

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 THE PRODUCT LIABILITY
ADVISORY COUNCIL, INC. AS
AMICUS CURIAE IN SUPPORT OF
PETITION FOR A WRIT OF CERTIORARI**

—◆—
ALAN J. LAZARUS
FAEGRE DRINKER BIDDLE & REATH LLP
4 Embarcadero Center, 27th Fl.
San Francisco, CA 94111-4180
(415) 591-7500
alan.lazarus@faegredrinker.com
*Attorneys for Amicus Curiae
Product Liability Advisory Council, Inc.*

TABLE OF CONTENTS

	Page
INTEREST OF <i>AMICUS CURIAE</i>	1
SUMMARY OF ARGUMENT	2
ARGUMENT	5
I. The Ninth Circuit’s Standard Of Review, Interpretation Of Rule 702, And Approach To Reliability Gatekeeping In Product Liability And Toxic Tort Cases Are Inconsistent With <i>Joiner</i> , Rule 702, And The Standards And The Law As Applied In Other Circuits.....	5
A. Governing Standards For Admission Of Expert Testimony	5
B. The Ninth Circuit’s Method Of Reviewing <i>De Novo</i> District Court Gatekeeping Exclusions Circumvents The Deference Required By <i>Joiner</i> And Lowers The Bar For Admission Of Expert Causation Testimony	7
II. The District Court, Compelled By The Ninth Circuit’s Relaxed Reliability Standards And The Threat Of Rigorous Review Of Exclusion Rulings, Erroneously Admitted Plaintiff’s Causation Testimony That Exposure To Glyphosate Caused Plaintiff’s NHL.....	20

TABLE OF CONTENTS – Continued

	Page
III. The Court Should Grant This Petition To Require Deferential Review And Rigorous Reliability Gatekeeping In The Ninth Circuit	24
CONCLUSION.....	25

TABLE OF AUTHORITIES

	Page
FEDERAL CASES	
<i>Alaska Rent-A-Car, Inc. v. Avis Budget Group, Inc.</i> , 738 F.3d 960 (9th Cir. 2013).....	10
<i>Allison v. McGhan Med. Corp.</i> , 184 F.3d 1300 (11th Cir. 1999).....	17
<i>Clark v. Takata Corp.</i> , 192 F.3d 750 (7th Cir. 1999).....	17
<i>Clausen v. M/V NEW CARISSA</i> , 339 F.3d 1049 (9th Cir. 2003).....	18
<i>Daubert v. Merrell Dow Pharmaceuticals, Inc.</i> , 509 U.S. 579 (1993)	5, 9, 12, 17
<i>Daubert v. Merrell Dow Pharms., Inc.</i> , 43 F.3d 1311 (9th Cir. 1995).....	<i>passim</i>
<i>General Elec. Co. v. Joiner</i> , 522 U.S. 136 (1997)	<i>passim</i>
<i>Goebel v. Denver & Rio Grande W. R. Co.</i> , 346 F.3d 987 (10th Cir. 2003).....	16
<i>Kilpatrick v. Breg</i> , 613 F.3d 1329 (11th Cir. 2010).....	17
<i>Leathers v. Pfizer, Inc.</i> , 233 F.R.D. 687 (N.D. Ga. 2006)	19
<i>Messick v. Novartis Pharmaceuticals Corp.</i> , 747 F.3d 1193 (9th Cir. 2014).....	<i>passim</i>
<i>Mitchell v. Gencorp Inc.</i> , 165 F.3d 778 (10th Cir. 1999).....	17
<i>Moore v. Ashland Chem, Inc.</i> , 151 F.3d 269 (5th Cir. 1998).....	17

TABLE OF AUTHORITIES – Continued

	Page
<i>Rider v. Sandoz Pharms. Corp.</i> , 295 F.3d 1194 (11th Cir. 2002).....	19
<i>Rosen v. Ciba-Geigy Corp.</i> , 78 F.3d 316 (7th Cir. 1996).....	17
<i>Siharath v. Sandoz Pharms. Corp.</i> , 131 F.Supp.2d 1347 (N.D. Ga. 2001).....	19
<i>Tamraz v. Lincoln Elec. Co.</i> , 620 F.3d 665 (6th Cir. 2010).....	17, 19
<i>Wendell v. GlaxoSmithKline, LLC</i> , 858 F.3d 1227 (9th Cir. 2017).....	<i>passim</i>
 RULES	
Federal Rule of Evidence 104(a)	3
Federal Rule of Evidence 702.....	<i>passim</i>

INTEREST OF *AMICUS CURIAE*¹

The Product Liability Advisory Council, Inc. (PLAC) is a non-profit professional association of corporate members representing a broad cross-section of American and international product manufacturers. PLAC's current corporate membership list is available on its website.² In addition, several hundred of the leading product liability defense attorneys in the country are sustaining (i.e., non-voting) members of PLAC.

