is not any "biomarker or genetic signature" to show NHL is caused by Roundup. *Id.* at 83a. The district court noted that, "under a strict interpretation of *Daubert*, perhaps [this] would be the end of the line" for the Respondent's experts, but "the Ninth Circuit's recent decisions reflect a view that district courts should typically admit specific causation opinions that lean strongly toward the 'art' side of the spectrum," such as ruling out idiopathy. *Id.* at 83a–84a (citing

Messick, 747 F.3d at 1198 and *Wendell*, 858 F.3d at 1237). The district court accordingly allowed the experts to testify on specific causation. *Id.* at 85a.

The Ninth Circuit affirmed. It relied on *Wendell*, which held that causation experts may reliably rule out idiopathy for a disease with a 70% idiopathy rate based largely on their "clinical experience." *Id.* at 36a (citing *Wendell*, 858 F.3d at 1233–34). And, citing *Messick*, it purported to distinguish the decisions of other circuits that have rejected differential etiology opinions because the experts excluded there did not rely on their "extensive clinical experience." *See id.* at 24a (discussing *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig.*, 892 F.3d 624 (4th Cir. 2018) and *Tamraz*, 620 F.3d 665). But a subjective appeal to "wealth of experience," *see id.* at 25a, is just as much an unscientific *ipse dixit* as the opinions the other courts of appeals have rejected. Moreover, "[w]hen the causes of a disease are largely unknown . . . differential etiology is of little assistance," since it is not possible to reliably rule out other causes. Restatement (Third) of Torts: Liab. for Physical and Emotional Harm § 28 cmt. c(4) (Am. L. Inst. 2010).

The decision below is thus a natural outgrowth of the Ninth Circuit's repeated error of deferring to mere invocations of clinical experience and differential etiology. It confirms that the error of *Messick* and *Wendell* is now entrenched in the Ninth Circuit. And this latest manifestation of this longstanding error—which could impact thousands of cases—presents the Court an ideal vehicle to grant review. This Court should grant review and reverse to ensure that in the

Ninth Circuit, as in other circuits, expert methods must be both reliable and reliably applied.

III. THE NINTH CIRCUIT'S RULE 702 PRECEDENTS CONFLICT WITH SIX OTHER CIRCUITS.

The Ninth Circuit has long been an outlier in giving a pass to invocations of subjective clinical experience and the differential etiology method. The other courts of appeals have hewed more closely to Rule 702's demand for reliability—both in method and in application. They have made clear that reliability remains a "distinct concept[]" from qualification, and "the courts must take care not to conflate them." *United States v. Frazier*, 387 F.3d 1244, 1260–61 (11th Cir. 2004) (en banc). They likewise appreciate that the results of a differential etiology are "far from reliable *per se*." *Johnson v. Arkema, Inc.*, 685 F.3d 452, 468 (5th Cir. 2012). Merely "[c]alling something a 'differential diagnosis' or 'differential etiology' does not by itself answer the reliability question." *Tamraz*, 620 F.3d at 674; *accord McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1253 (11th Cir. 2005).

Rather, invocation of differential etiology prompts three more questions:

> (1) Did the expert accurately diagnose the nature of the alleged injury?
>
> (2) Did the expert reliably rule in all possible causes of the alleged injury?
>
> (3) Did the expert reliably rule out the rejected causes?

If a court answers "no" to any of these questions, it must exclude the expert's opinion. *See Pluck v. BP Oil Pipeline Co.*, 640 F.3d 671, 678 (6th Cir. 2011); *accord Huerta v. BioScrip Pharmacy Servs.*, 429 F. App'x. 768, 773 (10th Cir. 2011); *Guinn v. AstraZeneca Pharms. LP*, 602 F.3d 1245, 1253 (11th Cir. 2010). This holds true for even the most well-qualified expert: "at all times the district court must still determine the reliability of the opinion, not merely the qualifications of the expert who offers it." *Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1336 (11th Cir. 2010). This approach to scrutinizing the application of differential etiology—and not merely the expert's qualifications and judgment—is shared by at least six other courts of appeals. In particular, these courts have rejected differential etiology opinions when, as here, the expert had no basis to rule out the possibility of an idiopathic cause or another risk factor could have caused the alleged harm:

