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 CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, AND THE AMERICAN TORT REFORM ASSOCIATION AS *AMICI CURIAE* SUPPORTING PETITIONER

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INTRODUCTION AND INTEREST OF THE *AMICI CURIAE* [1]

Federal law plainly preempts the state-law claims at issue here. California law, as interpreted and applied through the jury verdict below, would require Monsanto to place a cancer warning on its Roundup products. Federal law, as enforced by the EPA, requires that Monsanto's Roundup labeling *not* include a cancer warning. Whether analyzed under express preemption doctrine (see 7 U.S.C. § 136v(b) (state law "shall not impose * * * any requirements for labeling or packaging in addition to or different from those required" by FIFRA)), or under conflict preemption principles, the judgment below is preempted. If left uncorrected, it will bring disuniformity to federal preemption doctrine, and it will threaten many businesses with billions of dollars of damages liability for failing to take actions that are illegal under federal law. That perverse result cannot stand.

Moreover, the court of appeals could only affirm the admission of plaintiffs' expert evidence by applying a uniquely expansive interpretation of the standards announced in *Daubert* v. *Merrill Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and Federal Rule of Evidence 702. Indeed, as the district court explicitly recognized, "a wider range of expert opinions (arguably much wider) will be admissible in this circuit" than elsewhere. Pet. App. 84a. That kind of inter-circuit disparity in evidentiary standards is untenable, particularly in na-

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[1] All parties received timely notice of *amici*'s intent to file this brief pursuant to Rule 37.2(a), and have consented to the filing of this brief. No counsel for a party authored this brief in whole or in part, and no person other than the *amici*, their members, or their counsel have made a monetary contribution intended to fund the preparation or submission of the brief.

tional tort cases like this one, where plaintiffs have their choice of forum. The Court should grant certiorari to bring uniformity in this area, as well.

The Chamber of Commerce of the United States of America (the Chamber) is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases, like this one, that raise issues of concern to the nation's business community.

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, non-profit association that represents the nation's leading biopharmaceutical and biotechnology companies. PhRMA's mission is to advocate for public policies that encourage the discovery of life-saving and life-enhancing medicines. PhRMA's members invest billions of dollars each year to research and develop new drugs, more than 500 of which have been approved since 2000. The members of PhRMA closely monitor legal issues that affect the entire industry, and PhRMA often offers its perspective in cases raising such issues.

The American Tort Reform Association (ATRA) is a broad-based coalition of businesses, corporations, municipalities, associations, and professional firms that have pooled their resources to promote reform of the civil justice system with the goal of ensuring fairness, balance, and predictability in civil litigation. For more than three decades, ATRA has filed *amicus* briefs in cases involving important liability issues.

Amici have a strong interest in ensuring both that the preemptive force of federal laws is fully implemented—thus alleviating the need for businesses to navigate a patchwork of inconsistent state regulation—and that federal evidentiary standards, particularly those dealing with expert scientific evidence, are enforced evenhandedly across the nation.

SUMMARY OF ARGUMENT

The Court should grant certiorari to address both questions presented.

I. First, the court of appeals' preemption ruling places Monsanto in an impossible position: California law says it must warn consumers of cancer risk from its glyphosate-containing Roundup products, but federal law says it must not make those warnings. Compare, *e.g.*, Pet. App. 10a-11a (discussing $25 million jury verdict for state-law failure to warn claims), with *id.* at 196a (EPA notice informing registrants that "pesticide products bearing [a cancer] warning statement due to the presence of glyphosate are misbranded pursuant to section 2(q)(1)(A) of FIFRA").

That head-to-head collision between federal and state law is exactly what federal preemption doctrine is designed to avoid. Regardless of whether this case is analyzed under FIFRA's express preemption clause or under the doctrines of conflict or impossibility preemption, the verdict below cannot stand. See, *e.g.*, *Mutual Pharm. Co.* v. *Bartlett*, 570 U.S. 472, 486 (2013) ("When federal law forbids an action that state law requires, the state law is 'without effect.'") (quoting *Maryland* v. *Louisiana*, 451 U.S. 725, 746 (1981)). The Court should grant certiorari to remedy the confusion wrought on federal preemption law by this anomalous result.