PLAC's primary purpose is to file *amicus curiae* briefs in cases with issues that affect the development of product liability law and impact PLAC's members. Since 1983, PLAC has submitted over 1100 amicus briefs in state and federal courts, including many briefs in this Court.

PLAC's interest in this action arises from the profound impact on its members of unreliable expert testimony, and any dilution of the reliability requirements for expert testimony that have governed federal court adjudications for decades. Product liability and toxic tort cases are peculiarly expert-driven and even

¹ No counsel for any party authored any part of this brief. No party or counsel for a party made a monetary contribution used or intended to be used to fund the preparation or submission of this brief. Nor did any person or entity other than *amicus curiae* make any such monetary contribution. Counsel for the parties were given notice of the intent to file this brief more than 10 days before the filing deadline and counsel for all parties consented to the filing of this brief.

² https://plac.com/Membership/Corporate_Membership.aspx.

minor modifications in the standards of admissibility for expert testimony can significantly affect the fairness and reliability of jury verdicts in these cases. As this Court has noted, expert testimony on complex subjects beyond the ken of jurors has a powerful impact, justifying a rigorous gatekeeping role for district courts. Any compromise of that role created by circuit court precedents is a cause for great concern to PLAC.

As we show below, the Ninth Circuit’s gatekeeping standards are inconsistent with the precedents in other circuits and this Court, and frustrate the mission of Federal Rule of Evidence 702 (Rule 702) – to assure that juries receive only reliable expert opinions. The Ninth Circuit’s broad standard of *de novo* review exacerbates the damage by systematically circumventing the deferential review required by *General Elec. Co. v. Joiner*, 522 U.S. 136 (1997).



SUMMARY OF ARGUMENT

The Ninth Circuit applies a two-step standard for reviewing district court gatekeeping decisions that essentially applies *de novo* review rather than the deferential review required by *Joiner*. By categorically characterizing a district court’s application of Rule 702 to the record in a particular case as the selection of a “legal standard” or a “construction or interpretation” of Rule 702, the Ninth Circuit transforms fact-bound admissibility rulings into questions of law, allowing it to substitute its judgment for that of the assigned

gatekeeper. This independent review is particularly aggressive when the district court has concluded that key expert testimony must be excluded – a *de facto* differential standard of review that also violates *Joiner*.

The Ninth Circuit has also required district courts to apply Rule 702 with a “liberal thrust” – a thumb on the scale favoring admissibility. This systematic bias in favor of admissibility is inconsistent with the proponent’s burden under Federal Rule of Evidence 104(a) to establish by a preponderance of the evidence the reliability and admissibility of their expert’s testimony. It is also, again, a violation of *Joiner*, which rejected an 11th Circuit standard based on a purported “preference for admissibility.”

The combination of liberal admission standards and aggressive review of orders excluding key expert testimony both undermines Rule 702 and, as a practical matter, makes district courts “gun shy” when confronted with evidence that appears to lack reliability. The district court’s decision in this case is an example. Keenly sensitive to the Ninth Circuit’s mandated liberal thrust and its propensity to overturn district court orders finding causation testimony in products liability and toxic tort cases to be unreliable, the district court felt compelled to admit causation testimony that failed to meet the reliability standards widely applicable in other circuits, as the district court itself acknowledged, repeatedly.

Beyond the general dilution of Rule 702 resulting from the “liberal thrust favoring admissibility,” the

Ninth Circuit's *de novo* gatekeeping has generated *specific* outlier standards that weaken district courts' ability to assure evidentiary reliability. The court has declared that specific causation opinions offered by doctors based on a "differential diagnosis" are a special breed of opinion, more art than science, justifying particular deference to their clinical experience and expertise and toleration of a high degree of subjectivity. Nothing in Rule 702, nor in the decisions of this Court or other circuits, authorizes courts to grant a free pass through the gate for experts' offering primarily subjective specific causation opinions that evade verification.

