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 ATLANTIC LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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INTEREST OF THE *AMICUS CURIAE* [1]

Established in 1977, the Atlantic Legal Foundation (atlanticlegal.org) is a national, nonprofit, public interest law firm whose mission is to advance the rule of law and civil justice by advocating for individual liberty, free enterprise, property rights, limited and efficient government, sound science in judicial and regulatory proceedings, and school choice. With the benefit of guidance from the distinguished legal scholars, corporate legal officers, private practitioners, business executives, and prominent scientists who serve on its Board of Directors and Advisory Council, the Foundation pursues its mission by participating as *amicus curiae* in carefully selected appeals before the Supreme Court, federal courts of appeals, and state supreme courts.

The Foundation is widely recognized for its efforts to keep unreliable science out of courtrooms. For example, on behalf of esteemed scientists such as Nicholaas Bloembergen (a Nobel laureate in physics) and Bruce Ames (one of the world's most frequently cited biochemists), the Foundation submitted amicus briefs in each of the "*Daubert* trilogy" of cases—

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[1] Petitioner's and Respondent's counsel of record were provided timely notice in accordance with Supreme Court Rule 37.2(a), and have consented to the filing of this brief. In accordance with Supreme Court Rule 37.6, *amicus curiae* Atlantic Legal Foundation certifies that no counsel for a party authored this brief in whole or part, and that no party or counsel other than the Foundation and its counsel made a monetary contribution intended to fund its preparation or submission.

Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993); *General Electric Co. v. Joiner*, 522 U.S. 136 (1997); and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999)—concerning admissibility of expert testimony under Federal Rule of Evidence 702. In *Daubert*, 509 U.S. at 590, the Court quoted the Foundation's brief on the meaning of "scientific . . . knowledge" as used in Rule 702(a).

The Foundation also long has advocated for judicial enforcement of express preemption provisions intended to achieve and maintain national uniformity of regulation, especially with regard to the labeling of products which if misused, are potentially hazardous. States should not be permitted, either through statutory or regulatory enactments, or by means of tort law, to flout federal regulatory statutes' preemption provisions and thereby undermine congressionally mandated, nationally uniform, science-based regulation of products such as Roundup, the widely used residential and agricultural herbicide involved in this appeal.

Petitioner Monsanto Company's appeal falls squarely within the Atlantic Legal Foundation's sound-science-in-the-courtroom mission. Both of the questions presented implicate the vital role played by expert federal regulatory agencies—here, the Environmental Protection Agency (EPA)—entrusted with the responsibility for regulating nationally uniform, product-specific health and safety warnings that are based on extensive review of reliable scientific data.

The Foundation is submitting this brief to urge the Court to grant review and clarify its jurisprudence concerning the "parallel requirements" exception to the express preemption provision contained in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136v(b), which broadly prohibits States from imposing labeling requirements that are "in addition to or different from" federal requirements. The Court also should grant review to reinforce federal district judges' crucial gatekeeper role under Rule 702 and the *Daubert* line of cases, and to address the close relationship between that gatekeeper responsibility and due process.

SUMMARY OF ARGUMENT

In *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005), the Court recognized the "important role" that FIFRA's express preemption provision, 7 U.S.C. § 136v(b), plays in achieving and maintaining a system of nationally uniform, product-specific pesticide labeling, whose content, including health and safety warnings, is regulated solely by EPA. *Id.* at 452 (explaining that § 136v(b) "pre-empts competing state labeling standards . . . prescribing the . . . wording of warnings.") As *Bates* holds, state labeling requirements that are "in addition to or different from" EPA's pesticide labeling requirements include those that are imposed through common-law failure-to-warn claims. State-law failure-to-warn claims—such as the cancer-related failure-to-warn claims upon which this bellwether litigation, and thousands of other Roundup suits, are premised—not

only "set a standard for a product's labeling" in contravention to § 136v(b), *id.* at 446, but also undermine EPA's scientifically based determinations as to what specific warnings are, and are not, warranted on a particular pesticide product's labeling. False, misleading, or unnecessary health and safety warnings on pesticide labels are deleterious. They discourage use of highly beneficial products such as Roundup, and detract from warnings and precautionary statements that truly are needed to protect health and the environment.