II. Second, the Court should also grant certiorari to address the Ninth Circuit's *Daubert* holding, which applied what the district court rightly understood to be a less "strict interpretation of *Daubert*" than that used in other circuits. Pet. App. 83a; see also *id.* at 84a ("[A] wider range of expert opinions (arguably much wider) will be admissible in this circuit."). That circuit conflict demands this Court's intervention, particularly given the overriding importance of uniform standards for the admission of expert evidence in mass tort litigation. The Court should not permit the decision below to sow uncertainty in this critical area of the law, either. Certiorari is therefore warranted.

ARGUMENT

I. The Court should grant certiorari to address the court of appeals' anomalous preemption ruling.

The Court should review the Ninth Circuit's manifestly erroneous conclusion that a regulated business may be subjected to state tort liability for failing to provide a warning that—according to the expert federal agency charged with implementing and enforcing the relevant statute—is not only unnecessary but illegal under federal law.

A. Uniformity in federal preemption—both under FIFRA and beyond—is an issue of immense importance to regulated businesses operating nationwide.

Amici count among their members thousands of businesses subject to comprehensive federal regulatory schemes like FIFRA. These reticulated administrative standards may advance certain public ends (such as chemical safety) while ensuring a nationwide marketplace for the sale of goods and services in the United States.

Compliance with these substantial—often onerous—regulatory regimes imposes significant costs on businesses. Those costs would be multiplied fifty-fold if the States were permitted to impose different or even conflicting requirements on precisely the same conduct. Cf., *e.g.*, U.S. Chamber of Commerce Foundation, *The Regulatory Impact on Small Business* 18 (Mar. 2017) (discussing the burdens of state regulation on businesses, including one study finding the total cost of California regulations alone to be nearly $500 billion per year), https://perma.cc/G6SX-VTEC. Such duplicative compliance costs stifle innovation, drive up prices for consumers, and constrain the job-creating powers of American businesses.

To counteract the significant costs that such a patchwork of state regulations would otherwise impose, Congress has enacted several express preemption provisions specifically to ensure that federal law supplies a uniform, national standard. See, *e.g.*, *Fort Halifax Packing Co.* v. *Coyne*, 482 U.S. 1, 11 (1987) ("It is * * * clear that ERISA's pre-emption provision was prompted by recognition that employers establishing and maintaining employee benefit plans are faced with the task of coordinating complex administrative activities. A patchwork scheme of regulation would introduce considerable inefficiencies in benefit program operation * * *. Pre-emption insures that the administrative practices of a benefit plan will be governed by only a single set of regulations."); *City of Columbus* v. *Ours Garage & Wrecker Serv., Inc.*, 536 U.S. 424, 440 (2002) ("[S]tate economic regulation of motor carrier operations . . . is a huge problem for national and regional carriers attempting to conduct a standard way of doing business," such that "certain aspects of the State regulatory process should be preempted.") (first quoting H.R. Rep. No. 103-677, at 87 (1994) (Conf. Rep.), then

quoting Pub. L. No. 103-305, § 601(a)(2), 108 Stat. 1605 (1994)).

FIFRA's preemption provision was motivated by precisely this need for consistent regulation: "[I]magine 50 different labeling regimes prescribing the color, font size, and wording of warnings—that would create significant inefficiencies for manufacturers." *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431, 452 (2005). "Congress had [such] conflicting state labeling regulations in mind when crafting § 136v(b)." *Id.* at 452 n.26; see also *ibid.* (quoting industry representative's hearing testimony: "We ask this committee, therefore, to recognize, as the Congress has in a number of similar regulatory statutes, the industry's need for uniformity by providing for [preemption] in the act.").

Given that the purpose of express preemption clauses like FIFRA's is to ensure the existence of a single, uniform set of regulatory requirements, even one court of appeals decision erroneously denying preemption can have an outsized effect in undermining Congress's design. Cf., *e.g.*, *Northwest Airlines, Inc.* v. *Duncan*, 531 U.S. 1058, 1058 (2000) (O'Connor, J., dissenting) ("Because airline companies operate across state lines, the divergent pre-emption rules formulated by the Courts of Appeals currently operate to expose the airlines to inconsistent state regulations."). Plaintiffs often have a range of venues from which they may select, and they will invariably steer litigation—especially putative nationwide class actions—to courts that fail to give full effect to federal preemption law.