In sum, the Ninth Circuit has truly gone rogue in interpreting Rule 702 and in policing the gatekeeping decisions of the district courts. The Court should grant the petition of Monsanto Company and use this case to bring the Ninth Circuit into line, and allow Rule 702 to properly fulfill its remedial purpose of assuring reliability in the expert evidence submitted to juries.



ARGUMENT

- I. **The Ninth Circuit’s Standard Of Review, Interpretation Of Rule 702, And Approach To Reliability Gatekeeping In Product Liability And Toxic Tort Cases Are Inconsistent With *Joiner*, Rule 702, And The Standards And The Law As Applied In Other Circuits**
 - A. **Governing Standards For Admission Of Expert Testimony**

Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993) held that Rule 702 had superseded the *Frye* standard for admissibility of expert testimony, establishing a flexible standard for admissibility based on the separate anchor requirements of qualifications, reliability, and relevance (or “fit”). The Court assigned district court judges the role of “gatekeeper” to assure the reliability and relevance of the proffered expert testimony in their courtrooms.

Four years later, in keeping with the necessary flexibility of Rule 702’s reliability analysis and the fact-, context- and record-driven nature of reliability gatekeeping, the Court concluded that review of the product of the district courts’ rulings should be deferential – the decisions should be assessed for an abuse of the courts’ broad discretion. *Joiner*, 522 U.S. at 143. Rejecting the practice in the 11th Circuit of applying more stringent review to dispositive exclusions, the Court held that this deference was equally applicable to all gatekeeping rulings, regardless of their impact on the case – a rule of equal dignity. *Id.* at 142-43. The

Court also clarified that reliability gatekeeping under Rule 702 encompasses more than evaluating the reliability of the experts' *methodology*; however valid the expert's general methodology may be, the district court is required to determine whether the application of that methodology to the facts of the case, and the chain of reasoning employed by the expert in reaching the conclusion, was reliable. *Joiner*, 522 U.S. at 146.

Integral to the Court's equal dignity rule was the Court's rejection of the 11th Circuit's justification for applying a "particularly stringent standard of review" to decisions excluding expert evidence – the notion that a "harder look" is warranted because there is a preference in Rule 702 for admissibility. *Id.* at 140-41. The Court flatly held that the courts of appeal may not "categorically distinguish between rulings allowing expert testimony and rulings that disallow it." 522 U.S. at 142-43.

In 2000, Rule 702 was amended to synthesize the post-*Daubert* case law. See Federal Rule of Evidence 702 Advisory Committee Notes (hereafter "Advisory Committee Notes"). Ever since, the Rule has required expert testimony to meet the following standards for admission:

1. The expert must be **qualified** to testify as an expert, by their "knowledge, skill, experience, training or education";
2. the expert's specialized knowledge must be **helpful** to the trier of fact;

3. the expert's testimony must have an adequate **factual foundation** – the testimony must be “based on sufficient facts or data”;

4. the expert's testimony must be “the product of **reliable principles and methods**”; and

5. the expert must have “**reliably applied** the principles and methods to the facts of the case.”

B. The Ninth Circuit's Method Of Reviewing *De Novo* District Court Gatekeeping Exclusions Circumvents The Deference Required By *Joiner* And Lowers The Bar For Admission Of Expert Causation Testimony

The Ninth Circuit has employed a pseudo- abuse of discretion standard to review of district court gatekeeping rulings that ignores *Joiner's* fundamental command that review must be deferential.

As noted, *Joiner* also rejected the 11th Circuit's view that Rule 702 included a preference for admission, holding that decisions to admit and decisions to exclude expert testimony stand on equal footing on appeal – both are deserving of equal deference.

Both of these holdings have been systematically thwarted by the Ninth Circuit. As the district court here recognized – repeatedly – the Ninth Circuit has emphasized the “liberal thrust” of Rule 702 and freely reversed district courts for doing what they have been directed to do by this Court – rigorously scrutinize the

reliability of expert testimony. And the Ninth Circuit's review of rulings excluding expert causation opinions has been anything but deferential.