It is difficult to imagine a more clear-cut case for FIFRA preemption of state-law failure-to-warn claims than Roundup. The Petition explains that EPA not only has exhaustively reviewed scientific studies on glyphosate (the active ingredient in Roundup) and concluded that it does not cause cancer in humans, but also has squarely rejected the addition of a cancer warning on Roundup labeling. EPA even notified Monsanto that such a warning would be false and misleading and in violation of FIFRA's prohibition against distribution of misbranded products. *See* Pet. at 6-9.

The Ninth Circuit erroneously held that Respondent's state-law failure-to-warn claims are not preempted because California's common-law duty to warn is "parallel" to FIFRA's broadly worded definition of "misbranded." App. 13a. This cursory comparison conflicts with the guidance that the Court provided in *Bates*, which requires a court to undertake a rigorous "equivalency" analysis by considering any

EPA regulations that give content to FIFRA's general misbranding standards, and in so doing, take into account the scientifically based, product-by-product manner in which EPA actually regulates pesticide labeling. If the Ninth Circuit is correct that FIFRA preemption does not apply—thereby leaving individual juries free to impose their own requirements for pesticide label warnings—wherever a State's common-law duty to warn merely is consistent with FIFRA's general prohibition against distributing misbranded pesticides, there would be virtually nothing left to § 136v(b), and Congress' preemptive intent would be thwarted.

The Court should grant review to clarify that § 136v(b) applies—and the "parallel requirements" exception does not—where, as here, EPA has determined that a particular label warning is unwarranted and will not be allowed. A state-law requirement for inclusion of a cancer warning on a federally regulated pesticide product's label cannot be parallel or equivalent to, or in any way consistent with, an EPA requirement *prohibiting* such a warning on that product's label. In accordance with the EPA regulations and policies that implement FIFRA's general misbranding standard, the Agency would have classified Roundup as a "restricted use pesticide" for use only by certified applicators, and required a prominent warning statement on Roundup's labeling, if it had determined that glyphosate poses a risk of cancer in humans. Section 136v(b), therefore, expressly preempts state-law tort claims based on

Monsanto's "failure" to provide a cancer warning on Roundup's labeling.

Review also should be granted so that the Court can address the inexorable relationship between district courts' gatekeeper role under Federal Rule of Evidence 702, and the fundamental due process requirement for a fair trial. Where, as here, a district court shirks its gatekeeper duty by allowing unreliable expert testimony to mislead, confuse, and prejudice a jury, a defendant is deprived of due process. As is the case here, this can result in an unfair trial and an unwarranted award of tens of millions of dollars in compensatory and punitive damages. Unlike the Ninth Circuit's lax approach to Rule 702 and the *Daubert* trilogy's teaching, other circuits strictly enforce a district court's gatekeeper responsibility. *See, e.g.*, *Sardis v. Overhead Door Corp.*, No. 20-1411, 2021 WL 3699753, at *6 (4th Cir. Aug. 20, 2021) (holding that a district court in a wrongful death suit "abdicated its critical gatekeeping role to the jury and admitted . . . expert testimony without engaging in the required Rule 702 analysis").

The fact that the Ninth Circuit's decision was rendered here in the context of multidistrict litigation encompassing thousands of Roundup claimants greatly magnifies the need for this Court to intercede and address both questions presented.

ARGUMENT

A. The Court should grant review to clarify that under § 136v(b) of FIFRA, a state requirement for labeling is not "parallel" or "equivalent" to federal requirements for labeling if it mandates a label warning that EPA has determined is scientifically unwarranted

1. Under the heading "Uniformity," FIFRA broadly prohibits a State from imposing "any requirements for labeling" that are "in addition to or different from" those imposed under the Act. 7 U.S.C. § 136v(b). "[S]purred by growing environmental and safety concerns," *Bates*, 544 U.S. at 437, Congress, as part of an extensive overhaul of FIFRA in 1972, added § 136v(b) to the Act in order "to completely preempt State authority in regard to labeling." H.R. Rep. No. 92-511, at 16 (1971); *see Bates*, 544 U.S. at 437-40 (discussing FIFRA's legislative history); *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991, 992 (1984) (explaining that the 1972 amendments transformed FIFRA into "a comprehensive regulatory statute" and "gave EPA greater enforcement authority"). Of particular relevance here, the amendments "significantly strengthened FIFRA's registration and labeling standards." *Wisconsin Pub. Intervenor v. Mortier,* 501 U.S. 597, 601 (1991).