The Court therefore frequently grants certiorari to correct mistaken preemption rulings like the one below. See, *e.g.*, *Gobeille* v. *Liberty Mut. Ins. Co.*, 577 U.S. 312, 319 (2016) ("This Court granted certiorari to address the important issue of ERISA pre-emption"); *Int'l Paper Co.* v. *Ouellette*, 479 U.S. 481, 487 (1987) ("We

granted certiorari to resolve the circuit conflict on this important issue of federal pre-emption."). It should do so once again here.

B. The decision below disrupts uniformity, misapplies *Bates*, and brings confusion to the interpretation of identical preemption language.

The court of appeals' decision below not only is irreconcilable with this Court's FIFRA preemption jurisprudence, but also threatens to confuse the application of many similarly worded preemption provisions across the U.S. Code. Further review is imperative.

1. FIFRA's preemption clause provides that "[a] State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under" FIFRA. 7 U.S.C. § 136v(b). State "requirements" include common-law duties. *Bates*, 544 U.S. at 443.

Thus, while "a state-law labeling requirement is not pre-empted * * * if it is *equivalent to*, and fully consistent with, FIFRA's misbranding provisions," FIFRA's preemption clause "pre-empts any statutory or common-law rule that would impose a labeling requirement that *diverges from* those set out in FIFRA and its implementing regulations." *Bates*, 544 U.S. at 452 (emphases added).

As the Court has made clear, courts evaluating preemption under FIFRA "must ensure that nominally equivalent labeling requirements are *genuinely* equivalent" before they may escape preemption. *Bates*, 544 U.S. at 454. That is, the focus of the equivalence inquiry is not the "language" in which the state-law requirement is "phrased," but whether that requirement "in fact" imposes the same duties as federal law. *Id.* at 453-454 ("We emphasize that a state-law labeling re-

quirement must in fact be equivalent to a requirement under FIFRA in order to survive pre-emption.").

In sum, as the Court explained in *Bates*, FIFRA's preemption provision results in a simple rule: "[A] manufacturer should not be held liable under a state labeling requirement subject to § 136v(b) unless the manufacturer is also liable for misbranding as defined by FIFRA." *Bates*, 544 U.S. at 454.

2. The Ninth Circuit's decision below turns that straightforward reasoning on its head. Indeed, the court of appeals affirmed state tort liability for failing to include a cancer warning on Roundup labeling—a warning that EPA has concluded *would itself be a violation of FIFRA*. As EPA stated in a 2019 letter to registrants of pesticides containing glyphosate:

> Given EPA's determination that glyphosate is "not likely to be carcinogenic to humans," EPA considers the [cancer] warning language based on the chemical glyphosate to constitute a false and misleading statement. As such, pesticide products bearing the * * * warning statement due to the presence of glyphosate are misbranded pursuant to section 2(q)(1)(A) of FIFRA.

Pet. App. 196a.

Monsanto is thus placed in exactly the sort of Catch-22 that the Supremacy Clause and FIFRA's preemption provision are supposed to protect against: California law says it *must* warn of alleged cancer risks from glyphosate, while federal law—as interpreted and applied by the expert agency in charge of pesticides—says it *must not* include such a warning. That result cannot stand. See, *e.g.*, *Mutual Pharm. Co.* v. *Bartlett*, 570 U.S. 472, 486 (2013) ("When federal law forbids an action that state law requires, the state law is 'without

effect.'") (quoting *Maryland* v. *Louisiana*, 451 U.S. 725, 746 (1981)).

3. The court of appeals concluded otherwise, but could only do so by conducting the parallel-requirements inquiry at too high a level of generality. That is, rather than looking to whether California's tort duties are "*in fact* * * * equivalent" to FIFRA's requirements, as *Bates* instructs (544 U.S. at 453 (emphasis added)), the Ninth Circuit looked only to the "*elements* of California's duty to warn and FIFRA's misbranding provision," comparing the two in the broadest of terms. Pet. App. 13a-14a (emphasis added).