The problem lies largely in two leading decisions that compelled the result in the decisions below.

In *Messick v. Novartis Pharmaceuticals Corp.*, 747 F.3d 1193 (9th Cir. 2014), plaintiff's causation expert was Dr. Jackson, an oral and maxillofacial surgeon "with extensive experience diagnosing and treating osteonecrosis of the jaw" (ONJ). Plaintiff had been diagnosed with bisphosphonate-related ONJ (BRONJ) pursuant to diagnostic criteria established by AAOMS, a medical association. Bisphosphonates are a class of drugs used to treat a form of cancer. Dr. Jackson opined that plaintiff's BRONJ was not just related to bisphosphonate ingestion, it was specifically caused by the defendant's drug, rejecting several alternative potential causes, including the underlying cancer. AAOMS had concluded that the evidence was sufficient to support a strong association between bisphosphonate therapy and BRONJ, but not enough to establish a cause-and-effect relationship. *Id.* at 1198-99.

The Ninth Circuit held that the district court had abused its discretion in excluding as unreliable Dr. Jackson's testimony that the drug was a substantial factor in producing plaintiff's BRONJ.

Notwithstanding *Joiner*, the court's analysis established that reliability exclusions are disfavored

under Rule 702 in the Ninth Circuit, and their review is *not* deferential.

The court stated that though it reviews the district court's ruling for an abuse of discretion, "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.*'" 747 F.3d at 1196 (emphasis added). Moreover, "**Rule 702 should be applied with a 'liberal thrust' favoring admission,**" citing *Daubert*, 509 U.S. at 588 (and ignoring *Joiner*). *Ibid.* (emphasis added).

The court also indicated that the district court's gatekeeping license was essentially limited to excluding "junk science." *See id.* at 1197 ("We recently acknowledged the district court's duty to 'act as a "gatekeeper" to exclude junk science that does not meet Federal Rule of Evidence 702's reliability standards'"). That extremely narrow view of the scope of Rule 702's reliability requirements was also echoed in the court's conclusion:

While the district court must act as a gatekeeper to exclude "junk science" under *Daubert*, Federal Rule of Evidence 702 includes within its scope all evidence that would "help the trier of fact . . . to determine a fact in issue." 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 1199.³

Of course, Rule 702 nowhere mentions junk science or indicates it is the benchmark for exclusion. Nor does it authorize admission based solely on a finding that it would be helpful to the factfinder. Rather, the rule sets forth five separate general requirements for admission, as noted, and helpfulness to the trier of fact is but one of them.

As for the court’s command that “Rule 702 should be applied with a ‘liberal thrust’ favoring admission,” *id.* at 1196, the court took this phrase from the *Daubert* opinion out of context and twisted it into an overarching “standard” at odds with both the holding and reasoning in *Joiner*. *Joiner* rejected any preference for admission in Rule 702. And this Court’s use of the phrase “liberal thrust” in *Daubert* never suggested that Rule 702 should be interpreted and applied to favor admission; rather, the phrase was used to distinguish the “flexible” approach to ascertaining reliability under Rule 702/*Daubert* – assigning “general acceptance” of the expert’s methodology in the scientific community as only one of several factors to be considered in the reliability analysis – from the “rigid” and “austere” approach under *Frye*, which automatically excluded opinion testimony if the methodology had not

³ See also *Alaska Rent-A-Car, Inc. v. Avis Budget Group, Inc.*, 738 F.3d 960, 969 (9th Cir. 2013) (the district court’s gatekeeping obligation is meant to screen out “unreliable nonsense opinions”).

achieved general acceptance. That was the singular mention in *Daubert* of any “liberal thrust” and in context it provides *no support* for the Ninth Circuit’s purported rule that Rule 702 must be applied with a bias toward admission.

Ultimately, the court in *Messick* disagreed with the district court’s finding that Dr. Jackson’s causation opinion was unreliable because it lacked any scientific basis. The court of appeal emphasized that Dr. Jackson had referred “to his own extensive clinical experience” and his review of plaintiff’s medical records, treatment, and history, as well as the diagnostic criteria for BRONJ. In the court of appeal’s view, “[t]hese sources form an appropriate scientific basis for his opinions, and the district court abused its discretion in concluding otherwise.” 747 F.3d at 1198.