- **Fourth Circuit:** In *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig.*, the Fourth Circuit analyzed the expert's differential etiology, reasoning, and whether her deposition testimony corroborated her reasoning. 892 F.3d at 643–45. Noting that "simply calling an analysis a differential diagnosis doesn't make it so," the Fourth Circuit found that the expert's dismissal of other potential causes "in a cursory fashion . . . appeared closer to an *ipse dixit* than a reasoned scientific analysis." *See id.* The Fourth Circuit did not give the expert a pass because she had "impressive credentials," *see In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. &*

Prods. Liab. Litig., 150 F. Supp. 3d 644, 651 (D.S.C. 2015); instead, it affirmed the exclusion of her testimony, *see* 892 F.3d at 649; *see also Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 200–03 (4th Cir. 2001).

- **Eleventh Circuit:** In *Guinn*, the Eleventh Circuit analyzed the expert's differential etiology and its individual components, including the expert's review of the plaintiff's medical records. 602 F.3d at 1253–56. Because the expert had neither reliably ruled in her proffered cause nor reliably ruled out other potential causes, and also because she had not reviewed the plaintiff's medical records with the same rigor that she would have outside the courtroom, the Eleventh Circuit affirmed the exclusion of the expert's testimony. *Id.*; *see also Hendrix ex rel. G.P. v. Evenflo Co., Inc.*, 609 F.3d 1183, 1196–1204 (11th Cir. 2010). Likewise, in *Chapman v. Procter & Gamble Distrib., LLC*, the Eleventh Circuit excluded the plaintiff's specific causation expert for similar reasons, and also because the expert omitted any consideration of idiopathic causes from his analysis. 766 F.3d 1296, 1309–11 (11th Cir. 2014). The Eleventh Circuit reaffirmed its holding in *Guinn* that "[a]n expert's failure to enumerate a comprehensive list of alternative causes and to eliminate those potential causes" mandates the exclusion of their specific-causation testimony. *Id.* at 1310 (citing *Guinn*, 602 F.3d at 1254). It also reaffirmed that "[t]he failure to take into account the potential for idiopathically occurring [disease]—particularly

when [the disease] is a relatively new phenomenon in need of further study—place[s] the reliability of [the expert's] conclusions" in doubt. *Id.* at 1311 (quoting *Kilpatrick*, 613 F.3d at 1342).

- **Seventh Circuit:** In *Brown v. Burlington N. Santa Fe Ry. Co.*, the Seventh Circuit analyzed whether the expert's differential etiology deviated from recognized scientific practices and the expert's own stated procedures. 765 F.3d 765, 772–75 (7th Cir. 2014). As a result, the Seventh Circuit found that the expert failed to meaningfully investigate—and reliably rule out—other potential causes of the plaintiff's injury. *Id.* Though the plaintiff "wishe[d] to use [the expert's] quarter-century of experience in the field to rule out other potential causes," the Seventh Circuit held that "experience without reliable, testable methodology is not sufficient." *Id.* at 776.

- **Eighth Circuit:** In *Bland v. Verizon Wireless, (VAW) LLC*, the Eighth Circuit rigorously analyzed each step of the expert's differential etiology—including whether she investigated or searched for other possible causes and whether she possessed the requisite data and knowledge to reach her conclusion without "too great [of] an analytical gap." 538 F.3d 893, 897–99 (8th Cir. 2008) (quoting *Joiner*, 522 U.S. at 146). Because the expert failed to investigate other possible causes of the plaintiff's alleged injury—and because most cases of the plaintiff's alleged injury were idiopathic (had "no known

cause")—the Eighth Circuit properly affirmed the exclusion of the expert's opinion. *See id.*

- **Tenth Circuit:** In *Norris v. Baxter Healthcare Corp.*, the Tenth Circuit analyzed whether the plaintiff's experts had reliably applied the differential etiology method. 397 F.3d 878, 885–88 (10th Cir. 2005). After scrutinizing the underlying medical literature, the Tenth Circuit found it did not support the experts' opinions. *Id.* So the Tenth Circuit affirmed their exclusion: "We cannot allow [a] jury to speculate based on an expert's opinion which [in effect] relies only on clinical experience." *Id.* at 887–88; *see also Graves v. Mazda Motor Corp.*, 405 F. App'x 296, 299–300 (10th Cir. 2010); *Dodge v. Cotter Corp.*, 328 F.3d 1212, 1227 (10th Cir. 2003). And in *Hall v. Conoco Inc.*, the Tenth Circuit affirmed the exclusion of expert opinion based on unreliable differential etiology, primarily due to the expert's failure to reliably rule out idiopathic causes of "more than half of the cases" of plaintiff's ailment. 886 F.3d 1308, 1315 (10th Cir. 2018).