That incorrect focus also meant that the court looked past the most glaringly important facts in this case: that EPA has "repeatedly registered Roundup for sale without a cancer warning on the label" (Pet. App. 14a); has renewed its conclusion that glyphosate is "not likely to be carcinogenic to humans" after a "systematic review" of all "available evidence" (EPA, *Revised Glyphosate Issue Paper* 13, 138-144 (Dec. 12, 2017), tinyurl.com/eparevdglyphosate); and recently issued correspondence to registrants affirmatively informing them that labels warning of cancer risk "due to the presence of glyphosate *are misbranded*" under FIFRA (Pet. App. 196a (emphasis added)). Under any reasonable interpretation of the text, those facts are highly relevant to determining whether California tort law's demand of a cancer warning is "in addition to or different from" the labeling requirements of FIFRA—the statute implemented and enforced by EPA. 7 U.S.C. § 136v(b).

But the court of appeals dismissed those key facts because, in its view, EPA's registration decisions are "not conclusive of FIFRA compliance," and EPA's 2019 letter does not "carry the force of law." Pet App. 14a-15a. These objections miss the mark. Even if registra-

tion is not *conclusive* of compliance,[2] the court of appeals treated as *irrelevant* to compliance the fact that EPA—the sole entity to which Congress has granted FIFRA enforcement authority (see, *e.g.*, *No Spray Coal.* v. *City of New York*, 252 F.3d 148, 150 (2d Cir. 2001))—has repeatedly registered Roundup's label under FIFRA and has specifically rejected the need for the warning California tort law has required here. It was error for the court of appeals to determine that "Hardeman's state failure-to-warn claims are 'equivalent to' and 'fully consistent with' FIFRA" (Pet. App. 17a) without paying *any* heed to the considered views of the relevant expert agency on the exact question before the court. Cf. *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 883 (2000) ("plac[ing] some weight" on agency's informal interpretation of statute's preemptive reach).

Moreover, as Monsanto explains, the Ninth Circuit's elements-only approach to determining whether a state cause of action merely "seeks to enforce a federal requirement" (*Bates*, 544 U.S. at 448), brings it into

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[2] The court of appeals believed that this fact, based upon FIFRA's provision that "registration" establishes "prima facie evidence" of compliance rather than a complete "defense" to FIFRA liability (7 U.S.C. § 136a(f)(2)), "distinguishes this case from" cases evaluating preemption under the Food, Drug, and Cosmetics Act (FDCA) and its Medical Device Amendments (MDA), because those statutes do not contain a similar provision. Pet. App. 14a & n.6. To the contrary, however, a drug or device may be misbranded under federal law, notwithstanding FDA approval of its label, "based on new and scientifically significant information that was not before the FDA" at the time of approval. *Mutual Pharm. Co.*, 570 U.S. at 487 n.4 (citing 21 U.S.C. § 352(j)). So FDA approval is similarly "not dispositive of [FDCA] compliance" in all cases (cf. Pet. App. 15a), yet "when a claim challenges a [labeling] representation that the FDA blessed in the approval process, it is preempted" (*Wildman* v. *Medtronic, Inc.*, 874 F.3d 862, 868 (5th Cir. 2017)). The attempt to distinguish the FDCA cases therefore falls flat.

conflict with the other federal courts that instead consider whether the plaintiff has pleaded or established an actual *violation* of the relevant federal statute. Pet. 18-20; see, *e.g.*, *Brooks* v. *Mentor Worldwide LLC*, 985 F.3d 1272, 1279 (10th Cir. 2021) ("[T]o survive preemption, a plaintiff must plead conduct that * * * *violates the FDCA* (because state law may not impose additional or different duties).") (emphasis added); *Bass* v. *Stryker Corp.*, 669 F.3d 501, 510 (5th Cir. 2012) (concluding that plaintiff "has sufficiently pleaded parallel claims * * * to the extent that the claims are based upon * * * violations of federal regulations"); *Wolicki-Gables* v. *Arrow Int'l, Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011) ("To properly allege parallel claims, the complaint must set forth facts pointing to specific [federal] requirements *that have been violated*.") (quotation marks omitted; emphasis added); *Burrell* v. *Bayer Corp.*, 918 F.3d 372, 379 (4th Cir. 2019) (explaining that plaintiffs' "state-law claims would be preempted unless Bayer *had violated* parallel federal duties.") (emphasis added); cf. *McMullen* v. *Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005) ("State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law."). The Ninth Circuit did not require plaintiffs to make any such showing.