In endorsing Dr. Jackson’s ability to base a differential diagnosis opinion largely on clinical experience, the court explained that “[m]edicine partakes of art as well as science, and there is nothing wrong with a doctor relying on extensive clinical experience when making a differential diagnosis.” *Ibid.* The court thereby provided extra leeway for physicians to freely offer highly subjective causation conclusions.

The decision in ***Wendell v. GlaxoSmithKline, LLC***, 858 F.3d 1227 (9th Cir. 2017) built on *Messick* and reinforced the message to district courts that decisions to exclude experts would be shown no deference on appeal. Plaintiffs claimed a rare form of lymphoma, HSTCL, was caused by a combination of drugs

prescribed for their son's chronic inflammatory bowel disease. The district court excluded the testimony of their two causation experts for several reasons supported by Rule 702 and case law:

- Neither expert had conducted research on the causal connection between the combination of drugs and HSTCL; rather, they had developed their causation opinions specifically for litigation. 858 F.3d at 1232. *See* Advisory Committee Notes (one relevant reliability factor is “whether experts are ‘proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying’” (quoting *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) (*Daubert II*))).
- Both experts conceded that their opinions would not satisfy the standards for publication in a peer-reviewed medical journal. One explained that a journal would require more scientific rigor; the other explained that he was presenting an opinion, not data, and “opinions are not publishable.” *Id.* at 1237. The willingness of the witness to subject his opinions to peer review and publication is a factor bearing on reliability. *Daubert*, 509 U.S. at 593-94. *See also Daubert II*, 43 F.3d at 1318 (“That the research is accepted for publication in a reputable scientific journal after being subjected to the usual

rigors of peer review is a significant indication that it is taken seriously by other scientists, i.e., that it meets at least the minimal criteria of good science”).

- The experts could point to no epidemiology studies or even animal studies demonstrating a statistically significant link between the two drugs and HSTCL, and instead relied on anecdotal case reports that failed to accounting for alternative causes. The district court found this was especially problematic since the experts conceded that the substantial majority of cases of HSTCL (over 70%) are considered idiopathic, i.e., have no known cause. This high level of uncertainty hampered the experts’ ability to eliminate other potential causes. 858 F.3d at 1233.
- The experts had not presented any scientific basis to rule out the underlying inflammatory bowel disease as a cause, nor adequately ruled out an idiopathic etiology, rendering the causation opinions speculative. *Ibid.*
- The experts had not identified the biological mechanism by which the drug combination caused the development of HSTCL. *Id.* at 1236-37.

The court of appeals again explicitly engaged in *de novo* review to reverse, disagreeing with the district court’s reliability analysis, though finding it to be “a

close question.” The court faulted the district court for “ignor[ing] the experts’ experience” and “review of [the] medical records and history,” “reliance on a variety of literature and studies” (primarily the case reports), and “the fundamental importance of differential diagnosis by experienced doctors treating troubled patients.” 858 F.3d at 1233.

The court of appeals ultimately agreed that each factor identified by the district court was a valid reliability consideration, but emphasized repeatedly that none of them were separately determinative. *Id.* at 1236. It concluded that the district court had given them too much weight, and given too little weight to the fact that the experts were “highly qualified doctors” skilled in the diagnosis and treatment of lymphomas who had reviewed medical records and applied their education, training and experience and knowledge of the literature, and performed a differential diagnosis. *See* 858 F.3d at 1237 (“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 the disease”) (citing *Messick*, 747 F.3d at 1198).

Notably, the court observed that *Daubert*’s “mandate” that the focus “must be solely on principles and methodology, not on the conclusions they generate” “is especially important.” 858 F.3d at 1237. Of course, *Joiner* had substantially limited that principle, recognizing that the expert’s application of the principles and methods, and reasoning, were relevant to reliability as well. 522 U.S. at 146. *See* Advisory Committee

Notes. And the 2000 amendments to Rule 702 codified that modification.

The court again emphasized its strong preference for admission, observing that only “junk science” can be excluded under Rule 702, and that “the interests of justice favor” admission of evidence. It also reinforced its view that opinions based on clinical experience are admissible as partaking of the “art” of medicine, concluding:

Where, as here, two doctors who stand at or near the top of their field and have extensive clinical experience with the rare disease or class of disease at issue, are prepared to give expert opinions supporting causation, we conclude that *Daubert* poses no bar based on their principles and methodology.