To establish "a coordinated Federal-State administrative system" for the regulation of pesticides, H.R. Rep. No. 92-511, at 1, Congress allowed the States to retain a "supplementary role."

Bates, 544 U.S. at 442; *see* 7 U.S.C. § 136v(a) ("A State may regulate the sale or use of any federally registered pesticide . . . ."); *see also Mortier*, 501 U.S. at 614 (discussing § 136v(a)). For example, States have "primary enforcement authority for pesticide use violations." 7 U.S.C. § 136w-1(a); *see id.* § 136j(a)(2)(G) (making it unlawful "for any person . . . to use any registered pesticide in a manner inconsistent with its labeling"). Congress vested EPA, however, with exclusive authority to regulate the *content* of pesticide labeling. *See Mortier*, 501 U.S. at 615 (regulation of pesticide labeling "fall[s] within an area that FIFRA's 'program' pre-empts.").

2. Although *only* EPA has authority to regulate the content of pesticide labeling, the Court noted in *Bates* that "[n]othing in the text of FIFRA would prevent a State from making the violation of a *federal* labeling . . . requirement a state offense, thereby imposing its own sanctions on pesticide manufacturers who violate *federal* law." 544 U.S. at 442 (emphasis added). States can (and do) enforce their own statutes and regulations requiring pesticide manufacturers to comply with *federal* labeling requirements. *See id.* ("The imposition of state sanctions for violating state rules that *merely duplicate federal requirements* is equally consistent with the text of § 136v.") (emphasis added). For example, if a pesticide manufacturer failed to comply with an EPA requirement that a particular pesticide product's label include the signal word "CAUTION," a State (as well as EPA) could impose sanctions on the manufacturer (e.g., fines;

cancellation of the product's state registration) for violating that federal labeling requirement.

Section 136v(b), however, expressly preempts a State from imposing its own additional or different (i.e., divergent) requirements for the content of a pesticide's labeling. Preempted state requirements for labeling not only include those imposed by state statutes and regulations, but also through state common-law failure to warn claims. *See Bates,* 544 U.S. at 453 ("[T]he term 'requirements' in § 136v(b) reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties."); *id.* at 446 ("negligent-failure-to-warn claims are premised on common-law rules that qualify as 'requirements for labeling' . . . they set a standard for a product's labeling that the . . . label is alleged to have violated by containing . . . inadequate warnings"). Therefore, § 136v(b) "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." *Id.* at 453.

For example, as the Court explained in *Bates*, "a failure-to-warn claim alleging that a given pesticide's label should have stated 'DANGER' instead of the more subdued 'CAUTION' would be pre-empted" if EPA required CAUTION rather than DANGER on the product's label. *Id.* Any such state-law failure-to-warn claim would "set a standard for a product's labeling," *id.* at 446, that is "in addition to or different from" the specific labeling requirements imposed by EPA for that product. "While States are free to impose

liability predicated on a violation of the *federal* standards set forth in FIFRA and in any accompanying regulations promulgated by the Environmental Protection Agency, they may not impose liability for labeling requirements predicated on distinct *state* standards of care." *Id.* at 454 (Thomas, J., concurring) (emphasis added).