The Ninth Circuit's decision here thus injects further uncertainty into an area in which the lower courts' decisions are already in some disarray. The Court should take this opportunity to provide guidance on parallel-claim preemption before the doctrine becomes even more muddled by the Ninth Circuit's decision below.

4. Finally, the court of appeals' ruling conflicts with the Court's guidance on preemption for federally regu-

lated businesses attempting to comply with state tort duties.

As the Court has explained in the context of FDA-regulated drug labeling, state-law duties to change a product's federally approved label are preempted unless "the private party could *independently* do under federal law what state law requires of it." *PLIVA, Inc.* v. *Mensing*, 564 U.S. 604, 620 (2011) (emphasis added); see also *Mutual Pharm.*, 570 U.S. at 486-487. That is, "[t]he question" is whether the regulated party is free to change its label "unilaterally"; if instead it must "ask[]" the government to approve any proposed change before making it, compliance with the state requirement is impossible, and the state requirement is preempted. *Ibid.*

The court of appeals attempted to distinguish *PLIVA* on the grounds that "pesticide manufacturers are responsible for drafting their own product labels"; that "the manufacturer has a continuing obligation to adhere to FIFRA's labeling requirements"; and that "[w]hen a label needs to be changed, the manufacturer has the responsibility to change the label by drafting and submitting the label to EPA for approval." Pet. App. 20a (quotation marks omitted). But each of these propositions is true of drug labeling under the FDCA as well. See *Merck Sharpe & Dohme Corp.* v. *Albrecht*, 139 S. Ct. 1668, 1677 (2019) ("A drug manufacturer is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market. Thus, when the risks of a particular drug become apparent, the manufacturer has a duty to provide a warning that adequately describes that risk.") (citation and quotation marks omitted). The purported distinctions thus all fall flat.

The Ninth Circuit also pointed to a provision that permits manufacturers to "make minor modifications

to labeling without prior EPA approval if EPA is notified of the change." Pet. App. 20a; see 40 C.F.R. § 152.46(a) (providing for notification procedure and subsequent EPA action to approve or deny the change). First, as Monsanto points out, EPA's guidance on this procedure specifically provides that changes to "precautionary statements"—like the cancer warning California law requires here—may *not* be accomplished by this means. See Pet. 24.

Even if they could be, the FDCA includes a similar notification procedure for minor changes, and this Court has explained that its existence does not preclude impossibility preemption so long as the government agency is "fully informed * * * of the justifications for the warning required by state law" and the agency "in turn, informed the [regulated party] that [it] would not approve changing the * * * label to include that warning." *Merck*, 139 S. Ct. at 1678. Those requirements are more than satisfied by the actions EPA took in response to concerns about glyphosate's alleged carcinogenic potential here. See Pet. App. 195a-196a (discussing the "systematic review" that led to EPA's conclusion "that glyphosate 'is not likely to be carcinogenic to humans,'" and informing registrants that "pesticide products bearing [cancer warnings] due to the presence of glyphosate are misbranded" under FIFRA).

In sum, the court of appeals appears to have missed the preemptive forest for the trees. By conducting its parallel-requirements analysis at too high a level of generality and steadfastly refusing to consider EPA's actions, the Ninth Circuit has affirmed a judgment imposing liability for failure to include a warning that EPA—the sole entity with authority to implement and enforce FIFRA—has repeatedly, recently, and conclusively determined is not only unnecessary, but actually illegal under federal law. Whether analyzed under

express or conflict preemption, that outcome simply cannot be correct. See, *e.g.*, *Mutual Pharm.*, 570 U.S. at 486 ("When federal law forbids an action that state law requires, the state law is 'without effect.'") (quoting *Maryland*, 451 U.S. at 746). The Court should grant certiorari to correct this anomalous result and bring much-needed clarity to this important component of federal preemption jurisprudence.