858 F.3d at 1237.

In sum, *Messick* and *Wendell* confirm that the Ninth Circuit explicitly applies a bias in favor of admission that is nowhere in Rule 702 and inconsistent with *Joiner*. And it reviews the district court’s reliability gatekeeping *de novo* and exclusions particularly skeptically, also running afoul of *Joiner*.

As reflected in these decisions, the Ninth Circuit also dilutes reliability gatekeeping in toxic tort and products liability cases by finding the reliability requirements of Rule 702 satisfied by characteristics that do not, in fact, enhance the reliability of medical causation opinions: Impressive credentials, clinical experience and routine methodology (i.e., review of

medical records and history plus application of education, experience and training to reach an opinion), and the simple performance of a differential diagnosis, without any real regard for its reliability. In the Ninth Circuit, all of these factors serve to pry open the gate for expert testimony supporting causation, virtually automatically.

De Novo Review: Once the court exercises plenary review of the *application* of reliability factors, it is unclear what is left for the court to defer to. If the assessment of the particular expert's methodology, foundation and reasoning is the "construction and interpretation of Rule 702," rather than "actual application of the gatekeeper standard," then there is little of substance left to be given deference. *Compare, e.g., Goebel v. Denver & Rio Grande W. 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. We then review for abuse of discretion the trial court's actual application of the gatekeeper standard in deciding whether to admit or exclude an expert's testimony."). The abuse of discretion standard as employed by the Ninth Circuit, in contrast, simply eviscerates *Joiner*.

Qualifications: By the very terms of Rule 702, qualifications and reliability are separate and independent requirements. If impressive credentials were enough, then there would be little or no need for the second half of Rule 702. Nothing in the rule or the case law suggests that reliability can be established, or the

required showing relaxed, by the expert's level of experience or standing in the field. Rather, it has been Rule 702 canon that the opinion of even the most esteemed, well-credentialed and experienced expert must still be based on sufficient facts or data, reliable principles and methods, and the reliable application of those principles and methods. *See, e.g., Kilpatrick v. Breg*, 613 F.3d 1329, 1336 (11th Cir. 2010). *See also, e.g., Clark v. Takata Corp.*, 192 F.3d 750, 759 n.5 (7th Cir. 1999) (“A supremely qualified expert cannot waltz into the courtroom and render opinions unless those opinions are reliable and relevant”); *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 318 (7th Cir. 1996) (“a district judge asked to admit scientific evidence must determine whether the evidence is genuinely scientific, as distinct from being unscientific speculation offered by a genuine scientist”); *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1315-16 (9th Cir. 1995) (*Daubert II*) (“something doesn’t become ‘scientific knowledge’ just because it’s uttered by a scientist”). *Accord, e.g., Moore v. Ashland Chem, Inc.*, 151 F.3d 269, 278 (5th Cir. 1998) (en banc); *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1316-17 (11th Cir. 1999); *Mitchell v. Gencorp Inc.*, 165 F.3d 778, 783 (10th Cir. 1999); *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 677 (6th Cir. 2010).

In *Daubert*, this Court lauded the credentials of the proffered experts before holding that their opinions were subject to exclusion if their testimony was not reliable – but it never suggested that their credentials were a factor to be considered in the separate analysis of the reliability of their opinions. *See* 509 U.S. at 582,

583 & nn.1, 2. On remand, the Ninth Circuit panel made similar observations in the course of finding the experts' causation opinions lacked the requisite reliability. See *Daubert II*, 43 F.3d at 1315-16, 1319.

Differential Diagnosis: In both opinions the court of appeals sought to justify its deference to the experts and their qualifications by asserting that a specific causation analysis based on a “differential diagnosis” is something of a hybrid between art and science. “Medicine partakes of art as well as science, and there is nothing wrong with a doctor relying on extensive clinical experience when making a differential diagnosis.” *Messick*, 747 F.3d at 1198. But in the Ninth Circuit, as elsewhere, a reliable specific causation analysis must “rule in” the various potential causes by application of reliable scientific methods and procedures, and likewise, in eliminating potential causes from the differential list, “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.” *Clausen v. M/V NEW CARISSA*, 339 F.3d 1049, 1058 (9th Cir. 2003).