3. Section 136v(b)'s express prohibition against state labeling requirements that are "in addition to or different from" those imposed under FIFRA establishes EPA's exclusive authority to regulate the content of pesticide labeling, including determining what health-related warnings should—and should not—be provided. Although the Court held in *Bates*, *id.* at 447, that "a state-law labeling requirement is not pre-empted by § 136v(b) if it is equivalent to, and fully consistent with, FIFRA's misbranding provisions," it is implausible that Congress intended this implied exception to swallow the preemption provision itself. Instead, the Court's "'parallel requirements' reading of § 136v(b)" merely enables States to provide a remedy (in the absence of a federal remedy) to pesticide users "who are injured as a result of a manufacturer's violation of FIFRA's labeling requirements." *Id.* at 447, 448; *cf. Medtronic, Inc. v. Lohr*, 518 U.S. 470, 513 (1996) (O'Connor, J., concurring in part and dissenting in part) ("Section 360k [of the FDCA Medical Device Amendments] does not preclude States from imposing different or additional *remedies*, but only different or additional *requirements*").

For example, if an agricultural worker is injured because a pesticide's manufacturer distributes the product with labeling that fails to include an EPA-required statement mandating use of personal protective equipment, § 136v(b) would not preempt a state-law liability suit based on the manufacturer's violation of that EPA-imposed labeling requirement. *See id.* at 451 ("Private remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of FIFRA."). But § 136v(b) *would* preempt a liability suit based on the manufacturer's failure to provide labeling that mandates use of personal protective equipment if EPA did not impose such a labeling requirement for the product at issue. Any such suit would impose a state-law requirement for labeling that is in addition to or different from—*not* equivalent or parallel to, or consistent with—FIFRA's labeling requirements as implemented by EPA for that product, and therefore, would fall within §136v(b)'s preemptive scope.

Further, *Bates* repeatedly qualifies the Court's "concept of equivalence." *Id.* at 454. The Court "emphasize[d] that a state-law labeling requirement must in fact be equivalent to a requirement under FIFRA in order to survive pre-emption." *Id.* at 453. "[N]ominally equivalent [state-law] labeling requirements" are not enough; they must be "*genuinely* equivalent" to avoid preemption. *Id.* at 454. Equally important, "[s]tate-law requirements must also be measured against any relevant EPA

regulations that give content to FIFRA's misbranding standards." *Id.* at 453.

4. Despite these admonitions, the Ninth Circuit held here that "FIFRA does not expressly preempt Hardeman's claims because FIFRA's requirement that a pesticide not be misbranded is consistent with, if not broader than, California's common law duty to warn." App. 11a. Based on this superficial comparison, the court of appeals held that "[b]ecause FIFRA's misbranding requirements parallel those of California's common law duty, Hardeman's failure-to-warn claims effectively enforce FIFRA's requirement against misbranding and are thus not expressly preempted." *Id.* 13a.

As the Petition explains, however, assessing the equivalence of state and federal labeling requirements at such a high level of generality not only conflicts with *Bates*, but also renders § 136v(b) virtually meaningless. It destroys the nationwide, product-by-product labeling uniformity that Congress sought to achieve through § 136v(b). *See* Pet. at 14-15.

The state common-law duty on which Respondent's failure-to-warn claims are predicated—a requirement to include a cancer warning on Roundup's EPA-regulated and approved labeling—cannot possibly be "in fact" or "genuinely" equivalent to, or in any way consistent with, EPA's carefully considered, scientifically based requirements for Roundup labeling. This is because, as the Petition discusses, "[f]or decades, EPA has studied the enormous body of science on glyphosate and repeatedly concluded that

glyphosate does not cause cancer in humans." Pet. at 2.

Indeed, EPA took the extraordinary step of "informing glyphosate registrants that EPA would not approve labels of glyphosate-based products that included a cancer warning," and that any such label warning would be "false and misleading," and thus would render the product misbranded. *Id.* at 8; *see* App. 195a (EPA letter stating that glyphosate products accompanied by labeling that includes a California-required cancer warning "are misbranded . . . and as such do not meet the requirements of FIFRA"). Any such state-law labeling requirement that would violate FIFRA's misbranding prohibition necessarily would be "in addition to or different from" EPA's requirements for labeling, and therefore, expressly preempted. *See generally* 40 C.F.R. § 152.112(f) ("EPA will approve an application [for registration of pesticide product] . . . only if . . . the Agency has determined that the product is not misbranded . . . .").