II. The Court should resolve the conflicting constructions of the *Daubert* standard.

Certiorari is also warranted with respect to the court of appeals' application of the expert evidence standards of *Daubert* and Federal Rule of Evidence 702. As the district court recognized, the Ninth Circuit applies (and applied here) a more lenient interpretation of those standards than the one that obtains in other circuits, throwing the uniform nationwide administration of justice into disarray. The Court should grant certiorari to address this acknowledged circuit conflict in a critically important area of federal procedure.

A. Consistent nationwide evidentiary standards are essential, particularly in the mass tort context presented here.

The gatekeeping function of the district courts in screening out unreliable scientific and other expert evidence, as prescribed by Rule 702 and *Daubert*, is a matter of critical significance to the proper functioning of the federal judicial system. Indeed, "[t]he importance of *Daubert*'s gatekeeping requirement cannot be overstated." *United States* v. *Frazier*, 387 F.3d 1244, 1260 (11th Cir. 2004); accord, *e.g.*, *Dodge* v. *Cotter Corp.*, 328 F.3d 1212 (10th Cir. 2012) (noting "the fundamental importance of properly performing the gatekeeper function.").

1. The importance of *Daubert* and its assurance of reliable expert testimony only continues to increase as modern trials become more and more reliant on expert witnesses. "[S]cience in all its forms—hard science, soft science, even so-called 'junk' science—has in recent years invaded the courtroom to an unparalleled extent." Hon. Jed S. Rakoff, *Science and the Law: Uncomfortable Bedfellows*, 38 Seton Hall L. Rev. 1379, 1379 (2008). Indeed, "[s]cientific issues" now "permeate the law." Hon. Stephen Breyer, *Introduction*, *in* Federal Judicial Center, *Reference Manual on Scientific Evidence* 3 (3d ed. 2011); see also *General Elec. Co.* v. *Joiner*, 522 U.S. 136, 148-149 (1997) (Breyer, J., concurring) (because "modern life * * * depends upon the use of artificial or manufactured substances, such as chemicals," it is "particularly important to see that judges fulfill their *Daubert* gatekeeping function, so that they help assure that the powerful engine of tort liability * * * points toward the right substances and does not destroy the wrong ones."). The failure of courts to take science seriously, and to welcome only reliable expert testimony into the judicial process, undermines the judicial system and injures the parties—including but not limited to business defendants—who depend on that system for fair and accurate determinations of legal liability.

As this case itself demonstrates, unreliable expert testimony sometimes is the only evidence on which a multimillion dollar award of damages rests. But even when other evidence is available, expert evidence often has an oversized impact on the jury. The Federal Rules "grant expert witnesses testimonial latitude unavailable to other witnesses" (*Kumho Tire Co.* v. *Carmichael*, 526 U.S. 137, 148 (1999)), allowing them to offer "opinions * * * that are not based on firsthand knowledge or

observation" (*id.*), including opinions on the "ultimate issue" in a case (Fed. R. Evid. 704(a)). Experts are granted this authority even though their "testimony often will rest upon an experience confessedly foreign in kind to [the jury's] own." *Kumho*, 526 U.S. at 149 (quotation marks omitted). As a result, "[e]xpert evidence can be both powerful and quite misleading because of the difficulty in evaluating it." *Daubert*, 509 U.S. at 595.

Because expert testimony can have such a disproportionate influence on juries, the admission of unreliable expert testimony often imposes hydraulic pressure on the rest of the litigation. Defendants that confront adverse expert rulings are often compelled to settle, rather than take their chances with a jury, even when there are real doubts about the science involved. See Margaret A. Berger, *The Admissibility of Expert Testimony*, *in* Federal Judicial Center, *Reference Manual on Scientific Evidence* 19 (3d ed. 2011) ("[A]n inability by the defendant to exclude plaintiffs' experts undoubtedly affects the willingness of the defendant to negotiate a settlement."); Rakoff, *supra*, at 1391 (recounting that in a mass pharmaceutical products liability action, "shortly after my [*Daubert*] decision came down, most of the 800 cases settled, for amounts that seemingly reflected the mid-point nature of what I allowed in the way of expert testimony.").