Clinical Experience: The court's reliance on the expert's clinical experience as a badge of reliability also overlooks that clinical practice is primarily, and often exclusively, concerned with diagnosis and treatment, not with reaching a scientifically sound conclusion as to an actual cause. Diagnosis and treatment may very well “partake of art as well as science,” but a rigorous analysis of cause-and-effect relies far more

heavily on science and is not part of day-to-day clinical practice.

More discerning courts have recognized that ordinarily causal judgments in clinical practice are largely a product of the doctor's "clinical hunch," not a sophisticated and rigorous scientific investigation into cause-and-effect. *See, e.g., Leathers v. Pfizer, Inc.*, 233 F.R.D. 687, 695 (N.D. Ga. 2006) (discussing the significant differences between clinical practice and reliable causation methodology under Rule 702). *See also Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194, 1196 (11th Cir. 2002) (affirming exclusion of a clinician's causation testimony, noting that the district court (*Siharath v. Sandoz Pharms. Corp.*, 131 F.Supp.2d 1347, 1371-72 (N.D. Ga. 2001)) "drew a careful distinction between clinical process, in which conclusions must be extrapolated from incomplete data, and the scientific method, in which conclusions must be drawn from an accepted process").⁴ The point is not that clinicians are incapable of forming reliable science-based opinions, but that clinical experience in and of itself cannot logically be viewed as an independent marker of reliability for complex general and/or specific causation conclusions. Nothing about ordinary clinical experience treating patients for poorly understood or multi-factorial diseases provides any significant expertise or indicia of

⁴ *See also* App. 173a (district court's order excluding general causation opinions of Dr. Nabhan, in part because his deference to the International Agency for Research on Cancer (IARC) "may well be appropriate clinical practice" but "is not a reliable way to reach a general causation opinion"); *Tamraz*, 620 F.3d at 671, 673.

reliability for a complex causation conclusion. Nor, as is the rule in the Ninth Circuit, can clinical experience be treated as a virtually complete substitute for finding a sufficient factual foundation, reliable scientific methodology, and reliable application of scientific methodology.⁵

Against this backdrop, the district court decided Monsanto's motions to exclude Mr. Hardeman's causation experts.

II. The District Court, Compelled By The Ninth Circuit's Relaxed Reliability Standards And The Threat Of Rigorous Review Of Exclusion Rulings, Erroneously Admitted Plaintiff's Causation Testimony That Exposure To Glyphosate Caused Plaintiff's NHL

The district court erred in admitting the testimony of Plaintiff's causation experts, for the reasons explained by Monsanto. *See* Pet. 26-35. It is easy to see why. The court was compelled by Ninth Circuit precedent and the Circuit's preference for admissibility to apply a quasi-presumption that the expert testimony

⁵ Of course, the same holds true for the common clinical methods – reviewing the plaintiff/patient's medical records and history and applying one's knowledge, education, and experience. To be sure, those efforts are often *necessary* to support a causation opinion, but especially when evaluating the potential causes of a complex and poorly understood disease process, they will rarely be *sufficient*. Rather than just assume these exercises support reliability of a causation analysis, courts must consider how and to what extent these routine practices truly add a measure of reliability to a particular causation analysis in a given case.

was reliable, to admit the testimony unless it clearly qualified as “junk science,” and to find the testimony reliable as long as the experts were well-qualified, reviewed some relevant literature, reviewed Plaintiff’s medical records and history, and performed a differential diagnosis. To do anything but admit the testimony under these circumstances, in the Ninth Circuit, invites reversal.

Here, the district court freely admitted that a straightforward application of Rule 702 as interpreted by most circuits would have supported exclusion, but bound by the Ninth Circuit’s standards and preference for admission, decided to admit the testimony. *See* App. 83a (noting that the absence of a basis for differentiating between cases of NHL caused by glyphosate and those that were not might “be the end of the line” under a strict interpretation of *Daubert*, “[b]ut in the Ninth Circuit, that is clearly not the case”) (citing *Wendell* and *Messick*); *id.* at 83a-84a (“Recognizing that ‘[m]edicine partakes of art as well as science,’ 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”); *id.* at 84a (*Wendell* and *Messick* “are impossible to read without concluding that district courts in the Ninth Circuit must be more tolerant of borderline expert opinions than in other circuits”) (comparing decisions from the 4th and 6th Circuits); *ibid.* (in exercising their discretion, district judges “must account for the fact that a wider range of expert opinions (arguably much wider) will be admissible in this circuit”);