- **Sixth Circuit:** In *Tamraz*, the Sixth Circuit scrutinized an expert's differential etiology opinion to determine whether it met all three prongs of the reliability test outlined above. 620 F.3d at 674–76. The Sixth Circuit noted that "unknown (idiopathic) causation" accounted for "the vast majority" of cases of the plaintiff's alleged ailment, "making it impossible to ignore and difficult to rule out." *Id.* at 675. After independently reviewing the medical literature

> and finding no concrete support for the expert's conclusion, the Sixth Circuit held that the expert's "speculative" methodology and conclusion were too unreliable to satisfy Rule 702 and should have been excluded. *Id.* at 672, 674–76, 678.

These decisions all recognize that under Rule 702, "[t]he trial court's gatekeeping function requires more than simply 'taking the expert's word for it.'" Fed. R. Evid. 702 advisory committee's note to 2000 amendments. Simply put, "not everything a knowledgeable person says is 'knowledge' under Rule 702, no more than everything a scientist says is 'scientific.'" *Tamraz*, 620 F.3d at 677. Thus, a "district court judge asked to admit scientific evidence must determine whether the evidence is genuinely scientific, as distinct from being . . . speculation offered by a genuine scientist." *Id.* (quoting *Rosen v. Ciba-Giegy Corp.*, 78 F.3d 316, 318 (7th Cir. 1996)). These other circuits correctly hold that "an expert must do more than just state that she is applying a respected methodology; she must follow through with it." *Brown*, 765 F.3d at 773; *see also In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 796–97 (3d Cir. 2017) (affirming the exclusion of an expert who "did not . . . reliably apply" methods that "are themselves reliable").

Rule 702 imposes "exacting standards of reliability," *Weisgram v. Marley Co.*, 528 U.S. 440, 455 (2000), and courts must "ensure that the courtroom door remains closed to junk science," *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 267 (2d Cir. 2002). It is therefore "vital . . . that judges not be

deceived by the assertions of experts who offer credentials rather than analysis." *Minasian v. Standard Chartered Bank, PLC*, 109 F.3d 1212, 1216 (7th Cir. 1997). To that end, "close judicial analysis of expert testimony is necessary," *Nelson v. Tennessee Gas Pipeline Co.*, 243 F.3d 244, 252 (6th Cir. 2001), and courts must ensure that they "'inspect the reasoning of qualified scientific experts,'" *Rodriguez v. Stryker Corp.*, 680 F.3d 568, 572 (6th Cir. 2012) (citation omitted).

Here, the Ninth Circuit's continued practice of permitting an expert's credentials to stand in for the reliable application of a reliable method contradicts Rule 702 and potentially impacts thousands of cases. Because the scientific data do not show that Roundup causes NHL or that Roundup caused the Respondent's NHL, it is imperative that beneficial consumer products like Roundup are not falsely linked to NHL based on methodologically infirm and litigation-driven causation theories. As Justice Breyer has explained:

> [M]odern life, including good health as well as economic well-being, depends upon the use of artificial or manufactured substances, such as chemicals. And it may, therefore, prove 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.

Joiner, 522 U.S. at 148–49 (Breyer, J., concurring).

CONCLUSION

The Petition should be granted.

Respectfully submitted,

CORY L. ANDREWS
JOHN M. MASSLON II
WASHINGTON LEGAL FOUNDATION
2009 Mass. Ave., NW
Washington, DC 20036

MATTHEW P. STEINBERG
DECHERT LLP
1095 Ave. of the Americas
New York, NY 10036

JONATHAN S. TAM
Counsel of Record
DECHERT LLP
1 Bush St #1600
San Francisco, CA 94104
(646) 731-6172
jonathan.tam@dechert.com

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