According to the Ninth Circuit's opinion, "if a violation of California's duty to warn would also be a violation of FIFRA's misbranding provision, then they impose parallel requirements fully consistent with each other." App. 12a. (citing *Bates*, 544 U.S. at 454). But here, exactly the opposite is true: EPA has determined that *compliance* with a state-law duty to provide a label warning about Roundup's alleged cancer risk would violate FIFRA's misbranding provisions. *See* App. 195a. Such a state-law duty,

therefore, would impose labeling requirements that are in addition to or different from, not parallel or equivalent to, or consistent with, EPA's labeling requirements for Roundup.

5. *Bates* points to FIFRA's prohibition against distribution or sale of "misbranded" pesticides merely as the *general* federal standard for pesticide labeling. *Id.* at 447; *see* 7 U.S.C. § 136j(a)(1)(F) (making it unlawful to distribute or sell "any pesticide which is . . . misbranded"); *id.* § 136(q) (multi-part definition of "misbranded," including where a pesticide's label "does not contain a warning . . . adequate to protect health"). The Ninth Circuit's erroneous "parallel requirements" analysis is oblivious to this Court's admonitions in *Bates* that the equivalency of "[s]tate-law requirements also must be measured against any relevant EPA regulations that give content to FIFRA's misbranding standards," and that such a comparison "will necessarily affect the scope of pre-emption under § 136v(b)." 544 U.S. at 453 & 453 n.28; *see also id.* at 454 (Breyer, J., concurring).

The labeling requirements imposed under FIFRA are not limited to "FIFRA's broadly phrased misbranding standards." *Id.* at 453. FIFRA's labeling requirements also include EPA's pesticide labeling regulations, and the Agency's implementing, product-specific labeling determinations, such as its determination that a cancer warning on Roundup labeling is scientifically unwarranted.

When considering EPA regulations that give content to FIFRA's misbranding standards, it is

important to understand that there are many thousands of different FIFRA-registered pesticide products. Individual products differ as to active ingredient, inert ingredient, concentration, and type of formulation. As a result, although EPA has promulgated baseline regulations for pesticide labeling, *see* 40 C.F.R. Part 156, those rules are only where EPA's regulation of pesticide labeling begins. In reality, EPA regulates pesticide labeling on a product-by-product (or active ingredient-by-active ingredient) basis that takes extensive toxicology and other types of EPA-required scientific studies into account. EPA's online *Label Review Manual*, which "compiles existing interpretations of statutory and regulatory provisions and reiterates existing Agency policies" regarding pesticide labeling, reflects the product-specific manner in which EPA's Office of Pesticide Programs regulates the content of pesticide labeling. *EPA Label Review Manual* home page, https://www.epa.gov/pesticide-registration/label-review-manual (last visited Aug. 31, 2021).

The Ninth Circuit's inadequate "parallel requirements" comparison, App. 15a, misplaces reliance on the Third Circuit's post-*Bates* FIFRA preemption opinion in *Indian Brand Farms v. Novartis Crop Protection, Inc.*, 617 F.3d 207 (3rd Cir. 2010). Citing *Bates*, the Third Circuit explained that a court "must look to the *requirements* imposed by FIFRA . . . If equivalency is found between the claim and the statutory text, the Court should determine whether there are 'any EPA regulations that further

refine those general standards in any way that is relevant to petitioners' allegations.'" *Id.* at 222 (quoting *Bates*, 544 U.S. at 453 n.27). In other words, the type of superficial comparison undertaken by the Ninth Circuit between FIFRA's definition of misbranded and California's common-law duty to warn, *see* App. 12a-13a, is *not enough* to establish equivalency for purposes of avoiding FIFRA preemption of failure-to-warn claims.

6. The most relevant EPA labeling regulations for purposes of this litigation pertain to labeling of "restricted use pesticides." Under 7 U.S.C. § 136a(d) (Classification of Pesticides) EPA can classify a product for restricted use, meaning that it can be applied only "by or under the direct supervision of a certified applicator." *Id.* § 136a(d)(1)(C)(ii). EPA's implementing regulations specify that one of the criteria for classifying a pesticide for restricted use is where it "may cause significant . . . chronic or delayed toxic effects on man as a result of single or multiple exposures to the product ingredients or residues"—for example, where EPA determines that despite mitigation measures, use of a pesticide may cause cancer. 40 C.F.R. § 152.170(b)(vi).