ibid. (“Under Ninth Circuit caselaw, doctors enjoy wide latitude in how they practice their art when offering causation opinions”); *id.* at 101a (the Ninth Circuit’s “great emphasis” on the “liberal thrust favoring admission” “has resulted in slightly more room for deference to experts in close cases than might be appropriate in some other Circuits” (comparing decisions from the 3rd and 11th Circuits); “this is a difference that could matter in close cases”).

Even applying the Ninth Circuit’s erroneous pro-admissibility standard, the district court found admissibility to be a “close question” at every turn. Admissibility of the general causation opinions was a “very close question,” App. 91a, 179a, in part because “the evidence of a causal link between glyphosate exposure and NHL in the human population seems rather weak.” App. 93a. *See also* App. 94a. Specific causation (which was highly dependent on an admissible general causation opinion) “is again a close question, but the plaintiffs have barely inched over the line.” App. 79a.

The Ninth Circuit, reviewing *de novo* “whether the district court applied the correct legal standard under *Daubert*,” and applying the “liberal thrust favoring admission,” affirmed the admission of Plaintiff’s experts, App. 22a-23a. Responding to Monsanto’s criticism of the district court’s application of *Wendell* and *Messick*, the court of appeals found that the district court “followed this court’s precedent and thus cannot be faulted for following binding case law.” App. 23a.

The court went on to challenge the district court's description of the circuit as "an outlier following a more flexible *Daubert* approach than other circuits." App. 24a. The court reiterated its view from the prior cases that clinical experience, record and history review, and differential diagnosis provide a sufficient scientific basis for causation opinions. App. 24a-25a. But "[d]espite [the district court's] incorrect assumption that this court is more permissive than others in admitting *Daubert* testimony," the court of appeals held that the district court "still employed the correct legal standard for reliability" when it admitted the testimony. The court maintained that it was consistent with *Daubert* to accord "slight deference to experts with borderline opinions." App. 26a.

The court also doubled-down on the proposition that opinions based on extensive clinical experience, i.e., the art side of the medical spectrum, are admissible. App. 26a-27a. And the court declined the suggestion "that the application of art is limited to exceptional circumstances." App. 27a. Rather, experts are freely allowed "to rely on clinical experience, or 'art,'" whenever they "conduct[] differential diagnosis to render specific causation opinions." *Ibid.*

Thus, this case magnifies and perpetuates the significant wayward approach to Rule 702 established in *Messick* and *Wendell*. The Ninth Circuit now has its own trilogy of Rule 702 decisions, cementing the Circuit as a defiant outlier in its reading and application of Rule 702 and the precedents of this and other courts.

III. The Court Should Grant This Petition To Require Deferential Review And Rigorous Reliability Gatekeeping In The Ninth Circuit

The Ninth Circuit's Rule 702 jurisprudence is out of whack. Contrary to *Joiner* and the Rule itself, district courts are compelled to apply Rule 702 in a manner favoring the admission of expert testimony, and to accept *causation* testimony predicated primarily on subjective impressions based on credentials and *diagnostic* experience. The court of appeals reinforces these expectations by routinely exercising *de novo* review to substitute its judgment for the district courts when they have excluded causation testimony by well-credentialed medical experts employing the technique of differential diagnosis. This Court's intervention is necessary, and the Petition should be granted.



CONCLUSION

For the foregoing reasons, as well as the reasons stated in the Petition, PLAC respectfully requests that the Court grant Petitioner Monsanto Company's Petition for a Writ of Certiorari and reverse the Ninth Circuit's systematic circumvention of *Joiner* and subversion of Rule 702.

Respectfully submitted,

ALAN J. LAZARUS

FAEGRE DRINKER BIDDLE & REATH LLP

Four Embarcadero Center, 27th Fl.

San Francisco, CA 94111-4180

(415) 591-7500

alan.lazarus@faegredrinker.com

Attorneys for Amicus Curiae

Product Liability Advisory Council, Inc.