In multi-plaintiff toxic tort and product liability cases in particular, if the plaintiffs' expert testimony is admitted, "a defendant often feels irresistible pressure to settle the action rather than risk a battle of the experts at trial that, if the defendant loses, can cost exponentially more than the settlement cost of the action." Christopher R.J. Pace, *Admitting and Excluding General Expert Testimony: The Eleventh Circuit Construct*, 37 Am. J. Trial Advoc. 47, 48 (2013). Indeed,

such "plaintiffs' likelihood of success is commonly driven by the admissibility of their experts' general causation testimony under Rule 702 of the Federal Rules of Evidence and *Daubert*." *Ibid.*

In other words, as one court of appeals recently explained, the "risk" of "exposing jurors to 'dubious scientific testimony' that can ultimately 'sway[]' their verdict * * * is notably amplified in products liability cases, for 'expert witnesses necessarily must play a significant part' in establishing or refuting liability." *Sardis* v. *Overhead Door Corp.*, __ F.4th ___, 2021 WL 3699753, at *1 (4th Cir. Aug. 20, 2021) (first quoting *Nease* v. *Ford Motor Co.*, 848 F.3d 219, 231 (4th Cir. 2017), then quoting *Chace* v. *General Motors Corp.*, 856 F.2d 17, 20 (4th Cir. 1988)). This case thus presents an excellent vehicle to reach an issue that—while undoubtedly important—in many instances is not fully litigated through verdict or appeal due to settlement pressure.

2. Not only are the stakes of the *Daubert* decision generally higher in the mass tort and product liability contexts than elsewhere, but the consequences of disuniformity in the governing standards is felt more acutely in this area as well. Plaintiffs' attorneys may often steer putative nationwide classes to courts in circuits with an unusually lenient standard for admitting expert evidence, thereby frustrating the uniform administration of justice. Or, if cases are consolidated and assigned using the multi-district litigation mechanism, the result is that the governing evidentiary standard—which can frequently be dispositive of liability (see Pace, *supra*)—is left up to that procedural device.

That is no way to run a legal system whose ultimate end is justice and predictability. Nor a legal system in which tens of millions of dollars are at stake in

each individual case. See Pet. App. 10a-11a (affirming compensatory and punitive damages award of over $25 million). The Court should take this opportunity to restore nationwide uniformity in the application of *Daubert* and Rule 702.

B. The Ninth Circuit's approach to *Daubert* for medical causation conflicts with other circuits, and leads to peculiar results.

1. As the district court below recognized, the Ninth Circuit applies the *Daubert* standard more expansively than other circuits in medical causation cases.

In reaching its conclusions about the admissibility of plaintiff's evidence, the district court repeatedly observed that "the opinions 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." Pet. App. 84a (comparing *Wendell* v. *GlaxoSmithKline LLC*, 858 F.3d 1277, 1233-1237 (9th Cir. 2017), and *Messick* v. *Novartis Pharm. Corp.*, 747 F.3d 1193, 1198-1199 (9th Cir. 2014), with *In re Lipitor Mktg., Sales Practices & Prods. Liab. Litig.*, 892 F.3d 624, 644-645 (4th Cir. 2018), and *Tamraz* v. *Lincoln Elec. Co.*, 620 F.3d 665, 677-678 (6th Cir. 2010)).

That is, the district court explained, "district judges * * * must account for the fact that a wider range of expert opinions (arguably much wider) will be admissible in this circuit" than elsewhere. Pet. App. 84a; see also *id.* at 83a ("[T]here [is no] evidence suggesting that NHL presents differently when caused by exposure to glyphosate. Under a strict interpretation of *Daubert*, perhaps that would be the end of the line for the plaintiffs and their experts (at least without much stronger epidemiological evidence). But in the Ninth Circuit that is clearly not the case."); *id.* at 93a (noting

that "Ninth Circuit case law" required it to admit expert testimony "confidently identif[ying] a causal link" between glyphosate and cancer, even though "the evidence of [that] causal link * * * seems rather weak" and "the largest and most recent[] [studies] suggest there is no link at all.").

In short, the district court has identified precisely the sort of inter-circuit variance in evidentiary standards that is untenable, and thus requires intervention from this Court. And the district court is not alone in its view of the Ninth Circuit's law. See Hon. Thomas D. Schroeder, *Toward a More Apparent Approach to Considering the Admission of Expert Testimony*, 95 Notre Dame L. Rev. 2039, 2050 (2020) ("Ninth Circuit caselaw appears to interpret *Daubert* as liberalizing the admission of expert testimony, which may explain decisions from that circuit that set it apart from most others.").