The labeling requirements for restricted use pesticides are set forth in a regulation, 40 C.F.R. § 156.10(j)(2), and in greater detail on pages 6-2 through 6-4 of the *Label Review Manual.* If a pesticide product has been classified for restricted use based on EPA's determination that its active ingredient may cause cancer in humans, then a prominent restricted-

use statement must appear at the top of the product's label with warning language specified by EPA. *See Label Review Manual* at 6-3 – 6-4.

Because EPA has determined that glyphosate does not cause cancer in humans, it has not classified Roundup as a restricted use pesticide product. As a result, the label warning requirements for restricted use pesticides that EPA has determined pose a risk of cancer in humans do not apply to Roundup. For this reason, state-law claims based on failure to provide a cancer warning on Roundup's labeling necessarily are "in addition to or different from" EPA's requirements for labeling, and thus, are expressly preempted by § 136v(b).

7. The Court should grant certiorari to clarify its parallel requirements preemption jurisprudence, at least in the context of FIFRA. More specifically, the Court should hold that § 136v(b) expressly preempts a state-law failure-to-warn claim if it is premised on a pesticide manufacturer's failure to provide a particular, product-specific or active ingredient-specific health or safety warning that, as here, EPA has determined is scientifically unwarranted.

As soon as the Court issued *Bates*, the plaintiffs' bar seized upon the Court's parallel requirements exception as a supposedly simple way to circumvent § 136v(b) and avoid preemption of pesticide failure-to-warn claims. *See, e.g.*, Leslie A. Brueckner, *Why Bates Matters: A Response to the Critique of the U.S. Supreme Court's Holding in Bates v. Dow AgroSciences*, 20 BNA Toxics Law Rptr. 784 (Aug. 25,

2005) ("[M]ost failure to warn . . . claims will easily pass this test."). Indeed, some trial courts were quick to hold—contrary to *Bates*, and without waiting for the meticulous district court preemption analysis required by the Court's remand order, *see* 544 U.S. at 453, 454—that a cursory comparison of state common-law duties with FIFRA's multi-part definition of misbranded, or with EPA regulations that merely parrot the definition, is all that is needed for a state-law claim for failure-to-warn, or for false and misleading (i.e., fraudulent) label statements, to be preempted. *See, e.g.*, *Booth v. Bd. of Regents*, No. Civ.A. 7:05-CV-34, 2005 WL 2099246, at *3 (M.D. Ga. Aug. 30, 2005) ("In this case, the requirements that would be imposed by the Georgia law of fraud are consistent with FIFRA."); *Central Valley Fresh Produce, Inc. v. Wilbur-Ellis Co.*, No. 04 CE CG 00542 (Cal. Super. Ct., Fresno Cty., June 30, 2005) ("[H]ere plaintiff's claims of inadequate warnings or instructions on the product label appear to be consistent with FIFRA's misbranding provisions, since the statute expressly forbids false or misleading statements on a product as well as inadequate instructions or warnings.").

The Ninth Circuit's similarly shallow, expansive, and facile reading of the parallel requirements exception creates a gaping loophole that eviscerates FIFRA's preemption provision, as well as directly conflicts with the equivalency assessment required by *Bates*. And the fact that the Ninth Circuit's preemption opinion in this bellwether case, unless

reversed, will govern or influence *thousands* of pending Roundup failure-to-warn suits throughout the nation, *see* Pet. at 3, 35—and also may prompt the filing of future pesticide failure-to-warn suits, especially within the Ninth Circuit, where a multitude of FIFRA-registered agricultural and residential pesticides are used every day—makes the need for this Court's immediate intercession even more compelling.

B. The Court should grant review to reaffirm that a district court's adherence to its gatekeeper role under Federal Rule of Evidence 702 is essential to due process and a fair trial

Due process requires a fair trial. Where, as here, a district court has failed to fulfill its Rule 702 gatekeeper duty by allowing a jury, in accordance with the Ninth Circuit's lenient admissibility standards, to hear plaintiff-side expert testimony that is scientifically unreliable and largely speculative, *see* Pet. at 9-10, 27-29, the resulting juror confusion and prejudice deprives a defendant of due process and a fair trial.

The Petition discusses in detail how the Ninth Circuit has distorted Federal Rule of Evidence 702's expert testimony admissibility standards "beyond recognition in ways that diverge from the standards applied by other circuits." Pet. 27. One of those other circuits is the Fourth Circuit, which in its recent opinion in *Sardis v. Overhead Door Corp.*, *supra* at *6, discusses at length how Rule 702, as interpreted by this Court in the *Daubert* trilogy of cases, and as

amended in light of those precedents, "imposes a special gatekeeping obligation on the trial judge to ensur[e] that an expert's testimony both rests on a *reliable* foundation and is *relevant* to the task at hand" (internal quotation marks omitted).

The Fourth Circuit further explained:

> Federal Rule of Evidence 702 appoints trial judges as "gatekeepers of expert testimony" to protect the judicial process from "the potential pitfalls of junk science." If a trial court abdicates that duty by opening the gate indiscriminately to any proffered expert witness—particularly one with whom it recognizes "legitimate concerns,"—*it risks exposing jurors to "dubious scientific testimony" that can ultimately "sway[ ]" their verdict.* That risk is notably amplified in products liability cases, for "expert witnesses necessarily may play a significant part" in establishing or refuting liability.

Id. at *1 (internal citations omitted) (emphasis added). This is precisely the situation in the present litigation, where the Ninth Circuit, under its lax interpretation of Rule 702, affirmed the district court's decision allowing a runaway jury to hear causation testimony that "rested on little more than subjective intuitions," and on "art" rather than sound science. Pet. at 3, 27.

Exposing a jury to expert testimony that is scientifically unreliable not only violates Rule 702 and conflicts with the *Daubert* line of cases, but also impairs due process. "Evidence that purports to be based on science beyond the common knowledge of the average person that does not meet the judicial standard for scientific validity can mislead, confuse, and mystify the jury." Victor E. Schwartz & Cary Silverman, *The Draining of Daubert and the Recidivism of Junk Science in Federal and State Courts*, 35 Hofstra L. Rev. 217, 220 (2006) (internal quotation marks omitted). Excluding such testimony from the courtroom fosters due process and judicial fairness because "[a]t its core" the battle against unreliable scientific testimony, including what is commonly referred to as junk science, "is ultimately intended to prevent fraud on society and the legal system." Henry P. Sorett, *Junk Science in the States: The Battle Lines*, Atl. Legal Found., Science in the Courtroom Rev. (Autumn 2000), at 31. A trial court's responsibility to act as a gatekeeper that admits *only* expert scientific testimony that is reliable under the standards of Rule 702 is essential to due process. "[F]irm control over the conduct of litigation . . . prevent[s] litigation from . . . being degraded by 'junk science,' appeals to prejudice, runaway jury verdicts, and other justly reprobated abuses of the legal process." *Braun v. Lorillard Inc.*, 84 F.3d 230, 232 (7th Cir. 1996).

"Junk science could be generally defined as scientific testimony based on idiosyncratic, invalid, or

unreliable science, in which the methodologies used are not generally accepted by the relevant scientific community." Thomas G. Gutheil, M.D. & Harold J. Bursztajn, M.D., *Attorney Abuses of Daubert Hearings: Junk Science, Junk Law, or Just Plain Obstruction?,* 33 J. Am. Acad. Psychiatry L. 150 (2005). It is "'the science of things that aren't so.'" Peter Huber, *Junk Science and the Jury*, 1990 U. Chi. Legal F. 251, 276 (1990) (quoting Irving Langmuir, *Pathological Science* (1953)).