2. The court of appeals below denied that its standard was any different than that of other circuits (see Pet. App. 24a), but its attempts to distinguish the cases cited by the district court do not stand up to scrutiny.

For example, in *Tamraz* the Sixth Circuit rejected expert testimony attempting to prove causation through differential diagnosis as speculative, *notwithstanding* the expert's "extensive experience with diagnosing" the relevant disease. *Tamraz*, 620 F.3d at 673 (quotation marks and ellipsis omitted); see also *id.* at 674 ("[S]imply claiming that an expert used the 'differential diagnosis' method is not some incantation that opens up the *Daubert* gate.") (quotation marks omitted). Meanwhile, under the Ninth Circuit's approach, "*Daubert* poses no bar" to admitting doctors' causation testimony so long as they "have extensive clinical experience with the rare disease * * * at issue, [and] are

prepared to give expert opinions supporting causation." Pet. App. 26a-27a (quoting *Wendell*, 858 F.3d at 1237); see also *id.* at 27a (citing *Messick*, 747 F.3d at 1198, as "allowing 'extensive clinical experience' to form the basis of [a] differential diagnosis opinion."). That is not the same standard.

Similarly, the Fourth Circuit has explained that the fact "[t]hat [a drug] may cause an increased risk of [a disease] notwithstanding certain other risk factors *is insufficient* to conclude that the drug was a substantial contributing factor in an individual patient" through differential diagnosis. *In re Lipitor*, 892 F.3d at 644 (emphasis added). Yet the Ninth Circuit stated that an expert "*could* conclude" that a substance "was a substantial cause because 'literature show[ed] that patients exposed to' the drugs in question were 'at an increased risk for' the disease"—and thus upheld the admission of plaintiff's causation expert on the ground that "an expert *can* rule out idiopathy by reliably concluding that * * * a strong association exists between the disease and [a] known risk factor" (here, glyphosate). Pet. App. 34a (emphases added) (citing *Wendell*, 858 F.3d at 2135, 1237). Once again, the Ninth Circuit's causation jurisprudence has gone down an entirely different path than that of the other courts of appeals.

Indeed, the Ninth Circuit's approach allowed the district court to permit admittedly "shaky" general causation evidence (Pet. App. 79a) to be bootstrapped into serving as the primary *specific* causation evidence supporting the notion that glyphosate, rather than an idiopathic cause, was the root of plaintiff's cancer. *Id.* at 84a-85a ("Relying on the plaintiffs' admissible general causation opinions—which assert a robust connection between glyphosate and NHL—the experts concluded that glyphosate was a substantial factor in

causing the plaintiffs' NHL."). In the Fourth Circuit's words, this approach essentially "obviate[s] the need for any specific causation evidence at all" (*In re Lipitor*, 892 F.3d at 644), contrary to the district court's proper gatekeeping function under *Daubert*.

3. Finally, the Ninth Circuit's anomalous approach to expert causation evidence is of exceptional importance given the frequency of medical expert testimony on causation. The cases involving such testimony are legion: A Westlaw search for federal court decisions discussing both "differential diagnosis" and "*Daubert*" returned nearly 1,500 hits.

Moreover, because of the geographic size and enormous population of the Ninth Circuit, its aberrant decision in particular will have significant consequences for businesses seeking to defend their rights to proper judicial gatekeeping under *Daubert*. And that is to say nothing of the importance of this case itself: As Monsanto points out, "the district court has stated it will apply the Ninth Circuit's *Daubert* standard in *all* the MDL cases (wherever they originated), despite that standard's 'relatively higher tolerance for questionable expert testimony.'" Pet. 35 (quoting Dkt. 4549 at 3-4, *In re Roundup*, No. 3:16-md-02741-VC (N.D. Cal. July 10, 2019)). Thus, the decision below sets the evidentiary standard for cases resolving billions of dollars of damages claims in this one setting alone. The Court should not allow the Ninth Circuit's flawed application of *Daubert* to stand.

CONCLUSION

The Court should grant the petition.

Respectfully submitted.

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