Any discussion of how admission of unreliable scientific testimony in jury trials impairs due process must begin with the *Daubert* trilogy—*Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993); *General Electric Co. v. Joiner*, 522 U.S. 136 (1997); and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999). Emphasizing "the 'gatekeeper' role of the trial judge in screening [scientific] evidence" for reliability, *Joiner*, 522 U.S. at 142, "*Daubert* attempts to strike a balance between a liberal admissibility standard for relevant evidence on the one hand and the need to exclude misleading 'junk science' on the other." *United States v. Lavictor*, 848 F.3d 428, 441 (6th Cir. 2017); *see also McKiver v. Murphy-Brown LLC*, 980 F.3d 937, 1008 (4th Cir. 2020) (*Daubert* "attempted to ensure that courts screen out junk science") (internal quotation marks omitted); *United States v. Machado-Erazo*, 901 F.3d 326, 339 (D.C. Cir. 2018) (*Daubert* was "spawned by 'junk science' masquerading as science"); Debra L. Worthington, et al., *Hindsight Bias, Daubert, and the Silicone Breast*

Implant Litigation: Making the Case for Court-Appointed Experts in Complex Medical and Scientific Litigation, 8 Psychol., Pub. Pol'y, and the Law 154, 159 (2002) ("With *Daubert*, the Supreme Court attempted to redress the distortions caused by the increasing influence of junk science in the courtroom.").

Concurring in *Kumho Tire*, Justice Scalia cautioned "that the discretion [the Court] endorses — trial-court discretion in choosing the manner of testing expert reliability — is not discretion to abandon the gatekeeping function [or] to perform the function inadequately." *Kumho Tire*, 526 U.S. at 158-59 (Scalia, J., concurring). "Rather, it is discretion to choose among *reasonable* means of excluding expertise that is *fausse* and science that is junky." *Id.* at 159.

This Court, "by stressing the judge's role as a gatekeeper, appears implicitly to have assumed that the judge should protect the jury." Neil Vidmar & Shari Seidman Diamond, *Juries and Expert Evidence*, 66 Brook. L. Rev. 1121, 1125 (2001). Indeed, despite its loose interpretation of Rule 702, the Ninth Circuit has acknowledged that "[d]istrict judges play an active and important role as gatekeepers examining the full picture of the experts' methodology and preventing shoddy expert testimony and junk science from reaching the jury." *Murray v. S. Route Maritime SA*, 870 F.3d 915, 923 (9th Cir. 2017); *see also Thomas v. Novartis Pharm. Corp.*, 443 F. App'x 58, 60 (6th Cir. 2011) ("Under *Daubert* and its progeny, district courts

must exercise a gatekeeping role in screening the reliability of expert testimony to keep 'junk science' away from juries."); *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1310 (11th Cir. 1999) ("While meticulous *Daubert* inquiries may bring judges under criticism for donning white coats and making determinations that are outside their field of expertise, the Supreme Court has obviously deemed this less objectionable than dumping a barrage of questionable scientific evidence on a jury, who would likely be even less equipped than the judge to make reliability and relevance determinations and more likely than the judge to be awestruck by the expert's mystique.").

A fair personal injury trial requires judges to shield juries from unreliable scientific testimony, including junk science, also because such testimony "attempts to make causation appear more plausible in cases where it is doubtful, thus enhancing jurors' inherent tendency to engage in hindsight bias." Worthington, *supra* at 158; *see also* Schwartz, *supra* at 220 ("Expert testimony, whether presented by plaintiffs or defendants, can strongly influence juries," including because "[a]n expert witness has extraordinary powers and privileges in court."). This is why part of a trial court's *Daubert* gatekeeper role is to exclude even evidence that is relevant "'if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury.'" *Daubert*, 509 U.S. 495 (quoting Fed. R. Evid. 403).

The Court should grant review here to correct the Ninth Circuit's recurring departure from the requirements of Rule 702 and the principles established by *Daubert* and its progeny. As with the FIFRA preemption issue, the expert testimony admissibility issues in this bellwether case are particularly important because of the potential impact that the Ninth Circuit's decision otherwise will have on thousands of additional Roundup cases.

CONCLUSION

The Court should grant the petition for a writ of certiorari.

Respectfully submitted,

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